IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P., GALDERMA S.A. and GALDERMA RESEARCH AND DEVELOPMENT, S.N.C.,	)	
Plaintiffs,	)	C.A. No. 10-45 (LPS) CONSOLIDATED
v.	)	
TOLMAR, INC.,	)	
Defendant.	)	
GALDERMA LABORATORIES, L.P., GALDERMA S.A. and GALDERMA RESEARCH AND DEVELOPMENT, S.N.C.,	)	
Plaintiffs,	)	
v.	)	
ACTAVIS MID ATLANTIC LLC,	)	
Defendant.	)	

STIPULATED AMENDED COMPLAINT TO TOLMAR INC. AND ACTAVIS MID ATLANTIC LLC FOR PATENT INFRINGEMENT

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Galderma Research & Development, S.N.C. (collectively "Galderma") for their Amended Complaint for patent infringement against Defendants Tolmar Inc. ("Tolmar") and Actavis Mid Atlantic LLC ("Actavis") (collectively "the Defendants") allege as follows:

JURISDICTION AND PARTIES

1. Plaintiff Galderma Laboratories, L.P. is a Texas limited partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. Galderma Laboratories, L.P. is engaged in the business of research, development, manufacture, and sale of dermatological and pharmaceutical products.

2. Plaintiff Galderma S.A. is a Swiss company having a principal place of business at World Trade Center, Avenue de Gratta-Paille 1, Case Postale 552, 1000 Lausanne 30 Grey. Galderma S.A. is engaged in the business of research, development, manufacture, and sale of dermatological and pharmaceutical products.

3. Plaintiff Galderma Research & Development, S.N.C. is a French company having a principal place of business at 2400 Route Des Colles, Les Templiers, 06410 Biot, France. Galderma Research & Development, S.N.C. is engaged in the business of research and development of dermatological and pharmaceutical products. Galderma Research & Development, S.N.C. is the current owner of United States Patent Nos. 7,579,377 ("the '377 patent"); 7,737,181("the '181 patent"); 7,834060 ("the '060 patent"); 7,838,558 ("the '558 patent"); and 7,868,044 ("the '044 patent") (collectively "Patents-in-Suit").

4. Upon information and belief, Tolmar is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526. Tolmar is engaged in the research, development, marketing, and sale of pharmaceutical products. Upon information and belief, Tolmar's products are marketed and sold for distribution in Delaware and throughout the United States.

5. Upon information and belief, Actavis is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960. Actavis is engaged in the manufacturing, offering for sale, and sale of generic pharmaceutical products. Upon information and belief, Actavis's products are marketed and sold for distribution in Delaware and throughout the United States.

6. The Court has personal jurisdiction over the Defendants because they are both Delaware corporations; and each, respectively, has a registered agent in Delaware.

7. 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 AGAINST TOLMAR
(Infringement of the '377 Patent Under 35 U.S.C. § 271(e)(2))

8. Galderma realleges and incorporates by reference paragraphs 1-7.

9. The '377 patent, entitled "Administration of 6-[3-(1-adamantyl)-4methoxyphenyl]-2-naphthoic acid For The Treatment of Dermatological Disorders," was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the United States Patent and Trademark Office ("PTO") on August 25, 2009. The '377 is currently owned by Galderma Research & Development, S.N.C. and expires on September 10, 2026. This expiration date includes a 1278-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '377 patent, including the PTO's Certificate of Correction of the patent term adjustment, is attached as Exhibit A. A true and correct copy of the Issue Notification reflecting the PTO's original '377 patent term adjustment calculation (reflecting a patent term adjustment of 714 days prior to the decision in *Wyeth & Elan Pharma Int'l Ltd. v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010)) is attached as Exhibit B.

10. Galderma Laboratories, L.P. is the holder of New Drug Application ("NDA") No. 21-753 for the use of Differin® 0.3% gel in the topical treatment of *acne vulgaris*. The FDA approved NDA No. 21-753 on June 19, 2007. The '377 patent is listed in the

Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-753.

11. Galderma manufactures and sells various dosage strengths of topical gels and cream containing the active ingredient 6-[3-(1-adamantyl)-4methoxyphenyl]-2-naphthoic acid (also known as "adapalene") in the United States under the brand name Differin®.

12. Upon information and belief, Tolmar submitted or caused to be submitted to the FDA ANDA No. 200-298 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of adapalene gel, 0.3% ("Tolmar's Adapalene Gel") in the United States before the expiration of the '377 patent.

13. Upon information and belief, ANDA No. 200-298 contains a Paragraph IV certification alleging that the claims of the '377 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale or importation of Tolmar's Adapalene Gel prior to the expiration of the '377 patent.

14. Tolmar sent or caused to be sent to Galderma a letter dated December 10, 2009 notifying Galderma that Tolmar had submitted ANDA No. 200-298; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging noninfringement of claims of the '377 patent.

15. Under 35 U.S.C. § 271(e)(2)(A), Tolmar infringed one or more claims of the '377 patent, in violation of Galderma's patent rights, by submitting to the FDA ANDA No. 200-298, which seeks approval to commercially market—before the expiration date of the '377 patent—Tolmar's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '377 patent.

16. Upon information and belief, Tolmar has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '377 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Tolmar's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '377 patent by users of Tolmar's Adapalene Gel.

17. Upon information and belief, Tolmar seeks approval of an indication for Tolmar's Adapalene Gel that is claimed in the '377 patent.

18. Upon information and belief, Tolmar knows that if ANDA No. 200-298 is approved, physicians will prescribe, and patients will use, Tolmar's Adapalene Gel in accordance with the indications sought by Tolmar and will infringe one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT II FOR PATENT INFRINGEMENT AGAINST ACTAVIS
(Infringement of the '377 Patent Under 35 U.S.C. § 271(e)(2))

20. Galderma realleges and incorporates by reference paragraphs 1-19.

21. Upon information and belief, Actavis submitted or caused to be submitted to the FDA ANDA No. 201-000 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of adapalene gel, 0.3% ("Actavis's Adapalene Gel") in the United States before the expiration of the '377 patent.

22. Upon information and belief, ANDA No. 201-000 contains a Paragraph IV certification alleging that the claims of the '377 patent are invalid, unenforceable, and/or would

not be infringed by the commercial manufacture, use, offer for sale or importation of the Actavis's Adapalene Gel prior to the expiration date of the '377 patent.

23. Actavis sent or caused to be sent to Galderma a letter dated September 28, 2010, notifying Galderma that Actavis had submitted ANDA No. 201-000; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging that the claims of the '377 patent would not be infringed by Actavis's Adapalene Gel.

24. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '377 patent, in violation of Galderma's patent rights, by submitting to the FDA ANDA No. 201-000, which seeks approval to commercially market—before the expiration date of the '377 patent—Actavis's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '377 patent.

25. Upon information and belief, Actavis has also induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '377 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Actavis's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '377 patent by users of Actavis's Adapalene Gel.

26. Upon information and belief, Actavis seeks approval of an indication for Actavis's Adapalene Gel that is claimed in the '377 patent.

27. Upon information and belief, Actavis knows that if ANDA No. 201-000 is approved, physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indication(s) sought by Actavis and will infringe one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT III FOR DECLARATORY JUDGMENT AGAINST TOLMAR
(Declaratory Judgment of Patent Infringement of the '377 Patent Under 35 U.S.C. § 271(a)-(c))

29. Galderma realleges and incorporates by reference paragraphs 1-28.

30. 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.

31. Upon information and belief, if the FDA approves ANDA No. 200-298, Tolmar or its agents plan to begin marketing, selling, and offering to sell Tolmar's Adapalene Gel in the United States immediately or soon after receiving FDA approval for the indication(s) sought in ANDA No. 200-298.

32. The manufacture, sale, offer for sale, and/or importation of Tolmar's Adapalene Gel so labeled, if approved by the FDA, will induce and contribute to infringement of one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

33. Tolmar's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '377 patent in violation of Galderma's patent rights.

34. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Tolmar as to liability for the infringement of the '377 patent claims. Tolmar's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Tolmar's threatened imminent actions.

COUNT IV FOR DECLARATORY JUDGMENT AGAINST ACTAVIS
(Declaratory Judgment of Patent Infringement of the '377 Patent Under 35 U.S.C. § 271(a)-(c))

35. Galderma realleges and incorporates by reference paragraphs 1-34.

36. 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.

37. Upon information and belief, if the FDA approves ANDA No. 201-000, Actavis or its agents plan to begin marketing, selling, and offering to sell Actavis's Adapalene Gel in the United States immediately or soon after receiving FDA approval for the indication(s) sought in ANDA No. 201-000.

38. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel, if approved by the FDA, will induce and contribute to infringement of one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

39. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '377 patent in violation of Galderma's patent rights.

40. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the infringement of the '377 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

COUNT V FOR PATENT INFRINGEMENT AGAINST TOLMAR
(Infringement of the '181 Patent Under 35 U.S.C. § 271(e)(2))

41. Galderma realleges and incorporates by reference paragraphs 1-40.

42. The ’181 patent, entitled “Pharmaceutical Compositions Comprising 0.3% By Weight of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid For The Treatment of Dermatological Disorders,” was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the PTO on June 15, 2010. The ’181 patent is currently owned by Galderma Research & Development, S.N.C. and expires on August 29, 2024. This expiration date includes a 536-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the ’181 patent is attached as Exhibit C. A true and correct copy of the Issue Notification reflecting the ’181 patent term adjustment is attached as Exhibit D.

43. Within thirty days of issuance, the ’181 patent was listed in the Orange Book for NDA No. 21-753.

44. Upon information and belief, Tolmar submitted or caused to be submitted to the FDA ANDA No. 200-298 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Tolmar’s Adapalene Gel in the United States before the expiration of the ’181 patent.

45. Upon information and belief, Tolmar’s current ANDA No. 200-298 contains a Paragraph IV certification alleging that the claims of the ’181 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Tolmar’s Adapalene Gel prior to the expiration date of the ’181 patent.

46. Tolmar sent or caused to be sent to Galderma a letter dated October 28, 2010, notifying Galderma that Tolmar had submitted to the FDA a Paragraph IV certification for ANDA No. 200-298; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging that claims in the ’181 patent are invalid and would not be infringed by Tolmar’s Adapalene Gel.

47. Under 35 U.S.C. § 271(e)(2)(A), Tolmar infringed one or more claims of the '181 patent, in violation of Galderma's patent rights, in submitting to the FDA ANDA No. 200-298 and its amendments, which seek approval to commercially market—before the expiration date of the '181 patent—Tolmar's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '181 patent.

48. Upon information and belief, Tolmar has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '181 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Tolmar's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '181 patent by users of Tolmar's Adapalene Gel.

49. Upon information and belief, Tolmar seeks approval of an indication for Tolmar's Adapalene Gel that is recited in the '181 patent.

50. Upon information and belief, Tolmar knows that if ANDA No. 200-298 is approved, physicians will prescribe, and patients will use, Tolmar's Adapalene Gel in accordance with the indications sought by Tolmar and will infringe one or more claims of the '181 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT VI FOR PATENT INFRINGEMENT AGAINST ACTAVIS
(Infringement of the '181 Patent Under 35 U.S.C. § 271(e)(2))

52. Galderma realleges and incorporates by reference paragraphs 1-51.

53. Upon information and belief, Actavis submitted or caused to be submitted to the FDA ANDA No. 201-000 under 21 U.S.C. § 355(j), seeking to obtain approval for the

commercial manufacture, use, and sale Actavis's Adapalene Gel in the United States before the expiration of the '181 patent.

54. Upon information and belief, Actavis's ANDA No. 201-000 contains a Paragraph IV certification alleging the claims of the '181 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale or importation of the Actavis's Adapalene Gel prior to the expiration date of the '181 patent.

55. Actavis sent or caused to be sent to Galderma a letter dated September 28, 2010, notifying Galderma that Actavis had submitted ANDA No. 201-000; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging noninfringement of claims of the '181 patent.

56. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '181 patent, in violation of Galderma's patent rights, by submitting to the FDA ANDA No. 201-000, which seeks approval to commercially market—before the expiration date of the '181 patent—Actavis's Adapalene Gel, the manufacture, sale, or use of which would directly infringe one or more claims of the '181 patent.

57. Upon information and belief, Actavis has also induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '181 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Actavis's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '181 patent by users of Actavis's Adapalene Gel.

58. Upon information and belief, Actavis seeks approval of an indication for Actavis's Adapalene Gel that is recited in the '181 patent.

59. Upon information and belief, Actavis knows that if ANDA No. 201-000 is approved, physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indications sought by Actavis, and will infringe one or more claims of the '181 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT VII FOR DECLARATORY JUDGMENT AGAINST TOLMAR
(Declaratory Judgment of Patent Infringement of the '181 Patent Under 35 U.S.C. § 271(a)-(c))

61. Galderma realleges and incorporates by reference paragraphs 1-60.

62. 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.

63. The manufacture, sale, offer for sale, and/or importation of Tolmar's Adapalene Gel so labeled, if approved by the FDA, will directly infringe, and will induce and contribute to infringement of, one or more claims of the '181 patent under 35 U.S.C. § 271(a), (b) and/or (c), in violation of Galderma's patent rights.

64. Tolmar's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '181 patent in violation of Galderma's patent rights.

65. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Tolmar as to liability for the infringement of the '181 patent claims. Tolmar's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Tolmar's threatened imminent actions.

COUNT VIII FOR DECLARATORY JUDGMENT AGAINST ACTAVIS
(Declaratory Judgment of Patent Infringement of the '181 Patent Under 35 U.S.C. § 271(a)-(c))

66. Galderma 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(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel so labeled, if approved by the FDA, will directly infringe, and will induce and contribute to infringement of, one or more claims of the '181 patent under 35 U.S.C. § 271(a), (b) and/or (c), in violation of Galderma's patent rights.

69. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '181 patent in violation of Galderma's patent rights.

70. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the infringement of the '181 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

COUNT IX FOR PATENT INFRINGEMENT AGAINST TOLMAR
(Infringement of the '060 Patent Under 35 U.S.C. § 271(e)(2))

71. Galderma realleges and incorporates by reference paragraphs 1-70.

72. The '060 patent, entitled "Administration of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid For The Treatment of Dermatological Disorders," was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the PTO on November 16, 2010. The '060 patent is currently owned by Galderma Research & Development

and expires on March 12, 2023. A true and correct copy of the '060 patent is attached as Exhibit E.

73. Within thirty days of issuance, the '060 patent was listed in the Orange Book for NDA No. 21-753.

74. Upon information and belief, Tolmar submitted or caused to be submitted to the FDA ANDA No. 200-298 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Tolmar's Adapalene Gel in the United States before the expiration of the '060 patent.

75. Upon information and belief, Tolmar's current ANDA No. 200-298 contains a Paragraph IV certification alleging that the claims of the '060 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Tolmar's Adapalene Gel prior to the expiration date of the '060 patent.

76. Tolmar sent or caused to be sent to Galderma a letter dated January 14, 2011, notifying Galderma that Tolmar had submitted to the FDA a Paragraph IV certification for ANDA No. 200-298; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging claims in the '060 patent are invalid and would not be infringed by Tolmar's Adapalene Gel.

77. Under 35 U.S.C. § 271(e)(2)(A), Tolmar infringed one or more claims of the '060 patent, in violation of Galderma's patent rights, in submitting to the FDA ANDA No. 200-298 and its amendments, which seek approval to commercially market—before the expiration date of the '060 patent —Tolmar's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '060 patent.

78. Upon information and belief, Tolmar has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '060 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Tolmar's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of '060 patent by users of Tolmar's Adapalene Gel.

79. Upon information and belief, Tolmar seeks approval of an indication for Tolmar's Adapalene Gel that is recited in the '060 patent.

80. Upon information and belief, Tolmar knows that if ANDA No. 200-298 is approved, physicians will prescribe, and patients will use, Tolmar's Adapalene Gel in accordance with the indications sought by Tolmar and will infringe one or more claims of the '060 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT X FOR PATENT INFRINGEMENT AGAINST ACTAVIS
(Infringement of the '060 Patent Under 35 U.S.C. § 271(e)(2))

82. Galderma realleges and incorporates by reference paragraphs 1-81.

83. Upon information and belief, Actavis submitted or caused to be submitted to the FDA ANDA No. 201-000 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Actavis's Adapalene Gel in the United States before the expiration of the '060 patent.

84. Upon information and belief, Actavis's current ANDA No. 201-000 contains a Paragraph IV certification alleging that the claims of the '060 patent are invalid,

unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Actavis's Adapalene Gel prior to the expiration date of the '060 patent.

85. Actavis sent or caused to be sent to Galderma a letter dated January 24, 2011, notifying Galderma that Actavis had submitted to the FDA a Paragraph IV certification for ANDA No. 201-000; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging that claims of the '060 patent are invalid and would not be infringed by Actavis's Adapalene Gel.

86. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '060 patent, in violation of Galderma's patent rights, in submitting to the FDA ANDA No. 201-000 and its amendments, which seek approval to commercially market—before the expiration date of the '060 patent —Actavis's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '060 patent.

87. Upon information and belief, Actavis has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '060 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Actavis's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of '060 patent by users of Actavis's Adapalene Gel.

88. Upon information and belief, Actavis seeks approval of an indication for Actavis's Adapalene Gel that is recited in the '060 patent.

89. Upon information and belief, Actavis knows that if ANDA No. 201-000 is approved, physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indications sought by Actavis and will infringe one or more claims of the '060 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT XI FOR DECLARATORY JUDGMENT AGAINST TOLMAR
(Declaratory Judgment of Patent Infringement of the '060 Patent Under 35 U.S.C. § 271(a)-(c))

91. Galderma realleges and incorporates by reference paragraphs 1-90.

92. 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.

93. The manufacture, sale, offer for sale, and/or importation of Tolmar's Adapalene Gel so labeled, if approved by the FDA, will induce and contribute to infringement of, one or more claims of the '060 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

94. Tolmar's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '060 patent in violation of Galderma's patent rights.

95. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Tolmar as to liability for the infringement of the '060 patent claims. Tolmar's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Tolmar's threatened imminent actions.

COUNT XII FOR DECLARATORY JUDGMENT AGAINST ACTAVIS
(Declaratory Judgment of Patent Infringement of the '060 Patent Under 35 U.S.C. § 271(a)-(c))

96. Galderma realleges and incorporates by reference paragraphs 1-95.

97. 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.

98. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel so labeled, if approved by the FDA, will induce and contribute to infringement of, one or more claims of the '060 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

99. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '060 patent in violation of Galderma's patent rights.

100. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the infringement of the '060 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

COUNT XIII FOR PATENT INFRINGEMENT AGAINST TOLMAR
(Infringement of the '558 Patent Under 35 U.S.C. § 271(e)(2))

101. Galderma realleges and incorporates by reference paragraphs 1-100.

102. The '558 patent, entitled "Administration of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid For The Treatment of Dermatological Disorders," was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the PTO on November 23, 2010. The '558 patent is currently owned by Galderma Research & Development, S.N.C. and expires on March 12, 2023. A true and correct copy of the '558 patent is attached as Exhibit F.

103. Within thirty days of issuance, the ’558 patent was listed in the Orange Book for NDA No. 21-753.

104. Upon information and belief, Tolmar submitted or caused to be submitted to the FDA ANDA No. 200-298 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Tolmar’s Adapalene Gel in the United States before the expiration of the ’558 patent.

105. Upon information and belief, Tolmar’s current ANDA No. 200-298 contains a Paragraph IV certification alleging that the claims of the ’558 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Tolmar’s Adapalene Gel prior to the expiration date of the ’558 patent.

106. Tolmar sent or caused to be sent to Galderma a letter dated January 14, 2011, notifying Galderma that Tolmar had submitted to the FDA a Paragraph IV certification for ANDA No. 200-298; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging claims in the ’558 patent are invalid and would not be infringed by Tolmar’s Adapalene Gel.

107. Under 35 U.S.C. § 271(e)(2)(A), Tolmar infringed one or more claims of the ’558 patent, in violation of Galderma’s patent rights, in submitting to the FDA ANDA No. 200-298 and its amendments, which seek approval to commercially market—before the expiration date of the ’558 patent —Tolmar’s Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the ’558 patent.

108. Upon information and belief, Tolmar has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the ’558 patent, in violation of Galderma’s patent rights, if the FDA approves the sale of Tolmar’s Adapalene Gel with

instructions and labeling that will result in direct infringement of one or more claims of the '558 patent by users of Tolmar's Adapalene Gel.

109. Upon information and belief, Tolmar seeks approval of an indication for Tolmar's Adapalene Gel that is recited in the '558 patent.

110. Upon information and belief, Tolmar knows that if ANDA No. 200-298 is approved, physicians will prescribe, and patients will use, Tolmar's Adapalene Gel in accordance with the indications sought by Tolmar and will infringe one or more claims of the '558 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT XIV FOR PATENT INFRINGEMENT AGAINST ACTAVIS
(Infringement of the '558 Patent Under 35 U.S.C. § 271(e)(2))

112. Galderma realleges and incorporates by reference paragraphs 1-111.

113. Upon information and belief, Actavis submitted or caused to be submitted to the FDA ANDA No. 201-000 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Actavis's Adapalene Gel in the United States before the expiration of the '558 patent.

114. Upon information and belief, Actavis's current ANDA No. 201-000 contains a Paragraph IV certification alleging that the claims of the '558 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Actavis's Adapalene Gel prior to the expiration date of the '558 patent.

115. Actavis sent or caused to be sent to Galderma a letter dated January 24, 2011, notifying Galderma that Actavis had submitted to the FDA a Paragraph IV certification for

ANDA 201-000; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging that claims of the '558 patent are invalid and would not be infringed by Actavis's Adapalene Gel.

116. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '558 patent, in violation of Galderma's patent rights, in submitting to the FDA ANDA No. 201-000 and its amendments, which seek approval to commercially market—before the expiration date of the '558 patent —Actavis's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '558 patent.

117. Upon information and belief, Actavis has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '558 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Actavis's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of '558 patent by users of Actavis's Adapalene Gel.

118. Upon information and belief, Actavis seeks approval of an indication for Actavis's Adapalene Gel that is recited in the '558 patent.

119. Upon information and belief, Actavis knows that if ANDA No. 201-000 is approved, physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indications sought by Actavis and will infringe one or more claims of the '558 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT XV FOR DECLARATORY JUDGMENT AGAINST TOLMAR
(Declaratory Judgment of Patent Infringement of the '558 Patent Under 35 U.S.C. § 271(a)-(c))

121. Galderma realleges and incorporates by reference paragraphs 1-120.

122. 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.

123. The manufacture, sale, offer for sale, and/or importation of Tolmar's Adapalene Gel so labeled, if approved by the FDA, will directly infringe, and will induce and contribute to infringement of, one or more claims of the '558 patent under 35 U.S.C. § 271(a), (b) and/or (c), in violation of Galderma's patent rights.

124. Tolmar's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '558 patent in violation of Galderma's patent rights.

125. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Tolmar as to liability for the infringement of the '558 patent claims. Tolmar's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Tolmar's threatened imminent actions.

COUNT XVI FOR DECLARATORY JUDGMENT AGAINST ACTAVIS
(Declaratory Judgment of Patent Infringement of the '558 Patent Under 35 U.S.C. § 271(a)-(c))

126. Galderma realleges and incorporates by reference paragraphs 1-125.

127. 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.

128. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel so labeled, if approved by the FDA, will directly infringe, and will induce and contribute to infringement of, one or more claims of the '558 patent under 35 U.S.C. § 271(a), (b) and/or (c), in violation of Galderma's patent rights.

129. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '558 patent in violation of Galderma's patent rights.

130. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the infringement of the '558 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

COUNT XVII FOR PATENT INFRINGEMENT AGAINST TOLMAR
(Infringement of the '044 Patent Under 35 U.S.C. § 271(e)(2))

131. Galderma realleges and incorporates by reference paragraphs 1-130.

132. The '044 patent, entitled "Method for the Treatment of Acne Using Compositions Comprising 0.3% By Weight of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid," was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the PTO on January 11, 2011. The '044 patent is currently owned by Galderma Research & Development, S.N.C. and expires on March 12, 2023. A true and correct copy of the '044 patent is attached as Exhibit G.

133. Within thirty days of issuance, the '044 patent was listed in the Orange Book for NDA No. 21-753.

134. Upon information and belief, Tolmar submitted or caused to be submitted to the FDA ANDA No. 200-298 under 21 U.S.C. § 355(j), seeking to obtain approval for the

commercial manufacture, use, and sale of Tolmar's Adapalene Gel in the United States before the expiration of the '044 patent.

135. Upon information and belief, Tolmar's current ANDA No. 200-298 contains a Paragraph IV certification alleging that the claims of the '044 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Tolmar's Adapalene Gel prior to the expiration date of the '044 patent.

136. Tolmar sent or caused to be sent to Galderma a letter dated February 9, 2011 notifying Galderma that Tolmar had submitted to the FDA a Paragraph IV certification for ANDA No. 200-298; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging that claims of the '044 patent are invalid and would not be infringed by Tolmar's Adapalene Gel.

137. Under 35 U.S.C. § 271(e)(2)(A), Tolmar infringed one or more claims of the '044 patent, in violation of Galderma's patent rights, in submitting to the FDA ANDA No. 200-298 and its amendments, which seek approval to commercially market—before the expiration date of the '044 patent—Tolmar's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '044 patent.

138. Upon information and belief, Tolmar has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '044 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Tolmar's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '044 patent by users of Tolmar's Adapalene Gel.

139. Upon information and belief, Tolmar seeks approval of an indication for Tolmar's Adapalene Gel that is recited in the '044 patent.

140. Upon information and belief, Tolmar knows that if ANDA No. 200-298 is approved, physicians will prescribe, and patients will use, Tolmar's Adapalene Gel in accordance with the indications sought by Tolmar and will infringe one or more claims of the '044 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT XVIII FOR PATENT INFRINGEMENT AGAINST ACTAVIS
(Infringement of the '044 Patent Under 35 U.S.C. § 271(e)(2))

142. Galderma realleges and incorporates by reference paragraphs 1-141.

143. Upon information and belief, Actavis submitted or caused to be submitted to the FDA ANDA No. 201-000 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Actavis's Adapalene Gel in the United States before the expiration of the '044 patent.

144. Upon information and belief, Actavis's current ANDA No. 201-000 contains a Paragraph IV certification alleging that the claims of the '044 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, or importation of Actavis's Adapalene Gel prior to the expiration date of the '044 patent.

145. Actavis sent or caused to be sent to Galderma a letter dated January 24, 2011,

notifying Galderma that Actavis had submitted to the FDA a Paragraph IV certification for ANDA 201-000; providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii); and alleging that claims of the '044 patent are invalid and would not be infringed by Actavis's Adapalene Gel.

146. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '044 patent, in violation of Galderma's patent rights, in submitting to the FDA ANDA No. 201-000 and its amendments, which seek approval to commercially market—before the expiration date of the '044 patent —Actavis's Adapalene Gel, the manufacture, use, or sale of which would directly infringe one or more claims of the '044 patent.

147. Upon information and belief, Actavis has induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '044 patent, in violation of Galderma's patent rights, if the FDA approves the sale of Actavis's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of '044 patent by users of Actavis's Adapalene Gel.

148. Upon information and belief, Actavis seeks approval of an indication for Actavis's Adapalene Gel that is recited in the '044 patent.

149. Upon information and belief, Actavis knows that if ANDA No. 201-000 is approved, physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indications sought by Actavis and will infringe one or more claims of the '044 patent under 35 U.S.C. § 271(b) and/or (c).

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

COUNT XIX FOR DECLARATORY JUDGMENT AGAINST TOLMAR
(Declaratory Judgment of Patent Infringement of the '044 Patent Under 35 U.S.C. § 271(a)-(c))

151. Galderma realleges and incorporates by reference paragraphs 1-150.

152. 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.

153. The manufacture, sale, offer for sale, and/or importation of Tolmar's Adapalene Gel so labeled, if approved by the FDA, will induce and contribute to infringement of, one or more claims of the '044 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

154. Tolmar's actions in actively aiding, abetting, encouraging, and inducing sales of Tolmar's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '044 patent in violation of Galderma's patent rights.

155. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Tolmar as to liability for the infringement of the '044 patent claims. Tolmar's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Tolmar's threatened imminent actions.

COUNT XX FOR DECLARATORY JUDGMENT AGAINST ACTAVIS
(Declaratory Judgment of Patent Infringement of the '044 Patent Under 35 U.S.C. § 271(a)-(c))

156. Galderma realleges and incorporates by reference paragraphs 1-155.

157. 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.

158. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel so labeled, if approved by the FDA, will induce and contribute to infringement of, one or more claims of the '044 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

159. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '044 patent in violation of Galderma's patent rights.

160. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the infringement of the '044 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Galderma respectfully requests that this Court enter judgment in its favor as follows:

a) declare that, under 35 U.S.C. § 271(e)(2)(A), the Defendants have respectively infringed United States the Patents-in-Suit by submitting ANDAs to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States generic adapalene gels prior to the expiration of said patents;

b) declare that the Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States of generic adapalene gel prior to the expiration of the Patents-in-Suit would constitute infringement of said patents in violation of Galderma's patent rights;

c) order that the effective date of any FDA approval of either of the Defendants' generic adapalene gels shall be no earlier than the latest expiration date of the Patents-in-Suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

d) enjoin the Defendants, and all persons acting in concert with them, from seeking, obtaining, or maintaining final approval of their ANDAs until the expiration of each of the Patents-in-Suit;

e) enjoin the Defendants, and all persons acting in concert with them, from commercially manufacturing, using, offering for sale, or selling either of the Defendants' generic adapalene gels within the United States, or importing either of the Defendants' generic adapalene gels into the United States, until the expiration of each of the Patents-in-Suit, in accordance with 35 U.S.C. § 271(e)(4)(B);

f) grant Galderma such further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL, LLP

/s/ Maryellen Noreika

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