IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER AG, and FOAMIX PHARMACEUTICALS LTD.,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bayer AG, Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer"), and Foamix Pharmaceuticals Ltd. ("Foamix", and collectively with Bayer, "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Teva Pharmaceuticals USA, Inc. ("Teva") of Abbreviated New Drug Application ("ANDA") No. 210928 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Bayer's FINACEA® (azelaic acid) Foam ("FINACEA® Foam") prior to expiration of U.S. Patent No. 7,700,076 ("the '076 patent"), U.S. Patent No. 8,435,498 ("the '498 patent"), U.S. Patent No. 8,722,021 ("the '021 patent"), U.S. Patent No. 8,900,554 ("the '554 patent"), U.S. Patent No. 9,211,259 ("the '259 patent"), and U.S. Patent No. 9,265,725 ("the '725 patent").

PARTIES

2. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981.

4. Plaintiff Foamix Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the State of Israel, with a place of business at 2 Holzman Street, Weizmann Science Park, Rehovot 76704, Israel.

5. Upon information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

6. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 210928, Teva will distribute and sell its generic product throughout the United States, including within Delaware.

JURISDICTION AND VENUE

7. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), and 2201.

8. Teva is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Teva is a corporation organized and existing under the laws of the state of Delaware.

9. In addition, this Court has personal jurisdiction over Teva because Teva has consented to jurisdiction in this judicial district in previous litigation, and because Teva has affirmatively availed itself of the courts of this district by filing claims in this district, including *In re Copaxone 775 Patent Litigation*, 1:16-cv-01267-GMS (D. Del.); *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, 1:17-cv-00249-GMS (D. Del.); and *Teva Pharmaceuticals USA, Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, 1:17-cv-00992-GMS (D. Del.).

BACKGROUND

10. FINACEA® Foam (active ingredient 15% azelaic acid) is a topical prescription medicine used to treat the inflammatory papules and pustules of mild to moderate rosacea.

11. The ’076 patent, entitled “Penetrating Pharmaceutical Foam” (Exhibit A hereto), was duly and legally issued on April 20, 2010, to Foamix Ltd., as assignee, and subject to the exclusive license referenced herein. The ’076 patent was thereafter assigned to Foamix Pharmaceuticals Ltd. on June 1, 2014. FINACEA® Foam and the use thereof are covered by one or more claims of the ’076 patent, which has been listed in connection with FINACEA® Foam in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

12. The ’498 patent, entitled “Penetrating Pharmaceutical Foam” (Exhibit B hereto), was duly and legally issued on May 7, 2013, to Foamix Ltd., as assignee, and subject to the exclusive license referenced herein. The ’498 patent was thereafter assigned to Foamix Pharmaceuticals Ltd. on June 1, 2014. FINACEA® Foam and the use thereof are covered by one or more claims of the ’498 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

13. The ’021 patent, entitled “Foamable Carriers” (Exhibit C hereto), was duly and legally issued on May 13, 2014, to Foamix Ltd., as assignee, and subject to the exclusive license referenced herein. The ’021 patent was thereafter assigned to Foamix Pharmaceuticals Ltd. on June 1, 2014. FINACEA® Foam and the use thereof are covered by one or more claims of the ’021 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

14. The ’554 patent, entitled “Foamable Composition and Uses Thereof” (Exhibit D hereto), was duly and legally issued on December 2, 2014, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use thereof are covered by one or more claims of the ’554 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

15. The ’259 patent, entitled “Antibiotic Kit and Composition and Uses Thereof” (Exhibit E hereto), was duly and legally issued on December 15, 2015, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use thereof are covered by one or more claims of the ’259 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

16. The ’725 patent, entitled “Dicarboxylic Acid Foamable Vehicle and Pharmaceutical Compositions Thereof” (Exhibit F hereto), was duly and legally issued on February 23, 2016, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use thereof are covered by one or more claims of the ’725 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

17. On December 8, 2006, Intendis GmbH (“Intendis”) took an exclusive license to the Finacea® Foam Product covered by certain Foamix patents and patent applications, including

those applications which ultimately led to the issuance of the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, and the ’725 patent (“Foamix patents”). In December 2013, Intendis and Bayer Pharma AG, the parent of Intendis, entered into a business lease agreement providing, among other things, for the substitution of Intendis by Bayer Pharma AG in existing agreements. Thus, effective January 1, 2014, the exclusive license to the Foamix patents was assigned to Bayer Pharma AG. Thereafter, effective as of January 1, 2017, the exclusive license was assigned to Bayer AG, the parent of Bayer Pharma AG.

18. Bayer HealthCare Pharmaceuticals Inc. is the holder of New Drug Application No. 207071 for FINACEA® Foam, which has been approved by the FDA.

19. On or around November 21, and November 22, 2017, Bayer and Foamix, respectively, received a notice letter dated November 20, 2017, from Teva stating that Teva had submitted to the FDA ANDA No. 210928 for an azelaic acid foam composition containing 15% azelaic acid (“Teva’s ANDA Product”) (“Notice Letter”). Teva’s ANDA Product is a drug product that is a generic version of FINACEA® Foam.

20. The purpose of Teva’s submission of ANDA No. 210928 was to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva’s ANDA Product prior to the expiration of the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, and the ’725 patent.

21. In its Notice Letter, Teva indicated that, in connection with its ANDA No. 210928, Teva had filed Paragraph IV Certifications with respect to each of the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, and the ’725 patent.

22. Bayer requested confidential access to materials necessary to ascertain whether Teva infringed the relevant patent, including Teva's ANDA, the Drug Master File, samples of its ANDA product, and records of testing conducted on its ANDA product. Counsel for Teva and counsel for Bayer were unable to agree on terms under which Bayer could review all of the materials requested and Teva refused to produce the documents and data.

23. This action is being commenced before the expiration of forty-five days from the receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 7,700,076

24. Plaintiffs fully incorporate each of the preceding paragraphs 1–23 as if fully set forth herein.

25. Upon information and belief, Teva's ANDA Product infringes one or more claims of the '076 patent either literally or under the doctrine of equivalents.

26. In its Notice Letter, Teva does not contest infringement as to claims 11, 13–16, 19, 21–22, 24–25, 27–28, or 46–51 of the '076 patent.

27. As an example, claim 11 of the '076 patent recites an oil in water foamable composition comprising:

a. about 5 to about 50% by weight of composition of a liquid, non-volatile hydrophobic solvent;

b. about 0.1 to 5% by weight of a surface-active agent selected from the group consisting of a polysorbate, a polyoxyethylene fatty acid ester, a polyoxyethylene alkyl ether, a sucrose ester, a partial ester of sorbitol, a partial ester of sorbitol anhydride, sodium methyl cocoyl taurate, sodium methyl oleoyl taurate, sodium lauryl sulfate, triethanolamine lauryl sulfate, a betaine, a mono-, di- or tri-ester of

sucrose with food fatty acids (sucrose esters), a monoglyceride, a diglyceride, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, Myrj 45 (Polyoxyethylene (8) Stearate), Myrj 49 (polyoxyethylene (20) stearate), Myrj 59 (polyoxoethylene (100) stearate), a polyoxyethylene cetyl ether, a polyoxyethylene palmityl ether, a polyethylene oxide hexadecyl ether, Brij 52 (polyoxyethylene (2) cetyl ether), Brij 56 (polyoxyethylene (10) cetyl ether), sorbitan monolaurate, isoceteth 20, cocamidopropyl betaine, and Myrj 52 (polyoxyethylene 40 stearate);

c. about 0.1 to 5% by weight of a gelling agent;

d. a therapeutic enhancer selected from the group consisting of propylene glycol, butylene glycols, glycerol, pentaerythritol, sorbitol, mannitol, oligosaccharides, dimethyl isosorbide, monooleate of ethoxylated glycerides having about 8 to 10 ethylene oxide units, polyethylene glycol 200-600, transcutol, glycofurol and cylcodextrins; and

e. a liquefied or compressed gas propellant at a concentration of about 3% to about 18% by weight of the total composition;

f. wherein the composition contains no more than 7.5% of methyl alcohol, ethyl alcohol, isopropyl alcohol, butyl alcohol, or mixtures thereof; and

g. wherein said composition is a stable emulsion in its predispensed state and forms a breakable foam upon dispensing.

28. Upon information and belief, Teva's ANDA Product infringes claim 11 of the '076 patent literally or under the doctrine of equivalents.

29. Teva's submission of ANDA No. 210928 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '076 patent was an act of infringement of the '076 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928, *i.e.*, prior to the expiration of the '076 patent.

31. Upon information and belief, Teva has knowledge of the claims of the '076 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

32. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '076 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

33. Upon information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '076 patent, and that Teva's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the'076 patent immediately and imminently upon approval of ANDA No. 210928.

34. The foregoing actions by Teva constitute and/or will constitute infringement of the ’076 patent, active inducement of infringement of the ’076 patent, and contributing to the infringement by others of the ’076 patent.

35. Unless Teva is enjoined from infringing the’076 patent, actively inducing infringement of the’076 patent, and contributing to the infringement by others of the’076 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 8,435,498

36. Plaintiffs fully incorporate each of the preceding paragraphs 1–35 as if fully set forth herein.

37. Upon information and belief, Teva’s ANDA Product and its proposed labeling directing use of Teva’s ANDA Product infringe one or more claims of the ’498 patent either literally or under the doctrine of equivalents.

38. In its Notice Letter, Teva does not contest infringement as to claims 1–2, 4, 12, 14–17, or 19–24 of the ’498 patent.

39. As an example, claim 1 of the ’498 patent recites a method of skin or mucosal surface application comprising spreading or collapsing a breakable thermally stable foam by mechanical force at or about a target site of a subject, the breakable thermally stable foam obtained by dispensing a foamable emulsion composition comprising:

a. about 0.1 to about 5% by weight of a surface-active agent;

b. about 5 to about 50% by weight of a liquid, non-volatile hydrophobic solvent;

c. about 0.1 to about 5% by weight of a gelling agent; and

d. a component selected from the group consisting of urea, a hydroxy acid, a therapeutic enhancer, and mixtures of two or more thereof;

e. water; and

f. a liquefied or a compressed gas propellant;

g. wherein the foamable emulsion composition contains no more than 7.5% by weight methyl alcohol, ethyl alcohol, isopropyl alcohol, butyl alcohol, or mixtures thereof.

40. Upon information and belief, Teva's ANDA Product and its proposed labeling directing use of Teva's ANDA Product infringe claim 1 of the '498 patent either literally or under the doctrine of equivalents.

41. Teva's submission of ANDA No. 210928 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '498 patent was an act of infringement of the '498 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928, *i.e.*, prior to the expiration of the '498 patent.

43. Upon information and belief, Teva has knowledge of the claims of the '498 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

44. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the ’498 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

45. Upon information and belief, Teva knows that Teva’s ANDA Product is especially made or adapted for use in infringing the ’498 patent, and that Teva’s ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the ’498 patent immediately and imminently upon approval of ANDA No. 210928.

46. The foregoing actions by Teva constitute and/or will constitute infringement of the ’498 patent, active inducement of infringement of the ’498 patent, and contributing to the infringement by others of the ’498 patent.

47. Unless Teva is enjoined from infringing the ’498 patent, actively inducing infringement of the ’498 patent, and contributing to the infringement by others of the ’498 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 8,722,021

48. Plaintiffs fully incorporate each of the preceding paragraphs 1–47 as if fully set forth herein.

49. Upon information and belief, Teva’s ANDA Product infringes one or more claims of the ’021 patent either literally or under the doctrine of equivalents.

50. In its Notice Letter, Teva does not contest infringement as to claims 1–5, 7–17, 20, or 23 of the ’021 patent.

51. As an example, claim 1 of the ’021 patent recites a foamable composition comprising a carrier and a liquefied or a compressed gas propellant, the carrier comprising:

a. about 0.1% to about 5% by weight of the carrier of the surface-active agent;

b. about 2% to about 75% by weight of the carrier of an organic solvent selected from the group consisting of an emollient, a polar solvent, an oil, and mixtures thereof;

c. about 0.01% to about 5% by weight of the carrier of at least one polymeric agent selected from the group consisting of a bioadhesive agent, a gelling agent, a film forming agent, and a phase change agent; and

d. water;

e. wherein upon release from a foam dispenser, a foam is produced; and

f. wherein the foam remains stable as a foam for at least 60 seconds at 37^{o} C.

52. Upon information and belief, Teva's ANDA Product infringes claim 1 of the '021 patent literally or under the doctrine of equivalents.

53. Teva's submission of ANDA No. 210928 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '021 patent was an act of infringement of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928, *i.e.*, prior to the expiration of the '021 patent.

55. Upon information and belief, Teva has knowledge of the claims of the '021 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's

ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

56. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the ’021 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

57. Upon information and belief, Teva knows that Teva’s ANDA Product is especially made or adapted for use in infringing the ’021 patent, and that Teva’s ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the ’021 patent immediately and imminently upon approval of ANDA No. 210928.

58. The foregoing actions by Teva constitute and/or will constitute infringement of the ’021 patent, active inducement of infringement of the ’021 patent, and contributing to the infringement by others of the ’021 patent.

59. Unless Teva is enjoined from infringing the ’021 patent, actively inducing infringement of the ’021 patent, and contributing to the infringement by others of the ’021 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 8,900,554

60. Plaintiffs fully incorporate each of the preceding paragraphs 1–59 as if fully set forth herein.

61. Upon information and belief, Teva’s ANDA Product infringes one or more claims of the ’554 patent either literally or under the doctrine of equivalents.

62. In its Notice Letter, Teva does not contest infringement as to claims 1, 3–5, 7–8, 10–16, or 18–20 of the ’554 patent.

63. As an example, claim 1 of the ’554 patent recites a composition comprising a foamable composition and a propellant, the foamable composition comprising:

a. an active agent;

b. at least one organic carrier selected from the group consisting of a hydrophobic organic carrier, an organic polar solvent, an emollient, and mixtures of any two or more thereof, at a concentration of about 2% to about 50% by weight of the foamable composition;

c. a surface active agent; and

d. water;

e. wherein the propellant is a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the foamable composition;

f. wherein the composition is stored in a container and upon release form a breakable foam that collapses upon application of shear force; and

g. wherein the foamable composition comprises less than 5% or about 5% by weight of the foamable composition of lower alcohols.

64. Upon information and belief, Teva’s ANDA Product infringes claim 1 of the ’554 patent literally or under the doctrine of equivalents.

65. Teva’s submission of ANDA No. 210928 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s ANDA Product prior to the expiration of the ’554 patent was an act of infringement of the ’554 patent under 35 U.S.C. § 271(e)(2)(A).

66. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva’s ANDA Product and the

proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928, *i.e.*, prior to the expiration of the '554 patent.

67. Upon information and belief, Teva has knowledge of the claims of the '554 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

68. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product would infringe one or more claims of the '554 patent, either literally or under the doctrine of equivalents.

69. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '554 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

70. Upon information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '554 patent, and that Teva's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the '554 patent immediately and imminently upon approval of ANDA No. 210928.

71. The foregoing actions by Teva constitute and/or will constitute infringement of the '554 patent, active inducement of infringement of the '554 patent, and contributing to the infringement by others of the '554 patent. Unless Teva is enjoined from infringing the '554 patent, actively inducing infringement of the '554 patent, and contributing to the infringement by

others of the ’554 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – INFRINGEMENT OF U.S. PATENT NO. 9,211,259

72. Plaintiffs fully incorporate each of the preceding paragraphs 1–71 as if fully set forth herein.

73. Upon information and belief, Teva’s ANDA Product and its proposed labeling directing use of Teva’s ANDA Product infringe one or more claims of the ’259 patent either literally or under the doctrine of equivalents.

74. In its Notice Letter, Teva does not contest infringement as to claims 1–5, 7, 10–11, 17–20, 23–26, 34–36, 42, 45, 48, 50, 52, 54–57, or 78–79 of the ’259 patent.

75. As an example, claim 1 of the ’259 patent recites a method of treating or alleviating disorders of a skin, body cavity or mucosal surface, wherein the disorder involves inflammation as one of its etiological factors, the method comprising:

a. releasing a foamable composition from an aerosol container to form an expanded thermally stable foam that collapses upon application of mechanical force, said foamable composition comprising a propellant and a composition, said composition comprising:

i. an antibiotic agent;

ii. a therapeutically active oil comprising about 10% to about 50% by weight of the composition of a capric/caprylic triglyceride;

iii. a surface-active agent;

iv. about 0.01% to about 5% by weight of the composition of at least one polymeric additive selected from the group consisting of a bioadhesive agent, a gelling agent, a film forming agent and a phase change agent; and

v. water;

vi. wherein the propellant comprises a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the foamable composition

b. administering the foam to a target area having a disorder of the skin, body cavity or mucosa; and

c. collapsing the foam by applying mechanical force, wherein the foam is absorbed onto the target area,

d. wherein the antibiotic agent is administered in a therapeutically effective amount;

e. wherein the composition contains less than 5% by weight of the composition of short chain alcohols having up to 5 carbon atoms in their carbon chain skeleton and one hydroxyl group; and

f. wherein the composition is a thermally stable breakable foam.

76. Upon information and belief, Teva's ANDA Product and its proposed labeling directing use of Teva's ANDA Product infringe claim 1 of the '259 patent either literally or under the doctrine of equivalents.

77. Teva's submission of ANDA No. 210928 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '259 patent was an act of infringement of the '259 patent under 35 U.S.C. § 271(e)(2)(A).

78. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928, *i.e.*, prior to the expiration of the '259 patent.

79. Upon information and belief, Teva has knowledge of the claims of the '259 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

80. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '259 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

81. Upon information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '259 patent, and that Teva's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the '259 patent immediately and imminently upon approval of ANDA No. 210928.

82. The foregoing actions by Teva constitute and/or will constitute infringement of the '259 patent, active inducement of infringement of the '259 patent, and contributing to the infringement by others of the '259 patent.

83. Unless Teva is enjoined from infringing the '259 patent, actively inducing infringement of the '259 patent, and contributing to the infringement by others of the '259 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 9,265,725

84. Plaintiffs fully incorporate each of the preceding paragraphs 1–83 as if fully set forth herein.

85. Upon information and belief, Teva's ANDA Product infringes one or more claims of the '725 patent either literally or under the doctrine of equivalents.

86. As an example, claim 1 of the '725 patent recites a foamable composition comprising a foamable carrier and a propellant, the foamable carrier comprising:

a. about 15% by weight of an azelaic acid;

b. about 11% by weight of medium-chain triglycerides;

c. about 11% by weight of propylene glycol;

d. about 5% by weight of dimethyl isosorbide;

e. about 3% by weight of PEG-40 stearate;

f. about 1% by weight of a cetostearyl alcohol;

g. about 1% by weight of polysorbate 80;

h. about 0.5% by weight of a monoglyceride, a diglyceride, or a combination;

i. about 0.3% by weight of a xanthan gum;

j. about 0.1% by weight of methylcellulose;

k. about 0.1% by weight of a benzoic acid;

l. water;

m. sodium hydroxide; and

n. wherein the pH of said foamable carrier is about 4.5–5.3; and

o. wherein the propellant is at a concentration of about 3% to about 25% by weight of the total composition.

87. Upon information and belief, Teva's ANDA Product infringes claim 1 of the '725 patent literally or under the doctrine of equivalents.

88. Teva's submission of ANDA No. 210928 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '725 patent was an act of infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

89. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928, *i.e.*, prior to the expiration of the '725 patent.

90. Upon information and belief, Teva has knowledge of the claims of the '725 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

91. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '725 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

92. Upon information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '725 patent, and that Teva's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the '725 patent immediately and imminently upon approval of ANDA No. 210928.

93. The foregoing actions by Teva constitute and/or will constitute infringement of the ’725 patent, active inducement of infringement of the ’725 patent, and contributing to the infringement by others of the ’725 patent.

94. Unless Teva is enjoined from infringing the ’725 patent, actively inducing infringement of the ’725 patent, and contributing to the infringement by others of the ’725 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

* * *

95. Teva has proceeded with knowledge of the patents-in-suit and with no reasonable basis to believe that it has not infringed and will not infringe those patents. This is an exceptional case.

* * *

WHEREFORE, the Plaintiffs request the following relief:

(a) A judgment that Teva has infringed the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, and the ’725 patent;

(b) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva’s ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, or the ’725 patent be not earlier that the expiration date of the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, and the ’725 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, offering for sale, selling, marketing,

distributing, or importing Teva's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, or the '725 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, or the '725 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, offering for sale, selling, marketing, distributing, or importing Teva's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, or the '725 patent, prior to the expiration date of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, or the '725 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, or the '725 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of the Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Adam L. Perlman
Stanley E. Fisher
Elise M. Baumgarten
Marta M. Chlistunoff
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
(202) 434-5000

January 3, 2018