William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, SALIX PHARMACEUTICALS, INC., and NORGINE B.V., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 19-12404 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited, Salix Pharmaceuticals, Inc., and Norgine B.V. (collectively, "Plaintiffs") by way of Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a corporation organized and existing under the laws of California, having its principle place of business at 400 Somerset Blvd., Bridgewater, New Jersey 08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 209381, which covers Plenvu®.

3. Plaintiff Norgine B.V. ("Norgine") is a corporation organized and existing under the laws of the Netherlands, having a corporate headquarters at Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

4. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, having its U.S. headquarters at 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva, Israel, 004951033. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 8,999,313 B2 ("the '313 patent"); 9,326,969 B2 ("the '969 patent"); 9,592,252 B2 ("the '252 patent"); 9,707,297 B2 ("the '297 patent"); and 10,016,504 B2 ("the '504 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Teva's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic ascorbic acid/polyethylene glycol

3350/potassium chloride/sodium ascorbate/sodium chloride/sodium sulfate for oral solution, 7.54 g/140 g/2.2 g/48.11 g/5.2 g/9 g ("Teva's ANDA Product").

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Upon information and belief, this Court has jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Teva USA directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Teva Ltd., throughout the United States and in this judicial district, and this judicial district is a likely destination for Teva's ANDA Product. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Teva USA's U.S. headquarters is in Parsippany, New Jersey, and Teva USA operates and maintains facilities in Fairfield and Woodcliff Lake, New Jersey. Upon information and belief, Teva USA has a registered agent for service of process in this judicial district. Upon information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under the Business ID No. 0100250184. Upon information and belief, Teva USA is registered in the State of New Jersey as a "wholesale[r]" and "manufacturer and wholesale[r]" of drugs, with Registration Nos. 5003436 and 5000583, respectively. Upon information and belief, Teva USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. Upon information and belief, this Court has jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Teva Ltd. directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Teva's ANDA Product. Upon information and belief, Teva Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Teva Ltd. maintains continuous and systematic contacts with New Jersey through its New Jersey subsidiary, Teva USA. Upon information and belief, Teva Ltd. has previously submitted to the jurisdiction of this Court.

10. Upon information and belief, Defendants have a regular and established place of business in this judicial district because, for example, Teva USA, maintains places of business in this judicial district.

11. Upon information and belief, Teva USA and Teva Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States.

12. Teva USA and Teva Ltd. availed themselves of the rights, benefits, and privileges of this Court by filing complaints in the District of New Jersey in at least the following actions: *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Labs., Ltd., et al.*, Civil Action No. 17-cv-00517 (Teva USA and Teva Ltd.); *Teva Pharmaceuticals USA, Inc. et al. v. Sandoz Inc. et al.*, Civil Action No. 17-cv-00275 (Teva USA and Teva Ltd.); and *Teva Pharmaceutical USA, Inc. et al. v. Synthon Pharmaceuticals, Inc. et al.*, Civil Action No. 15-cv-00472 (Teva USA and Teva Ltd.).

13. Teva USA and/or Teva Ltd. consented to or did not contest jurisdiction of this Court, for example, in at least the following District of New Jersey actions: *Sebela Int'l Ltd. et al. v. Actavis Labs. FL, Inc. et al.*, Case No. 17-cv-04789 (Teva USA and Teva Ltd.); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 15-cv-06401 (Teva USA); *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 14-cv-07811 (Teva USA and Teva Ltd.).

14. Teva USA availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims, for example, in at least the following District of New Jersey actions: *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 15-cv-06401; *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 14-cv-07811.

15. Teva is subject to specific jurisdiction in this district based on the filing of its ANDA for its generic ascorbic acid/polyethylene glycol 3350/potassium chloride/sodium ascorbate/sodium chloride/sodium sulfate for oral solution, 7.54 g/140 g/2.2 g/48.11 g/5.2 g/9 g, product.

16. Teva has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, this judicial district and elsewhere.

17. Teva's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.

18. Upon information and belief, Teva intends to direct sales of its drugs into New Jersey, among other places, once it has requested FDA approval to market them.

19. Upon information and belief, Teva will engage in marketing of Teva's ANDA Product in New Jersey, upon approval of its ANDA.

20. Teva's ANDA filing regarding the '313, '969, '252, '297, and '504 patents at issue here is suit-related and has a substantial connection with this judicial district because it reliably, non-speculatively predicts activities by Teva in this judicial district.

21. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

22. Teva USA and/or Teva Ltd. did not contest venue in this judicial district in at least the following actions: *Sebela Int'l Ltd. v. Actavis Labs. FL, Inc.*, Case No. 17-cv-04789 (Teva USA and Teva Ltd.); *Sumitomo Dainippon Pharma Co., Ltd. v. Teva Pharmaceuticals USA, Inc.* Civil Action No. 15-cv-06401 (Teva USA); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-cv-07811 (Teva USA and Teva Ltd.).

23. Venue is proper against Teva USA because, *inter alia*, it maintains a regular and established place of business in this judicial district.

24. Venue is proper against Teva Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this district.

THE PATENTS IN SUIT

25. The U.S. Patent and Trademark Office ("PTO") issued the '313 patent on April 7, 2015. The '313 patent claims, *inter alia*, compositions for admixture with water, compositions, and kits comprising compositions for the preparation of colon cleansing solutions. Plaintiffs hold all substantial rights in the '313 patent and have the right to sue for infringement thereof. Norgine is the assignee of the '313 patent. A copy of the '313 patent is attached hereto as Exhibit A.

26. The PTO issued the ’969 patent on May 3, 2016. The ’969 patent claims, *inter alia*, methods of cleansing the colon. Plaintiffs hold all substantial rights in the ’969 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’969 patent. A copy of the ’969 patent is attached hereto as Exhibit B.

27. The PTO issued the ’252 patent on March 14, 2017. The ’252 patent claims, *inter alia*, colon cleansing solutions, kits comprising colon cleansing solutions, kits comprising compositions for the preparation of colon cleansing solutions, and methods of cleansing the colon. Plaintiffs hold all substantial rights in the ’252 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’252 patent. A copy of the ’252 patent is attached hereto as Exhibit C.

28. The PTO issued the ’297 patent on July 18, 2017. The ’297 patent claims, *inter alia*, kits comprising compositions for the preparation of colon cleansing solutions and kits comprising colon cleansing solutions. Plaintiffs hold all substantial rights in the ’297 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’297 patent. A copy of the ’297 patent is attached hereto as Exhibit D.

29. The PTO issued the ’504 patent on July 10, 2018. The ’504 patent claims, *inter alia*, solutions in water and methods of preparing solutions. Plaintiffs hold all substantial rights in the ’504 patent and have the right to sue for infringement thereof. Norgine is the assignee of the ’504 patent. A copy of the ’504 patent is attached hereto as Exhibit E.

30. Salix is the holder of NDA No. 209381 for Plenvu®, which the FDA approved on May 4, 2018. In conjunction with NDA No. 209381, the ’313, ’969, ’252, ’297, and ’504 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

31. Polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution is sold in the United States under the trademark Plenvu®.

TEVA'S INFRINGING ANDA SUBMISSION

32. Upon information and belief, Teva filed or caused to be filed with the FDA ANDA No. 213022, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

33. Upon information and belief, Teva's ANDA No. 213022 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Teva's ANDA Product, which Teva intends to be a generic version of Plenvu®.

34. Plaintiffs received a letter from Teva USA dated March 27, 2019, purporting to be a Notice of ANDA No. 213022 with Paragraph IV Certifications ("Teva's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Teva's Notice Letter was addressed to Salix and Norgine.

35. Teva's Notice Letter alleges that Teva USA has submitted to the FDA ANDA No. 213022 seeking "approval to engage in the commercial manufacture, use or sale of" Teva's ANDA Product.

36. Teva's Notice Letter states that Teva's ANDA No. 213022 "contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver" for Teva's ANDA Product.

37. Teva's Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, does not set forth any non-infringement defense related to any claims of the '313, '969, '252, '297, and '504 patents.

38. The ’313, ’969, ’252, ’297, and ’504 patents are listed in the Orange Book in conjunction with NDA No. 209381 for Plenvu®.

39. Upon information and belief, ANDA No. 213022 seeks approval of Teva’s ANDA Product that is the same, or substantially the same, as Plenvu®.

40. Upon information and belief, Teva USA’s actions related to ANDA No. 213022 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Teva Ltd.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the ’313 Patent Under § 271(e)(2)

41. Paragraphs 1–40 are incorporated herein as set forth above.

42. Under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the ’313 patent by submitting, or causing to be submitted to the FDA, ANDA No. 213022 seeking approval for the commercial marketing of Teva’s ANDA Product before the expiration date of the ’313 patent.

43. Upon information and belief, Teva’s ANDA Product will, if approved and marketed, infringe at least one claim of the ’313 patent.

44. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of Teva’s ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’313 patent.

45. If Teva’s marketing and sale of Teva’s ANDA Product prior to the expiration of the ’313 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’313 Patent

46. Paragraphs 1–45 are incorporated herein as set forth above.

47. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

49. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva’s ANDA Product before the expiration date of the ’313 patent, including Teva’s filing of ANDA No. 213022.

50. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’313 patent.

51. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Teva’s ANDA Product will constitute infringement of at least one claim of the ’313 patent.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the ’969 Patent Under § 271(e)(2)

52. Paragraphs 1–51 are incorporated herein as set forth above.

53. Under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the ’969 patent by submitting, or causing to be submitted to the FDA, ANDA No. 213022 seeking approval

for the commercial marketing of Teva's ANDA Product before the expiration date of the '969 patent.

54. Upon information and belief, Teva's ANDA Product will, if approved and marketed, infringe at least one claim of the '969 patent.

55. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of Teva's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '969 patent.

56. If Teva's marketing and sale of Teva's ANDA Product prior to the expiration of the '969 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '969 Patent

57. Paragraphs 1–56 are incorporated herein as set forth above.

58. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

59. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

60. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva's ANDA Product before the expiration date of the '969 patent, including Teva's filing of ANDA No. 213022.

61. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '969 patent.

62. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Teva's ANDA Product will constitute infringement of at least one claim of the '969 patent.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the '252 Patent Under § 271(e)(2)

63. Paragraphs 1–62 are incorporated herein as set forth above.

64. Under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '252 patent by submitting, or causing to be submitted to the FDA, ANDA No. 213022 seeking approval for the commercial marketing of Teva's ANDA Product before the expiration date of the '252 patent.

65. Upon information and belief, Teva's ANDA Product will, if approved and marketed, infringe at least one claim of the '252 patent.

66. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of Teva's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '252 patent.

67. If Teva's marketing and sale of Teva's ANDA Product prior to the expiration of the '252 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’252 Patent

68. Paragraphs 1–67 are incorporated herein as set forth above.

69. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

70. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

71. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva’s ANDA Product before the expiration date of the ’252 patent, including Teva’s filing of ANDA No. 213022.

72. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’252 patent.

73. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Teva’s ANDA Product will constitute infringement of at least one claim of the ’252 patent.

COUNT VII FOR PATENT INFRINGEMENT

Infringement of the ’297 Patent Under § 271(e)(2)

74. Paragraphs 1–73 are incorporated herein as set forth above.

75. Under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the ’297 patent by submitting, or causing to be submitted to the FDA, ANDA No. 213022 seeking approval

for the commercial marketing of Teva's ANDA Product before the expiration date of the '297 patent.

76. Upon information and belief, Teva's ANDA Product will, if approved and marketed, infringe at least one claim of the '297 patent.

77. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of Teva's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '297 patent.

78. If Teva's marketing and sale of Teva's ANDA Product prior to the expiration of the '297 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '297 Patent

79. Paragraphs 1–78 are incorporated herein as set forth above.

80. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

81. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

82. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva's ANDA Product before the expiration date of the '297 patent, including Teva's filing of ANDA No. 213022.

83. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '297 patent.

84. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Teva's ANDA Product will constitute infringement of at least one claim of the '297 patent.

COUNT IX FOR PATENT INFRINGEMENT

Infringement of the '504 Patent Under § 271(e)(2)

85. Paragraphs 1–84 are incorporated herein as set forth above.

86. Under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '504 patent by submitting, or causing to be submitted to the FDA, ANDA No. 213022 seeking approval for the commercial marketing of Teva's ANDA Product before the expiration date of the '504 patent.

87. Upon information and belief, Teva's ANDA Product will, if approved and marketed, infringe at least one claim of the '504 patent.

88. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of Teva's ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '504 patent.

89. If Teva's marketing and sale of Teva's ANDA Product prior to the expiration of the '504 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’504 Patent

90. Paragraphs 1–89 are incorporated herein as set forth above.

91. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

93. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva’s ANDA Product before the expiration date of the ’504 patent, including Teva’s filing of ANDA No. 213022.

94. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’504 patent.

95. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Teva’s ANDA Product will constitute infringement of at least one claim of the ’504 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Teva on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the ’313 patent by submitting or causing to be submitted ANDA No. 213022 to the FDA

to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva's ANDA Product before the expiration of the '313 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '969 patent by submitting or causing to be submitted ANDA No. 213022 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva's ANDA Product before the expiration of the '969 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '252 patent by submitting or causing to be submitted ANDA No. 213022 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva's ANDA Product before the expiration of the '252 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '297 patent by submitting or causing to be submitted ANDA No. 213022 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva's ANDA Product before the expiration of the '297 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '504 patent by submitting or causing to be submitted ANDA No. 213022 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva's ANDA Product before the expiration of the '504 patent;

6. Order that the effective date of any approval by the FDA of Teva's ANDA Product be a date that is not earlier than the expiration of the '313, '969, '252, '297, and '504 patents or such later date as the Court may determine;

7. Enjoin Teva from the commercial manufacture, use, import, offer for sale, and/or sale of Teva's ANDA Product until expiration of the '313, '969, '252, '297, and '504 patents or such later date as the Court may determine;

8. Enjoin Teva and all persons acting in concert with Teva from seeking, obtaining, or maintaining approval of Teva's ANDA No. 213022 until expiration of the '313, '969, '252, '297, and '504 patents;

9. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

10. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: May 9, 2019
Newark, New Jersey

s/ William P. Deni, Jr.
William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
cchevalier@gibbonslaw.com
jlower@gibbonslaw.com

Attorneys for Plaintiffs

Bryan C. Diner
Justin J. Hasford
Krista E. Bianco (*pro hac vice* to be submitted)
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
Tel: (202) 408-4000

Attorneys for Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc.

Martin H. Black (*pro hac vice* to be submitted)
DECHERT LLP
Cira Centre, 2929 Arch St.
Philadelphia, Pennsylvania 19104-2808
Tel: (215) 994-4000

Katherine A. Helm (*pro hac vice* to be submitted)
DECHERT LLP
3 Bryant Park
1095 Avenue of the Americas
New York, New York 10036
Tel: (212) 698-3500

Robert D. Rhoad
DECHERT LLP
502 Carnegie Center, Suite #104
Princeton, New Jersey, 08540
Tel.: (609) 955-3269

Attorneys for Plaintiff Norgine B.V.

CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: May 9, 2019
Newark, New Jersey

s/ William P. Deni, Jr.
William P. Deni, Jr.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com

Attorneys for Plaintiffs