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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RAYNER SURGICAL INC. and RAYNER INTRAOCULAR LENSES LTD., Plaintiffs, v. SOMERSET THERAPEUTICS, LLC, Defendant.	C.A. No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Rayner Surgical Inc. ("Rayner Surgical") and Rayner Intraocular Lenses Ltd. ("Rayner Intraocular") (collectively, "Rayner" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Somerset Therapeutics, LLC ("Somerset") and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq., and in particular 35 U.S.C § 271, arises from Somerset's submission of Abbreviated New Drug Application ("ANDA") No. 219384 ("Somerset ANDA") to the United States Food and Drug Administration ("FDA"). Through the Somerset ANDA,

Somerset seeks approval to market a generic version of Rayner's product OMIDRIA® (phenylephrine and ketorolac injection, 1%/0.3%) (the "ANDA Product") prior to the expiration of United States Patent No. 9,066,856 (the "'856 Patent"); United States Patent No. 9,486,406 (the "'406 Patent"); and United States Patent No. 9,855,246 (the "'246 Patent") (together, the "Patents-in-Suit"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq., and in particular 35 U.S.C. § 271.

THE PARTIES

3. Plaintiff Rayner Surgical is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 1255 Lynnfield Road, Suite 257, Memphis, TN 38119.

4. Plaintiff Rayner Intraocular is a private limited company organized and existing under the laws of the England, having a principal place of business at 10 Dominion Way, Worthing, West Sussex, England BN14 8AQ.

5. On information and belief, Defendant Somerset is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 300 Franklin Square Drive, Somerset, NJ 08873.

6. On information and belief, Somerset caused ANDA No. 219384 to be submitted to the FDA and seeks approval of the Somerset ANDA.

7. On information and belief, Somerset intends to commercially manufacture, market, offer for sale, and sell the ANDA Product throughout the United States, including in the State of New Jersey, in the event the FDA approves the Somerset ANDA.

JURISDICTION AND VENUE

8. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and 28 U.S.C. §§ 1338(a), 2201, and 2202.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

10. On information and belief, this Court has personal jurisdiction over Somerset at least because Somerset has its principal place of business in New Jersey.

11. This Court also has personal jurisdiction over Somerset because Somerset has continuous and systematic contacts with New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell the ANDA Product in the State of New Jersey upon approval of the Somerset ANDA.

12. On information and belief, Somerset is in the business of manufacturing, obtaining regulatory approval, marketing, distributing, and selling generic copies of branded pharmaceutical products throughout the United States, including within the State of New Jersey, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, from which Somerset derives a substantial portion of its revenue.

13. On information and belief, Somerset plans to sell the ANDA Product in the State of New Jersey, list the ANDA Product on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of New Jersey, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

14. On information and belief, Somerset knows and intends that the ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of OMIDRIA®, causing

injury to Rayner. Somerset intends to take advantage of its established channels of distribution in New Jersey for the sale of the ANDA Product.

15. On information and belief, Somerset has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture OMIDRIA® for sale and use throughout the United States, including this Judicial District.

16. Somerset has not contested personal jurisdiction in this Court in recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, Answer at 5–9, *American Regent, Inc. v. Somerset Therapeutics, LLC*, *et al.*, C.A. No. 24-cv-7807-BRM-CLW (D.N.J. Aug. 19, 2024); Answer at ¶¶ 28–30, 34, *Esperion Therapeutics, Inc. v. Renata Ltd.*, *et al.*, C.A. No. 2:24-cv-06017-JXN-CLW (D.N.J. Aug. 2, 2024); Answer at 4, *Nexus Pharms., Inc. v. Somerset Therapeutics, LLC*, *et al.*, C.A. No. 3:23-cv-01248-ZNQ-RLS (D.N.J. May 12, 2023).

17. Venue is proper in this Judicial District for Somerset pursuant to 28 U.S.C. § 1400 because, on information and belief, Somerset has a regular and established place of business in New Jersey and has committed acts of infringement in New Jersey. On information and belief, based on Somerset's presence in and connections to New Jersey, discoverable information in Somerset's possession, custody, or control regarding the Somerset ANDA will likely show that Somerset engaged in activities in New Jersey relevant to the preparation and/or submission of the Somerset ANDA in New Jersey.

RAYNER'S APPROVED OMIDRIA DRUG PRODUCT AND PATENTS

18. Rayner makes and sells OMIDRIA®, a combination product used during cataract surgery or intraocular lens replacement to maintain pupil size by preventing miosis and to reduce postoperative pain. OMIDRIA® contains two active ingredients: phenylephrine hydrochloride and

ketorolac tromethamine. A true and correct copy of the prescribing information for OMIDRIA® is attached as Exhibit A.

19. OMIDRIA® is a stable, sterile pharmaceutical formulation containing phenylephrine, ketorolac, citric acid, sodium citrate, and water for injection, and may include sodium hydroxide and/or hydrochloric acid for pH adjustment. OMIDRIA® is preservative free and contains no antioxidants.

20. OMIDRIA® is the first FDA-approved product for intraocular use during cataract surgery or intraocular lens replacement that both prevents intraoperative miosis (pupil constriction) and reduces postoperative pain.

21. Rayner Surgical is the holder of New Drug Application ("NDA") No. 205388 for OMIDRIA®. The FDA approved NDA No. 205388 for OMIDRIA® in May 2014.

22. Rayner Intraocular is the assignee and owner of the '856 Patent, the '406 Patent, and the '246 Patent.

23. The '856, '406, and '246 Patents are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for OMIDRIA®.

24. The '856 Patent, entitled "Stable Preservative-Free Mydriatic and Anti-Inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on June 30, 2015. A true and correct copy of the '856 Patent is attached as Exhibit B.

25. The '406 Patent, entitled "Stable Preservative-Free Mydriatic and Anti-Inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on November 8, 2016. A true and correct copy of the '406 Patent is attached as Exhibit C.

26. The '246 Patent, entitled "Stable Preservative-Free Mydriatic and Anti-Inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on January 2, 2018. A true and correct copy of the '246 Patent is attached as Exhibit D.

SOMERSET'S ANDA NO. 219384

27. On information and belief, Somerset has submitted or caused to be submitted ANDA No. 219384 to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of ketorolac tromethamine, phenylephrine hydrochloride solution, as a purported generic version of OMIDRIA®, prior to the expiration of the '856, '406, and '246 Patents.

28. Somerset mailed Plaintiffs a letter dated July 26, 2024, regarding "Notice of Paragraph IV Certification, ketorolac tromethamine; phenylephrine hydrochloride, Eq 0.3% Base; Eq 1% base" (the "Notice Letter"). The Notice Letter represented that Somerset has submitted to the FDA ANDA No. 219384 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Somerset's ANDA before the expiration of the patents listed in the Orange Book for OMIDRIA®. Hence, Somerset's purpose in submitting it's ANDA is to manufacture and market the ANDA Product before the expiration of the '856, '406, and '246 Patents.

29. In Somerset's Notice Letter, Somerset purported to offer access to portions of the Somerset ANDA on terms and conditions set forth in Somerset's Notice Letter (the "Somerset Offer"). Somerset requested that Plaintiffs accept the Somerset Offer before receiving access to the Somerset ANDA. The Somerset Offer contained unreasonable restrictions regarding access to its ANDA, well beyond those that would apply under a protective order and contravening 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information

accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

30. Outside counsel for Rayner attempted to negotiate in good faith with counsel for Somerset in order to reach agreement on reasonable terms of confidential access to Somerset's ANDA. Counsel for Rayner proposed edits to the Somerset Offer on August 21, 2024 consistent with protective orders entered in recent litigation involving similar subject matter in this Judicial District, and consistent with the purpose of 21 U.S.C. § 355(j)(5)(C)(i)(III). On August 27, 2024, counsel for Somerset responded with additional edits, including imposing additional restrictions. Counsel for Rayner responded promptly with proposed targeted revisions on August 28, 2024. Counsel for Somerset then took over a week before responding on September 5, 2024, and made further revisions. Somerset's delay in responding to Plaintiffs and providing revisions to the Somerset Offer were unreasonable and effectively deprived Plaintiffs of an opportunity to meaningfully review Somerset's ANDA, in contravention to the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III). To date, Plaintiffs have not received access to Somerset's ANDA.

31. On information and belief, if the FDA approves the Somerset ANDA, Somerset will manufacture, offer for sale, or sell the ANDA Product within the United States, including within New Jersey, or will import the ANDA Product into the United States, including New Jersey, and/or will import the ANDA Product into the United States including the State of New Jersey.

32. On information and belief, if the FDA approves the Somerset ANDA, Somerset will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in the United States.

33. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF THE '856 PATENT

34. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–33 as if fully set forth herein.

35. On information and belief, Somerset has submitted or caused the submission of the Somerset ANDA to the FDA, and continues to seek FDA approval of the Somerset ANDA.

36. On information and belief, Somerset has infringed one or more claims of the '856 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Somerset ANDA with a Paragraph IV certification and seeking FDA approval of the Somerset ANDA prior to the expiration of the '856 Patent, entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for the Somerset ANDA be a date which is not earlier than the expiration date of the '856 Patent.

37. On information and belief, FDA regulations provide that, "[g]enerally, a drug product intended for ophthalmic use . . . . must contain the same inactive ingredients and in the same concentration as the reference listed drug" and further that "in a product intended for ophthalmic use, an applicant may not change a buffer . . . for the purpose of claiming a therapeutic advantage over or difference from the listed drug . . . or by making a significant change in the pH or other change that may raise questions of irritability." 21 C.F.R. § 314.94(a)(9)(iv).

38. Claim 1 of the '856 Patent recites:

> A sterile liquid pharmaceutical formulation consisting essentially of phenylephrine, ketorolac and a buffer system in an aqueous carrier, wherein the formulation is stable for at least six months when stored at a temperature of from 5+/-3° C. to 25 +/-2° C.

39. On information and belief, Somerset's ANDA product is a sterile liquid pharmaceutical formulation consisting essentially of phenylephrine, ketorolac, and a buffer system

in an aqueous carrier. Somerset's Notice Letter does not dispute that the pharmaceutical formulation meets the stability requirement.

40. Somerset's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the '856 Patent. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of the Somerset ANDA, Somerset will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '856 Patent.

41. On information and belief, upon FDA approval of the Somerset ANDA, Somerset will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Somerset will also knowingly and intentionally accompany the ANDA Product with proposed prescribing information and a product insert that will include instructions for using and administering the ANDA Product. Accordingly, Somerset will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '856 Patent. In addition, on information and belief, Somerset will encourage acts of direct infringement with knowledge of the '856 Patent and knowledge that they are encouraging infringement.

42. Somerset had actual and constructive notice of the '856 Patent prior to filing the Somerset ANDA, and was aware that the filing of the Somerset ANDA with the request for FDA approval prior to the expiration of the '856 Patent would constitute an act of infringement of the '856 Patent.

43. In addition, upon information and belief, Somerset filed the Somerset ANDA without adequate justification for asserting the '856 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Somerset's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '856 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

44. Plaintiffs will be irreparably harmed if Somerset is not enjoined from infringing, and from actively inducing or contributing to the infringement of one or more claims of the '856 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Somerset, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '856 PATENT

45. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–44 as if fully set forth herein.

46. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. On information and belief, if the Somerset ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Somerset and its affiliates. Somerset will therefore directly infringe one or more claims of the '856 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

48. On information and belief, Somerset knows that health care professionals or patients will use the ANDA Product in accordance with the proposed prescribing information

sought by the Somerset ANDA and Somerset will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '856 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

49. On information and belief, Somerset's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Somerset ANDA. Any such conduct before the '856 Patent expires will directly infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '856 Patent under one or more of 35 U.S.C. §§ 271(a), (b) and (c).

50. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Somerset concerning liability for the infringement of one or more claims of the '856 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

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

52. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '406 PATENT

53. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–52 as if fully set forth herein.

54. On information and belief, Somerset has submitted or caused the submission of the Somerset ANDA to the FDA, and continues to seek FDA approval of the Somerset ANDA.

55. On information and belief, Somerset has infringed one or more claims of the '406 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Somerset ANDA with a Paragraph IV certification and seeking FDA approval of the Somerset ANDA prior to the expiration of the '406 Patent, entitling Plaintiffs to the relief provided by 35 U.S.C. §271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for the Somerset ANDA be a date which is not earlier than the expiration date of the '406 Patent.

56. On information and belief, FDA regulations provide that, "[g]enerally, a drug product intended for ophthalmic use . . . must contain the same inactive ingredients and in the same concentration as the reference listed drug" and further that "in a product intended for ophthalmic use, an applicant may not change a buffer . . . for the purpose of claiming a therapeutic advantage over or difference from the listed drug . . . or by making a significant change in the pH or other change that may raise questions of irritability." 21 C.F.R. § 314.94(a)(9)(iv).

57. Claim 2 of the '406 Patent recites:

> A liquid pharmaceutical formulation comprising phenylephrine, ketorolac and a buffer system in an aqueous carrier, wherein the formulation is stable without the inclusion of preservatives and antioxidants for at least six months when stored at a temperature of from 5+/-3°C. to 25+/-2 º C.

58. On information and belief, Somerset's ANDA product is a liquid pharmaceutical formulation having phenylephrine, ketorolac, and a buffer system in an aqueous carrier without inclusion of preservatives and antioxidants. Somerset's Notice Letter does not dispute that the pharmaceutical formulation meets the stability requirement.

59. Somerset's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the '406 Patent. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of the Somerset

ANDA, Somerset will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '406 Patent.

60. On information and belief, upon FDA approval of the Somerset ANDA, Somerset will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Somerset will also knowingly and intentionally accompany the ANDA Product with proposed prescribing information and a product insert that will include instructions for using and administering the ANDA Product. Accordingly, Somerset will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '406 Patent. In addition, on information and belief, Somerset will encourage acts of direct infringement with knowledge of the '406 Patent and knowledge that they are encouraging infringement.

61. Somerset had actual and constructive notice of the '406 Patent prior to filing the Somerset ANDA, and was aware that the filing of the Somerset ANDA with the request for FDA approval prior to the expiration of the '406 Patent would constitute an act of infringement of the '406 Patent.

62. In addition, upon information and belief, Somerset filed the Somerset ANDA without adequate justification for asserting the '406 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Somerset's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '406 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

63. Plaintiffs will be irreparably harmed if Somerset is not enjoined from infringing, and from actively inducing or contributing to the infringement of one or more claims of the '406 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Somerset, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '406 PATENT

64. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–63 as if fully set forth herein.

65. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. On information and belief, if the Somerset ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Somerset and its affiliates. Somerset will therefore directly infringe one or more claims of the '406 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

67. On information and belief, Somerset knows that health care professionals or patients will use the ANDA Product in accordance with the proposed prescribing information sought by the Somerset ANDA and Somerset will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '406 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

68. On information and belief, Somerset's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Somerset ANDA. Any such conduct

before the ’406 Patent expires will directly infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’406 Patent under one or more of 35 U.S.C. §§ 271(a), (b) and (c).

69. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Somerset concerning liability for the infringement of one or more claims of the ’406 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

70. Plaintiffs will be substantially and irreparably harmed by Somerset’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

71. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE ’246 PATENT

72. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–71 as if fully set forth herein.

73. On information and belief, Somerset has submitted or caused the submission of the Somerset ANDA to the FDA, and continues to seek FDA approval of the Somerset ANDA.

74. On information and belief, Somerset has infringed one or more claims of the ’246 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Somerset ANDA with a Paragraph IV certification and seeking FDA approval of the Somerset ANDA prior to the expiration of the ’246 Patent, entitling Plaintiffs to the relief provided by 35 U.S.C. §271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for the Somerset ANDA be a date which is not earlier than the expiration date of the ’246 Patent.

75. On information and belief, FDA regulations provide that, "[g]enerally, a drug product intended for ophthalmic use . . . must contain the same inactive ingredients and in the same concentration as the reference listed drug" and further that "in a product intended for ophthalmic use, an applicant may not change a buffer . . . for the purpose of claiming a therapeutic advantage over or difference from the listed drug . . . or by making a significant change in the pH or other change that may raise questions of irritability." 21 C.F.R. § 314.94(a)(9)(iv).

76. Claim 1 of the '246 Patent recites:

> A liquid intraocular ophthalmic pharmaceutical solution dosage form consisting essentially of phenylephrine, ketorolac, and a buffer system, in solution in a pH-adjusted aqueous carrier as a solvent, that is free of preservatives, antioxidants and solubilizing agents, and a nitrogen gas overlay in a single use container, wherein the phenylephrine is included at a concentration of 45 mM to 76 mM and the ketorolac is included at a concentration of about 8.5 mM to 14 mM, wherein the intraocular ophthalmic pharmaceutical solution is stable for a period of at least six months when stored at a temperature of from 5+/-3° C. to 25+/-2° C.

77. On information and belief, Somerset's ANDA product is a liquid intraocular ophthalmic pharmaceutical solution dosage form in a single use container consisting essentially of phenylephrine, at a concentration from 45 mM to 76 mM, ketorolac, at a concentration of from 8.5 mM to 14 mM, a buffer system in a pH-adjusted aqueous carrier, that is free of preservatives, antioxidants, and solubilizing agents, and a nitrogen gas overlay. Somerset's Notice Letter does not dispute that the pharmaceutical formulation meets the stability requirement.

78. Somerset's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, actively induce infringement, and/or contribute to infringement of one or more claims of the '246 Patent. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of the Somerset ANDA, Somerset will make, use, offer to sell, or sell the ANDA Product within the United States,

or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '246 Patent.

79. On information and belief, upon FDA approval of the Somerset ANDA, Somerset will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Somerset will also knowingly and intentionally accompany the ANDA Product with proposed prescribing information and a product insert that will include instructions for using and administering the ANDA Product. Accordingly, Somerset will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '246 Patent. In addition, on information and belief, Somerset will encourage acts of direct infringement with knowledge of the '246 Patent and knowledge that they are encouraging infringement.

80. Somerset had actual and constructive notice of the '246 Patent prior to filing the Somerset ANDA, and was aware that the filing of the Somerset ANDA with the request for FDA approval prior to the expiration of the '246 Patent would constitute an act of infringement of the '246 Patent.

81. In addition, upon information and belief, Somerset filed the Somerset ANDA without adequate justification for asserting the '246 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Somerset's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '246 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

82. Plaintiffs will be irreparably harmed if Somerset is not enjoined from infringing, and from actively inducing or contributing to the infringement of one or more claims of the '246 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Somerset, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '246 PATENT

83. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–82 as if fully set forth herein.

84. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

85. On information and belief, if the Somerset ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Somerset and its affiliates. Somerset will therefore directly infringe one or more claims of the '246 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

86. On information and belief, Somerset knows that health care professionals or patients will use the ANDA Product in accordance with the proposed prescribing information sought by the Somerset ANDA and Somerset will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '246 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

87. On information and belief, Somerset's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Somerset ANDA. Any such conduct

before the ’246 Patent expires will directly infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’246 Patent under one or more of 35 U.S.C. §§ 271(a), (b) and (c).

88. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Somerset concerning liability for the infringement of one or more claims of the ’246 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

89. Plaintiffs will be substantially and irreparably harmed by Somerset’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

90. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment that under 35 U.S.C. § 271(e)(2)(A), Somerset’s submission to the FDA of ANDA No. 219384 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the ’856 Patent was an act of infringement of one or more claims of the ’856 Patent;

(B) A Judgment that under 35 U.S.C. § 271(e)(2)(A), Somerset’s submission to the FDA of ANDA No. 219384 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the ’406 Patent was an act of infringement of one or more claims of the ’406 Patent;

(C) A Judgment that under 35 U.S.C. § 271(e)(2)(A), Somerset’s submission to the FDA of ANDA No. 219384 to obtain approval for the commercial manufacture, use, offer for sale,

or sale in, or importation into, the United States of the ANDA Product before the expiration of the '246 Patent was an act of infringement of one or more claims of the '246 Patent;

(D) A Declaratory Judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Somerset's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '856 Patent;

(E) A Declaratory Judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Somerset's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '406 Patent;

(F) A Declaratory Judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Somerset's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '246 Patent;

(G) The entry of a preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Somerset, its affiliates and subsidiaries, and all persons and entities acting in concert with Somerset from commercially manufacturing, using, offering for sale, or selling the ANDA Product within the United States, or importing the ANDA Product into the United States, until the expiration of the '856, '406, and '246 Patents;

(H) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 219384 shall be no earlier than the last expiration date of any of the '856, '406, and '246 Patents, or any later expiration of exclusivity for any of the '856, '406, and '246 Patents, including any extensions or regulatory exclusivities;

(I) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Somerset engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '856 Patent, or induces or contributes to such conduct, prior to the expiration of the '856 Patent;

(J) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Somerset engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '406 Patent, or induces or contributes to such conduct, prior to the expiration of the '406 Patent;

(K) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Somerset engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '246 Patent, or induces or contributes to such conduct, prior to the expiration of the '246 Patent;

(L) The entry of Judgment declaring that Somerset's acts render this case an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(M) An award to Plaintiffs of their costs and expenses in this action; and

(N) Such other and further relief as the Court deems just and proper.

Dated: September 6, 2024

Respectfully submitted,

s/ Charles M. Lizza

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LOCAL CIVIL RULES 11.2 AND 40.1 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: September 6, 2024

Respectfully submitted,

s/ Charles M. Lizza

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