IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UROGEN PHARMA LTD., and UROGEN PHARMA, INC., Plaintiffs, v. TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UroGen Pharma Ltd. and UroGen Pharma, Inc. (collectively, "Plaintiffs" or "UroGen") for their Complaint against Defendants Teva Pharmaceuticals, Inc. ("Teva Inc."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Defendants" or "Teva"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by Teva to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of generic versions of Plaintiffs' JELMYTO® (mitomycin) for pyelocalyceal solution, 40 mg/vial, prior to the expiration of U.S. Patent Nos. 9,040,074 ("the '074 patent"); and 9,950,069 ("the '069 patent") (collectively "the JELMYTO® patents").

THE PARTIES

2. Plaintiff UroGen Pharma Ltd. is a company existing under the laws of Israel, having its principal place of business at 9 Ha`Ta`Asiya Street, Ra'anana 4365007, Israel.

3. Plaintiff UroGen Pharma, Inc. is a corporation existing under the laws of Delaware, having its principal place of business at 400 Alexander Drive, 4th Floor, Princeton, NJ 08540.

4. UroGen is a biotech company dedicated to developing and commercializing innovative solutions to treat urothelial and specialty cancers. UroGen's breakthrough JELMYTO® therapy and innovative clinical pipeline aim to maximize the potential benefit of local delivery with UroGen's novel sustained-release RTGel® reverse-thermal hydrogel technology by bringing to patients transformative, nonsurgical approaches to treating challenging cancers.

5. On information and belief, Defendant Teva Inc. is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 400 Interpace Parkway #3, Parsippany, NJ 07054.

6. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway #3, Parsippany, NJ 07054.

7. On information and belief, Defendant Teva Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 124 Dvora HaNevi'a St, Tel Aviv 6944020, Israel.

8. On information and belief, Teva Inc. is a wholly owned subsidiary of Teva Ltd.

9. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

10. On information and belief, each of Teva Inc., Teva USA, and Teva Ltd. is in the business of, among other things, manufacturing, marketing, importing, preparing, and selling

generic versions of branded pharmaceutical drugs throughout the United States, including in the State of Delaware, either individually or in concert.

11. On information and belief, Teva Inc., Teva USA, and Teva Ltd. act in concert and agency with each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products. On information and belief, the acts of Teva Inc., Teva USA, Teva Ltd. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

12. On information and belief, Teva prepared and caused to be submitted to the FDA ANDA No. 218215 pursuant to § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and Section 314.95 of the Food and Drug Administration Regulation (21 C.F.R. § 314.95) (hereinafter "Teva's ANDA") concerning proposed drug product, mitomycin for pyelocalyceal solution, 40 mg/vial (hereinafter "Teva's Proposed ANDA Product"). On information and belief, Teva's ANDA refers to and relies upon UroGen Pharma Ltd.'s New Drug Application ("NDA") No. 211728 for JELMYTO®.

13. By letter dated February 20, 2024 (the "Teva Notice Letter"), Teva notified Plaintiff UroGen Pharma Ltd. that, as part of its ANDA, Teva had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '074 patent and the '069 patent, each of which is listed in the FDA's Approved Drug Product with Therapeutic Equivalence Evaluations (the "Orange Book") for JELMYTO®, asserting that the '074 patent and the '069 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Teva's Proposed ANDA Product.

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Teva by virtue of the fact that, *inter alia*, Teva has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of Delaware and throughout the United States.

16. This Court has personal jurisdiction over Teva Inc. because, *inter alia*, upon information and belief Teva Inc. is a corporation organized and existing under the laws of the State of Delaware.

17. On information and belief, Teva Inc. maintains continuous and systematic contacts with Delaware through its authorized agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808.

18. This Court has personal jurisdiction over Teva USA because, *inter alia*, upon information and belief Teva USA is a corporation organized and existing under the laws of the State of Delaware.

19. On information and belief, Teva USA maintains continuous and systematic contacts with Delaware through its authorized agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808.

20. This Court also has personal jurisdiction over Teva because Teva has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva develops, manufactures,

imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

21. In addition, this Court has personal jurisdiction over Teva because, among other things, on information and belief, (1) Teva filed Teva's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Teva's Proposed ANDA Product in the United States, including in Delaware, and (2) upon approval of Teva's ANDA, Teva will market, distribute, offer for sale, sell, and/or import Teva's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Teva's Proposed ANDA Product in Delaware. On information and belief, upon approval of Teva's ANDA, Teva's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; administered by healthcare professionals practicing in Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware and lead to foreseeable harm and injury to Plaintiffs. Teva has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware.

22. This Court also has personal jurisdiction over Teva Inc., Teva USA, and Teva Ltd. by virtue of the fact that each previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, e.g., *Azurity Pharms., Inc., et al. v. Teva Pharms., Inc.*, No. 23-1080 (D. Del.); *Celgene Corp., et al. v. Teva Pharms. Inc.*, No. 23-

1008 (D. Del.); *Bayer Pharma AG, et al. v. Teva Pharms. USA, Inc.*, No. 23-51 (D. Del); *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 23-152 (D. Del.); *Amicus Therapeutics US, LLC, et al. v. Teva Pharms. USA, Inc., et al.*, No. 22-1462 (D. Del.); *Neurocrine Biosciences, Inc. v. Teva Pharms. Inc., et al.*, No. 22-965 (D. Del.); *Otsuka Pharm. Co., Ltd. v. Teva Pharms., Inc., et al.*, No. 22-513 (D. Del.); and *Journey Med. Corp. et al. v. Teva Pharms., Inc., et al.*, No. 22-288 (D. Del.). On information and belief, Teva has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Lab'ys, Ltd., et al.*, No. 16-1267 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Biocon Ltd., et al.*, No. 16-278 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Amneal Pharms. LLC*, 15-124 (D. Del.); *Teva Pharms. USA Inc. v. AstraZeneca Pharms. LP, et al.*, No. 15-50 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Synthon Pharms., Inc., et al.*, No 14-1419 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Sandoz, Inc. et al.*, No. 14-1171 (D. Del.).

23. Alternatively, assuming that the above facts do not establish personal jurisdiction over Teva Ltd., this Court may exercise jurisdiction over Teva Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

24. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Teva to litigate this action in this District, and Teva is subject to personal jurisdiction in this District.

25. Venue is proper in this district for Teva under 28 U.S.C. § 1400(b).

JELMYTO®

26. UroGen Pharma Ltd. holds approved NDA No. 211728 for JELMYTO® (mitomycin) for pyelocalyceal solution, 40 mg/vial. The FDA approved NDA No. 211728 for JELMYTO® (mitomycin) for pyelocalyceal solution, 40 mg/vial, on April 15, 2020. JELMYTO® is an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC). JELMYTO® was granted Orphan Drug Exclusivity for this patient group through April 15, 2027.

27. JELMYTO® is supplied in a kit containing two vials of sterile lyophilized mitomycin for pyelocalyceal solution each containing, *inter alia*, 40 mg of mitomycin, and one vial of 20 mL sterile hydrogel, to be used as vehicle for reconstitution. Reconstituted JELMYTO® is instilled into a patient's pyelocalyceal system as a liquid by a healthcare professional via nephrostomy tube or ureteral catheter. Once instilled, JELMYTO® conforms to the cavity and becomes a gel, exposing the tissue to mitomycin over a prolonged period of time.

28. The dose of JELMYTO® to be instilled is 4 mg per mL with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin). JELMYTO® is instilled once weekly for six weeks. For patients with a complete response 3 months after JELMYTO® initiation, JELMYTO® instillations may be administered once a month for a maximum of 11 additional instillations.

THE PATENTS-IN-SUIT

29. On May 26, 2015, the '074 patent, entitled "Material and Method for Treating Internal Cavities," was duly and legally issued. The '074 patent is assigned to and owned by UroGen Pharma Ltd. A true and correct copy of the '074 patent is attached hereto as Exhibit A.

30. On April 24, 2018, the ’069 patent, entitled “Material and Method for Treating Internal Cavities,” was duly and legally issued. The ’069 patent is assigned to and owned by UroGen Pharma Ltd. A true and correct copy of the ’069 patent is attached hereto as Exhibit B.

31. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, and in conjunction with NDA No. 211728, the JELMYTO® patents are listed in the Orange Book for JELMYTO® (mitomycin) for pyelocalyceal solution, 40 mg/vial.

32. The submission of Teva’s ANDA and Teva’s certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sell, and/or import of Teva’s Proposed ANDA Product before the expiration of the JELMYTO® patents create an actual case or controversy with respect to infringement of the JELMYTO® patents.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,040,074 UNDER 35 U.S.C. § 271(e)

33. Plaintiffs incorporate each of the preceding paragraphs 1–32 as if fully set forth herein.

34. By submitting ANDA No. 218215 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s Proposed ANDA Product throughout the United States, including Delaware, prior to expiration of the ’074 patent, Teva committed an act of infringement of the ’074 patent under 35 U.S.C. § 271(e)(2)(A).

35. The ’074 patent is directed to thermoreversible hydrogel compositions, and methods for providing sustained-release topical treatment of a condition affecting an internal body cavity through their administration to the internal body cavity.

36. On information and belief, Teva intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product with proposed labeling immediately and imminently upon final approval of its ANDA.

37. On information and belief, Teva's Proposed ANDA Product consists of a powder that contains mitomycin in an amount of 40 mg/vial. On information and belief, Teva's Proposed ANDA Product will be sold with a sterile thermoreversible hydrogel composition for reconstitution comprising between 23% and 27% (w/w) poloxamer, between 0.1% and 0.2% HPMC and between 0.5% and 1% PEG-400. Thus, on information and belief, Teva's manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's Proposed ANDA Product prior to the expiration of the '074 patent will directly infringe at least one claim of the '074 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. On information and belief, the proposed labeling for Teva's Proposed ANDA Product will be substantially identical to the JELMYTO® label and instructs and encourages healthcare professionals to practice the claims of the '074 patent.

39. The JELMYTO® label states that JELMYTO® is indicated for "the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC)." The JELMYTO® label instructs healthcare professionals to reconstitute JELMYTO® in the supplied hydrogel prior to instillation and states that it is "instilled in the patient's pyelocalyceal system" where it "will fill and conform to the cavity and become a gel, thereby exposing the tissue to mitomycin over a prolonged period of time" (*see, e.g.*, JELMYTO® label at 1, 21, copy attached as Exhibit C). Thus, on information and belief, the use of Teva's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '074 patent under 35 U.S.C. § 271(a).

40. On information and belief, Teva has actual knowledge of the ’074 patent and its listing in the Orange Book as demonstrated by at least Teva’s reference to the ’074 patent in Teva’s Notice Letter. The foregoing acts by Teva constitute and/or will constitute infringement of the ’074 patent and/or active inducement of infringement of the ’074 patent under 35 U.S.C. § 271(b).

41. Teva’s Proposed ANDA Product constitutes a material part of at least one of the claims of the ’074 patent. On information and belief, Teva knows that Teva’s Proposed ANDA Product will be especially made or especially adapted for use in infringing the ’074 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

42. On information and belief, Teva knows that its commercial manufacture, use, offer for sale, sale and/or importation of Teva’s Proposed ANDA Product prior to the ’074 patent’s expiration will contribute to the direct infringement of one or more claims of the ’074 patent under 35 U.S.C. § 271(c).

43. On information and belief, Teva’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’074 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

44. If Teva’s infringement of the ’074 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,040,074 UNDER 35 U.S.C. §§ 271(a), (b) and/or (c)

45. Plaintiffs incorporate each of the preceding paragraphs 1–44 as if fully set forth herein.

46. The ’074 patent is directed to thermoreversible hydrogel compositions, and methods for providing sustained-release topical treatment of a condition affecting an internal body cavity through their administration to the internal body cavity.

47. On information and belief, Teva intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product with proposed labeling immediately and imminently upon final approval of its ANDA.

48. On information and belief, Teva's Proposed ANDA Product consists of a powder that contains mitomycin in an amount of 40 mg/vial. On information and belief, Teva's Proposed ANDA Product will be sold with a sterile thermoreversible hydrogel composition for reconstitution comprising between 23% and 27% (w/w) poloxamer, between 0.1% and 0.2% HPMC and between 0.5% and 1% PEG-400. Thus, on information and belief, Teva's manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's Proposed ANDA Product prior to the expiration of the '074 patent will directly infringe at least one claim of the '074 patent under 35 U.S.C. § 271(a), (b) and/or (c).

49. On information and belief, the proposed labeling for Teva's Proposed ANDA Product will be substantially identical to the JELMYTO® label and instructs and encourages healthcare professionals to practice the claims of the '074 patent.

50. The JELMYTO® label states that JELMYTO® is indicated for "the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC)." The JELMYTO® label instructs healthcare professionals to reconstitute JELMYTO® in the supplied hydrogel prior to instillation and states that it is "instilled in the patient's pyelocalyceal system" where it "will fill and conform to the cavity and become a gel, thereby exposing the tissue to mitomycin over a prolonged period of time" (*see, e.g.*, JELMYTO® label at 1, 21, copy attached as Exhibit C). Thus, on information and belief, the use of Teva's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '074 patent under 35 U.S.C. § 271(a).

51. On information and belief, Teva has actual knowledge of the ’074 patent and its listing in the Orange Book as demonstrated by at least Teva’s reference to the ’074 patent in Teva’s Notice Letter. The foregoing acts by Teva constitute and/or will constitute infringement of the ’074 patent and/or active inducement of infringement of the ’074 patent under 35 U.S.C. § 271(b).

52. Teva’s Proposed ANDA Product constitutes a material part of at least one of the claims of the ’074 patent. On information and belief, Teva knows that Teva’s Proposed ANDA Product will be especially made or especially adapted for use in infringing the ’074 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

53. On information and belief, Teva knows that its commercial manufacture, use, offer for sale, sale and/or importation of Teva’s Proposed ANDA Product prior to the ’074 patent’s expiration will contribute to the direct infringement of one or more claims of the ’074 patent under 35 U.S.C. § 271(c).

54. On information and belief, Teva’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’074 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

55. If Teva’s infringement of the ’074 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 9,950,069 UNDER 35 U.S.C. § 271(e)

56. Plaintiffs incorporate each of the preceding paragraphs 1–55 as if fully set forth herein.

57. By submitting ANDA No. 218215 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s Proposed ANDA Product throughout the United States, including

Delaware, prior to expiration of the ’069 patent, Teva committed an act of infringement of the ’069 patent under 35 U.S.C. § 271(e)(2)(A).

58. The ’069 patent is directed to thermoreversible hydrogel compositions, and methods for providing sustained-release topical treatment of a condition affecting an internal body cavity through their administration to the internal body cavity.

59. On information and belief, Teva intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product with proposed labeling immediately and imminently upon final approval of its ANDA.

60. On information and belief, Teva’s Proposed ANDA Product consists of a powder that contains mitomycin C in an amount of 40 mg/vial. On information and belief, Teva’s Proposed ANDA Product will be sold with a sterile thermoreversible hydrogel composition for reconstitution comprising between 23% and 27% (w/w) poloxamer, between 0.1% and 0.2% HPMC and between 0.5% and 1% PEG-400. Thus, on information and belief, Teva’s manufacture, use, sale, offer for sale, and/or importation into the United States of Teva’s Proposed ANDA Product prior to the expiration of the ’069 patent will directly infringe at least one claim of the ’069 patent under 35 U.S.C. § 271(a), (b) and/or (c).

61. On information and belief, the proposed labeling for Teva’s Proposed ANDA Product will be substantially identical to the JELMYTO® label and instructs and encourages healthcare professionals to practice the claims of the ’069 patent.

62. The JELMYTO® label states that JELMYTO® is indicated for “the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).” The JELMYTO® label instructs healthcare professionals to reconstitute JELMYTO® in the supplied hydrogel prior to instillation and states that it is “instilled in the patient’s pyelocalyceal system” where it “will fill

and conform to the cavity and become a gel, thereby exposing the tissue to mitomycin over a prolonged period of time" (*see, e.g.*, JELMYTO® label at 1, 21, copy attached as Exhibit C). Thus, on information and belief, the use of Teva's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '069 patent under 35 U.S.C. § 271(a).

63. On information and belief, Teva has actual knowledge of the '069 patent and its listing in the Orange Book as demonstrated by at least Teva's reference to the '069 patent in Teva's Notice Letter. The foregoing acts by Teva constitute and/or will constitute infringement of the '069 patent and/or active inducement of infringement of the '069 patent under 35 U.S.C. § 271(b).

64. Teva's Proposed ANDA Product constitutes a material part of at least one of the claims of the '069 patent. On information and belief, Teva knows that Teva's Proposed ANDA Product will be especially made or especially adapted for use in infringing the '069 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

65. On information and belief, Teva knows that its commercial manufacture, use, offer for sale, sale and/or importation of Teva's Proposed ANDA Product prior to the '069 patent's expiration will contribute to the direct infringement of one or more claims of the '069 patent under 35 U.S.C. § 271(c).

66. On information and belief, Teva's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '069 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

67. If Teva's infringement of the '069 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,950,069 UNDER 35 U.S.C. §§ 271(a), (b) and/or (c)

68. Plaintiffs incorporate each of the preceding paragraphs 1–67 as if fully set forth herein.

69. The ’069 patent is directed to thermoreversible hydrogel compositions, and methods for providing sustained-release topical treatment of a condition affecting an internal body cavity through their administration to the internal body cavity.

70. On information and belief, Teva intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product with proposed labeling immediately and imminently upon final approval of its ANDA.

71. On information and belief, Teva’s Proposed ANDA Product consists of a powder that contains mitomycin in an amount of 40 mg/vial. On information and belief, Teva’s Proposed ANDA Product will be sold with a sterile thermoreversible hydrogel composition for reconstitution comprising between 23% and 27% (w/w) poloxamer, between 0.1% and 0.2% HPMC and between 0.5% and 1% PEG-400. Thus, on information and belief, Teva’s manufacture, use, sale, offer for sale, and/or importation into the United States of Teva’s Proposed ANDA Product prior to the expiration of the ’069 patent will directly infringe at least one claim of the ’069 patent under 35 U.S.C. § 271(a), (b) and/or (c).

72. On information and belief, the proposed labeling for Teva’s Proposed ANDA Product will be substantially identical to the JELMYTO® label and instructs and encourages healthcare professionals to practice the claims of the ’069 patent.

73. The JELMYTO® label states that JELMYTO® is indicated for “the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).” The JELMYTO® label instructs healthcare professionals to reconstitute JELMYTO® in the supplied hydrogel prior

to instillation and states that it is "instilled in the patient's pyelocalyceal system" where it "will fill and conform to the cavity and become a gel, thereby exposing the tissue to mitomycin over a prolonged period of time" (*see, e.g.*, JELMYTO® label at 1, 21, copy attached as Exhibit C). Thus, on information and belief, the use of Teva's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '069 patent under 35 U.S.C. § 271(a).

74. On information and belief, Teva has actual knowledge of the '069 patent and its listing in the Orange Book as demonstrated by at least Teva's reference to the '069 patent in Teva's Notice Letter. The foregoing acts by Teva constitute and/or will constitute infringement of the '069 patent and/or active inducement of infringement of the '069 patent under 35 U.S.C. § 271(b).

75. Teva's Proposed ANDA Product constitutes a material part of at least one of the claims of the '069 patent. On information and belief, Teva knows that Teva's Proposed ANDA Product will be especially made or especially adapted for use in infringing the '069 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

76. On information and belief, Teva knows that its commercial manufacture, use, offer for sale, sale and/or importation of Teva's Proposed ANDA Product prior to the '069 patent's expiration will contribute to the direct infringement of one or more claims of the '069 patent under 35 U.S.C. § 271(c).

77. On information and belief, Teva's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '069 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

78. If Teva's infringement of the '069 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request the following relief:

A. A judgment that Teva has infringed one or more claims of U.S. Patent Nos. 9,040,074 and 9,950,069 by submitting and maintaining ANDA No. 218215 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Proposed ANDA Product before the expiration of the JELMYTO® patents, inclusive of any exclusivities and extensions, under 35 U.S.C. § 271(e)(2)(A);

B. A judgment (or a declaration) that Teva's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Teva's Proposed ANDA Product will infringe one or more claims of U.S. Patent Nos. 9,040,074 and 9,950,069 under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A judgment that U.S. Patent Nos. 9,040,074 and 9,950,069 remain valid and enforceable;

D. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Teva's Proposed ANDA Product prior to the expiration date of U.S. Patent Nos. 9,040,074 and 9,950,069 inclusive of any exclusivities and extensions;

E. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 218215 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of U.S. Patent Nos. 9,040,074 and 9,950,069 inclusive of any exclusivities and extensions;

F. Damages, including monetary and other relief, to Plaintiffs if Teva engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of Teva's Proposed ANDA Product prior to the expiration date of U.S. Patent Nos. 9,040,074 and 9,950,069, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of reasonable attorney fees;

H. An award of costs, expenses and disbursements in this action; and

I. Such other and further relief as the Court may deem just and proper.

Dated: April 2, 2024

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