IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI MATURE IP,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED, AUROMEDICS PHARMA LLC and EUGIA PHARMA SPECIALITIES LIMITED,	)	
Defendants	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC (hereinafter, "Sanofi U.S.") and Sanofi Mature IP (collectively, "Plaintiffs"), by their attorneys, 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 Eugia Pharma Specialities Limited ("Eugia") to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of cabazitaxel injection, for intravenous infusion, a generic version of Plaintiffs' JEVTANA® KIT (hereinafter "JEVTANA®"), prior to the expiration of U.S. Patent Nos. 10,583,110 ("the '110 patent"), 10,716,777 ("the '777 patent"), and 8,927,592 ("the '592 patent").

THE PARTIES

2. Plaintiff Sanofi U.S. is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Plaintiff Sanofi Mature IP is a company organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

4. Plaintiffs are owned by Sanofi, a global research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve human health.

5. Upon information and belief, Defendant Aurobindo Pharma Limited ("APL") is a corporation organized and existing under the laws of the Republic of India, having a place of business at Plot No. 11, Survey no.9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500084, Telangana, India. Upon information and belief, APL is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Eugia Pharma Specialities Ltd. and AuroMedics Pharma LLC, throughout the United States, including in Delaware.

6. Upon information and belief, Defendant Eugia Pharma Specialities Ltd. ("Eugia") is a corporation organized and existing under the laws of the Republic of India, having a place of business at Maitrivihar, Plot #2, Ameerpet, Hyderabad, Telangana 500038, India. Upon information and belief, Eugia is a wholly owned subsidiary of APL. Upon information and belief, Eugia is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including in Delaware.

7. Upon information and belief, Defendant AuroMedics Pharma LLC ("AuroMedics") is a limited liability company organized and existing under the laws of Delaware, having its corporate offices and a principal place of business at 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Upon information and belief, AuroMedics is a wholly owned subsidiary of APL. Upon information and belief, AuroMedics is in the business of, among other things,

manufacturing and selling generic versions of branded pharmaceutical drug products throughout the United States, including in Delaware.

8. Upon information and belief, AuroMedics is a United States agent for APL and Eugia regarding ANDA No. 216733.

9. Upon information and belief, APL, Eugia, and AuroMedics (collectively referred to hereinafter as "Eugia" unless otherwise noted) collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, APL, Eugia, and AuroMedics are agents of each other and/or operate in concert as integrated parts of the same business group. Upon information and belief, APL and Eugia acted in concert to develop Eugia's Proposed ANDA Product that is the subject of ANDA No. 216733 and, with AuroMedics, to seek regulatory approval from the FDA to market and sell Eugia's Proposed ANDA Product throughout the United States, including in Delaware.

10. Upon information and belief, APL, Eugia, and AuroMedics intend to act collaboratively to obtain approval for Eugia's ANDA No. 216733, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import Eugia's Proposed ANDA Product in the United States, including in Delaware.

11. On information and belief, Eugia assembled and caused to be submitted to the FDA ANDA No. 216733 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "the Eugia ANDA") concerning a proposed drug product, cabazitaxel intravenous solution, 60 mg/1.5 mL (40 mg/mL) (hereinafter "Eugia's Proposed ANDA Product"). The Eugia ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

12. By letter dated December 23, 2021, Eugia notified Plaintiffs that, as a part of its ANDA, Eugia had filed certifications 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 '777 patent, the '110 patent, the '592 patent, and U.S. Patent No. 7,241,907 ("the '907 patent"), each of which were listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for JEVTANA®, asserting that the '777 patent, the '110 patent, the '592 patent, and the '907 patent

are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Eugia's Proposed ANDA Product.

JURISDICTION AND VENUE

13. 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 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. This Court has personal jurisdiction over APL because, *inter alia*, APL, itself and through its subsidiaries Eugia and AuroMedics, 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, APL, itself and through its subsidiaries Eugia and AuroMedics, 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. In addition, APL is subject to personal jurisdiction in Delaware because, upon information and belief, it controls AuroMedics, a Delaware corporation, and therefore the activities of AuroMedics in this jurisdiction are attributed to APL.

15. In addition, this Court has personal jurisdiction over APL because, among other things, on information and belief, upon approval of Eugia's ANDA, APL and its subsidiaries AuroMedics and Eugia will market, distribute, offer for sale, sell, and/or import Eugia's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Eugia's Proposed ANDA Product in Delaware. On information and belief, upon approval of Eugia's ANDA, Eugia'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; dispensed by pharmacies located within 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, including Plaintiff Sanofi U.S., which is a Delaware company.

16. In addition, this Court has personal jurisdiction over APL because it regularly engages in patent litigation concerning Eugia's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 20-01528-CFC, D.I. 7 (D. Del. Dec. 4, 2020); *Amgen Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 16-00853-GMS, D.I. 10 (D. Del. Nov. 28, 2016).

17. In the alternative, APL is subject to jurisdiction throughout the United States, and specifically in the State of Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

18. For at least the above reasons, it would not be unfair or unreasonable for APL to litigate this action in this District, and APL is subject to personal jurisdiction in this District.

19. This Court has personal jurisdiction over Eugia because Eugia, itself and through its agents APL and AuroMedics, 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, Eugia, itself and through its agent AuroMedics and parent company APL, 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. In addition, Eugia is subject to personal jurisdiction in Delaware because, upon information and belief, AuroMedics, a Delaware corporation, is an agent of Eugia, and therefore the activities of AuroMedics in this jurisdiction are attributed to Eugia.

20. In addition, this Court has personal jurisdiction over Eugia because, among other things, on information and belief: (1) Eugia and its agent AuroMedics filed Eugia's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Eugia's Proposed ANDA Product in the United States, including in Delaware; and (2) upon

approval of Eugia's ANDA, Eugia, its agent AuroMedics, and its parent company APL will market, distribute, offer for sale, sell, and/or import Eugia's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Eugia's Proposed ANDA Product in Delaware. On information and belief, upon approval of Eugia's ANDA, Eugia'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; dispensed by pharmacies located within 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, including Plaintiff Sanofi U.S., which is a Delaware company.

21. In addition, this Court has personal jurisdiction over Eugia because it regularly engages in patent litigation concerning Eugia's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 20-01528-CFC, D.I. 7 (D. Del. Dec. 4, 2020).

22. In the alternative, Eugia is subject to jurisdiction throughout the United States, and specifically in the State of Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

23. For at least the above reasons, it would not be unfair or unreasonable for Eugia to litigate this action in this District, and Eugia is subject to personal jurisdiction in this District.

24. This Court has personal jurisdiction over AuroMedics because, on information and belief, AuroMedics is a limited liability company organized and existing under the laws of the Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, AuroMedics has consented to general jurisdiction in Delaware.

25. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over APL, Eugia, and AuroMedics.

26. Venue is proper in this district for AuroMedics under 28 U.S.C. § 1400(b) because, *inter alia*, AuroMedics is a corporation organized and existing under the laws of the State of Delaware.

27. Venue is proper in this district for APL and Eugia under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, APL and Eugia are corporations existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

JEVTANA® AND THE PATENTS-IN-SUIT

28. Sanofi U.S. holds approved NDA No. 201023 for cabazitaxel injection, 60 mg/ 1.5 mL (40 mg/mL), which is prescribed and sold in the United States under the trademark JEVTANA® KIT. The FDA approved NDA No. 201023 on June 17, 2010. JEVTANA® is approved for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

29. United States Patent No. 8,927,592 (copy attached as Exhibit A) is entitled "Antitumoral Use of Cabazitaxel" and was duly and legally issued by the United States Patent and Trademark Office on January 6, 2015. At the conclusion of IPR2016-00712, an *inter partes* review certificate amending the '592 patent to replace substitute claims 27-30 with claims 31-34 issued on August 23, 2021. The '592 patent is owned by Sanofi Mature IP. The '592 patent is directed to methods for increasing survival of certain prostate cancer patients with cabazitaxel, including the use of JEVTANA® in accordance with the labeling approved by the FDA.

30. The '592 patent is listed in the Orange Book for JEVTANA® (NDA No. 201023). The FDA was notified before September 22, 2021 of the *inter partes* review certificate and the use code was updated to correspond to the amended claims.

31. Claims 31-34 of the '592 patent are materially different from and patentably distinct from all originally issued claims of the '592 patent (claims 1-30) because, among other things, claims 31-34 of the '592 patent require administration of cabazitaxel with the intentional purpose of prolonging survival and administration of a premedication regimen, neither of which was a limitation in any original issued claim of the '592 patent.

32. United States Patent No. 10,583,110 (copy attached as Exhibit B) is entitled "Antitumoral Use of Cabazitaxel" and was duly and legally issued by the United States Patent and

Trademark Office on March 10, 2020. It is owned by Sanofi Mature IP. The '110 patent is related to the '592 patent by a chain of continuation applications and relies on the same provisional patent applications. The '110 patent is directed to methods for increasing survival of certain prostate cancer patients with cabazitaxel, including the use of JEVTANA® in accordance with the labeling approved by the FDA.

33. The claims of the '110 patent are materially different from and patentably distinct from all originally issued claims of the '592 patent (claims 1-30), because, among other things, the claims of the '110 patent require administration of cabazitaxel with the intentional purpose of prolonging survival and administration of a premedication regimen, neither of which was a limitation in any issued claim of the '592 patent.

34. United States Patent No. 10,716,777 (copy attached as Exhibit C) is entitled "Antitumoral Use of Cabazitaxel" and was duly and legally issued by the United States Patent and Trademark Office on July 21, 2020. It is owned by Sanofi Mature IP. The '777 patent is a continuation of the '110 patent and relies on the same provisional patent applications. The '777 patent is directed to methods for increasing survival of certain prostate cancer patients with cabazitaxel, including the use of JEVTANA® in accordance with the labeling approved by the FDA.

35. The claims of the '777 patent are materially different and patentably distinct from all originally issued claims of the '592 patent (claims 1-30), because, among other things, the claims of the '777 patent require administration of cabazitaxel with the intentional purpose of prolonging survival and administration of an H_2 antagonist, neither of which was a limitation in any issued claim of the '592 patent.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,583,110 UNDER 35 U.S.C. § 271(e)

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

37. Eugia, via its Notice Letter and prior litigation conduct, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product prior to the expiration of the '110 patent.

38. By submitting and maintaining its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product prior to the expiration of the '110 patent, Eugia has committed an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(A).

39. On information and belief, Eugia 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.

40. On information and belief, the proposed labeling for Eugia's Proposed ANDA Product will be substantially identical to the JEVTANA® label and instructs and encourages physicians to practice the claimed methods of the '110 patent.

41. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1, copy attached as Exhibit D).

42. The Dosage and Administration Section of the JEVTANA® label provides instructions on the recommended doses of JEVTANA®, which involve "the discretion of the treating healthcare provider," and refer such healthcare providers to the Clinical Studies Section of the label. (JEVTANA® label at § 2). The Clinical Studies Section of the JEVTANA® label describes, among other things, the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients. (JEVTANA® label at § 14). The Clinical Studies Section of the JEVTANA® label reports a difference in overall survival as the median time to death for the patients in the JEVTANA® + Prednisone arm vs. the Mitoxantrone + Prednisone arm of the TROPIC clinical study, provides a "p value" of <0.0001 for the difference, and reports a hazard ratio of 0.70, explicitly noting that it favors cabazitaxel. (JEVTANA® label at § 14.1, Table 5 and Figure 1). These data show a statistically significant increase in overall survival for the patients

in the JEVTANA® + Prednisone arm, corresponding to a 30% reduction in risk of death. (JEVTANA® label at § 14.1, Table 5 and Figure 1). A treatment shown to increase overall survival in a controlled clinical study is understood as prolonging the lives (i.e., increasing the life expectancies) of individual patients as compared to those patients receiving the control arm therapy from the clinical study. In other words, a finding of increased overall survival in a clinical study, as is true for the TROPIC study presented in the JEVTANA® label, demonstrates that the therapy will prolong the lives of individual patients. The JEVTANA® label therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '110 patent. (JEVTANA® label at §§ 1, 2, 14).

43. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 20 mg/m^2 who require dose reduction should receive 15 mg/m^2, and patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 15 mg/m^2, 20 mg/m^2, or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '110 patent.

44. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: . . . antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the premedications recited in the '110 patent claims in accordance with the claimed methods of the '110 patent.

45. Thus, on information and belief, the use of Eugia's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '110 patent under 35 U.S.C. § 271(a).

46. On information and belief, Eugia has actual knowledge of the '110 patent, as demonstrated by at least Eugia's 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) described in Eugia's Notice Letter, and will actively induce direct infringement of at least one claim of the '110 patent under 35 U.S.C. § 271(b) when its ANDA is approved and its Proposed ANDA Product is marketed, sold, distributed, and/or imported.

47. The foregoing acts by Eugia constitute and/or will constitute infringement of the '110 patent and/or active inducement of infringement of the '110 patent under 35 U.S.C. § 271(b).

48. If Eugia's infringement of the '110 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. 10,583,110 UNDER 35 U.S.C. § 271(B)

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

50. On information and belief, Eugia 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 and prior to the expiration of the '110 patent. Therefore, a case or controversy exists between Eugia and Plaintiffs as to infringement of the '110 patent.

51. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eugia's Proposed ANDA Product would infringe one or more claims of the '110 patent.

52. On information and belief, the proposed labeling for Eugia's Proposed ANDA Product will be substantially identical to the JEVTANA® label and instructs and encourages physicians to practice the claimed methods of the '110 patent.

53. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1).

54. The Dosage and Administration Section of the JEVTANA® label provides instructions on the recommended doses of JEVTANA®, which involve "the discretion of the treating healthcare provider," and refer such healthcare providers to the Clinical Studies Section of the label. (JEVTANA® label at § 2). The Clinical Studies Section of the JEVTANA® label describes, among other things, the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients. (JEVTANA® label at §, 14). The Clinical Studies Section of the JEVTANA® label reports a difference in overall survival as the median time to death for the patients in the JEVTANA® + Prednisone arm vs. the Mitoxantrone + Prednisone arm of the TROPIC clinical study, provides a "p value" of <0.0001 for the difference, and reports a hazard ratio of 0.70, explicitly noting that it favors cabazitaxel. (JEVTANA® label at § 14.1, Table 5 and Figure 1). These data show a statistically significant increase in overall survival for the patients in the JEVTANA® + Prednisone arm, corresponding to a 30% reduction in risk of death. (JEVTANA® label at § 14.1, Table 5 and Figure 1). A treatment shown to increase overall survival in a controlled clinical study is understood as prolonging the lives (i.e., increasing the life expectancies) of individual patients as compared to those patients receiving the control arm therapy from the clinical study. In other words, a finding of increased overall survival in a clinical study, as is true for the TROPIC study presented in the JEVTANA® label, demonstrates that the therapy will prolong the lives of individual patients. The JEVTANA® label therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those

patients for that purpose in accordance with the claimed methods of the '110 patent. (JEVTANA® label at §§ 1, 2, 14).

55. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 20 mg/m^2 who require dose reduction should receive 15 mg/m^2, and patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 15 mg/m^2, 20 mg/m^2, or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '110 patent.

56. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: . . . antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the premedications recited in the '110 patent claims in accordance with the claimed methods of the '110 patent.

57. Thus, on information and belief, the use of Eugia's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '110 patent under 35 U.S.C. § 271(a).

58. On information and belief, Eugia has actual knowledge of the '110 patent, as demonstrated by at least Eugia's 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) described in Eugia's Notice Letter, and will actively induce direct infringement of at least one claim of the '110 patent under 35 U.S.C.

§ 271(b) when its ANDA is approved and its Proposed ANDA Product is marketed, sold, distributed, and/or imported.

59. The foregoing acts by Eugia constitute and/or will constitute active inducement of infringement of the '110 patent under 35 U.S.C. §§ 271(b).

60. If Eugia's infringement of the '110 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. 10,716,777 UNDER 35 U.S.C. § 271(e)

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

62. Eugia, via its Notice Letter and prior litigation conduct, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product prior to the expiration of the '777 patent.

63. By submitting and maintaining its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product prior to expiration of the '777 patent, Eugia has committed an act of infringement of one or more claims of the '777 patent under 35 U.S.C. § 271(e)(2).

64. On information and belief, Eugia 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.

65. On information and belief, the proposed labeling for Eugia's Proposed ANDA Product will be substantially identical to the JEVTANA® label and instructs and encourages physicians to practice the claimed methods of the '777 patent.

66. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1).

67. The Dosage and Administration Section of the JEVTANA® label provides instructions on the recommended doses of JEVTANA®, which involve "the discretion of the treating healthcare provider," and refer such healthcare providers to the Clinical Studies Section of the label. (JEVTANA® label at § 2). The Clinical Studies Section of the JEVTANA® label describes, among other things, the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients. (JEVTANA® label at § 14). The Clinical Studies Section of the JEVTANA® label reports a difference in overall survival as the median time to death for the patients in the JEVTANA® + Prednisone arm vs. the Mitoxantrone + Prednisone arm of the TROPIC clinical study, provides a "p value" of <0.0001 for the difference, and reports a hazard ratio of 0.70, explicitly noting that it favors cabazitaxel. (JEVTANA® label at § 14.1, Table 5 and Figure 1). These data show a statistically significant increase in overall survival for the patients in the JEVTANA® + Prednisone arm, corresponding to a 30% reduction in risk of death. (JEVTANA® label at § 14.1, Table 5 and Figure 1). A treatment shown to increase overall survival in a controlled clinical study is understood as prolonging the lives (i.e., increasing the life expectancies) of individual patients as compared to those patients receiving the control arm therapy from the clinical study. In other words, a finding of increased overall survival in a clinical study, as is true for the TROPIC study presented in the JEVTANA® label, demonstrates that the therapy will prolong the lives of individual patients. The JEVTANA® label therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those

patients for that purpose in accordance with the claimed methods of the '777 patent. (JEVTANA® label at §§ 1, 2, 14).

68. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 20 mg/m^2 or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '777 patent.

69. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: . . . antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the H_2 antagonist recited in the '777 patent claims in accordance with the claimed methods of the '777 patent.

70. Thus, on information and belief, the use of Eugia's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '777 patent under 35 U.S.C. § 271(a).

71. On information and belief, Eugia has actual knowledge of the '777 patent, as demonstrated by at least Eugia's 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) described in Eugia's Notice Letter, and will actively induce direct infringement of at least one claim of the '777 patent under 35 U.S.C.

§ 271(b) when its ANDA is approved and its Proposed ANDA Product is marketed, sold, distributed, and/or imported.

72. The foregoing acts by Eugia constitute and/or will constitute infringement of the '777 patent and/or active inducement of infringement of the '777 patent under 35 U.S.C. § 271(b).

73. If Eugia's infringement of the '777 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. 10,716,777 UNDER 35 U.S.C. § 271(B)

74. Plaintiffs incorporate each of the preceding paragraphs 1 – 73 as if fully set forth herein.

75. On information and belief, Eugia 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 and prior to the expiration of the '777 patent. Therefore, a case or controversy exists between Eugia and Plaintiffs as to infringement of the '777 patent.

76. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eugia's Proposed ANDA Product would infringe one or more claims of the '777 patent.

77. On information and belief, the proposed labeling for Eugia's Proposed ANDA Product will be substantially identical to the JEVTANA® label and instructs and encourages physicians to practice the claimed methods of the '777 patent.

78. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1).

79. The Dosage and Administration Section of the JEVTANA® label provides instructions on the recommended doses of JEVTANA®, which involve "the discretion of the treating healthcare provider," and refer such healthcare providers to the Clinical Studies Section of the label. (JEVTANA® label at § 2). The Clinical Studies Section of the JEVTANA® label describes, among other things, the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients. (JEVTANA® label at § 14). The Clinical Studies Section of the JEVTANA® label reports a difference in overall survival as the median time to death for the patients in the JEVTANA® + Prednisone arm vs. the Mitoxantrone + Prednisone arm of the TROPIC clinical study, provides a "p value" of <0.0001 for the difference, and reports a hazard ratio of 0.70, explicitly noting that it favors cabazitaxel. (JEVTANA® label at § 14.1, Table 5 and Figure 1). These data show a statistically significant increase in overall survival for the patients in the JEVTANA® + Prednisone arm, corresponding to a 30% reduction in risk of death. (JEVTANA® label at § 14.1, Table 5 and Figure 1). A treatment shown to increase overall survival in a controlled clinical study is understood as prolonging the lives (i.e., increasing the life expectancies) of individual patients as compared to those patients receiving the control arm therapy from the clinical study. In other words, a finding of increased overall survival in a clinical study, as is true for the TROPIC study presented in the JEVTANA® label, demonstrates that the therapy will prolong the lives of individual patients. The JEVTANA® label therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '777 patent. (JEVTANA® label at §§ 1, 2, 14).

80. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be

used in select patients." Patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 20 mg/m^2 or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '777 patent.

81. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: . . . antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the H_2 antagonist recited in the '777 patent claims in accordance with the claimed methods of the '777 patent.

82. Thus, on information and belief, the use of Eugia's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '777 patent under 35 U.S.C. § 271(a).

83. On information and belief, Eugia has actual knowledge of the '777 patent, as demonstrated by at least Eugia's 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) described in Eugia's Notice Letter, and will actively induce direct infringement of at least one claim of the '777 patent under 35 U.S.C. § 271(b) when its ANDA is approved and its Proposed ANDA Product is marketed, sold, distributed, and/or imported.

84. The foregoing acts by Eugia constitute and/or will constitute active inducement of infringement of the '777 patent under 35 U.S.C. § 271(b).

85. If Eugia's infringement of the '777 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,927,592 UNDER 35 U.S.C. § 271(e)

86. Plaintiffs incorporate each of the preceding paragraphs 1 – 85 as if fully set forth herein.

87. Eugia, via its Notice Letter and prior litigation conduct, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product prior to the expiration of the '592 patent.

88. By submitting and maintaining its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product prior to the expiration of the '592 patent, Eugia has committed an act of infringement of one or more amended claims of the '592 patent under 35 U.S.C. § 271(e)(2)(A).

89. On information and belief, Eugia 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.

90. On information and belief, the proposed labeling for Eugia's Proposed ANDA Product will be substantially identical to the JEVTANA® label and instructs and encourages physicians to practice the claimed methods of the '592 patent.

91. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1).

92. The Dosage and Administration Section of the JEVTANA® label provides instructions on the recommended doses of JEVTANA®, which involve "the discretion of the

treating healthcare provider" and refer such healthcare providers to the Clinical Studies Section of the label. (JEVTANA® label at § 2). The Clinical Studies Section of the JEVTANA® label describes, among other things, the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients. (JEVTANA® label at § 14). The Clinical Studies Section of the JEVTANA® label reports a difference in overall survival as the median time to death for the patients in the JEVTANA® + Prednisone arm vs. the Mitoxantrone + Prednisone arm of the TROPIC clinical study, provides a "p value" of <0.0001 for the difference, and reports a hazard ratio of 0.70, explicitly noting that it favors cabazitaxel. (JEVTANA® label at § 14.1, Table 5 and Figure 1). These data show a statistically significant increase in overall survival for the patients in the JEVTANA® + Prednisone arm, corresponding to a 30% reduction in risk of death. (JEVTANA® label at § 14.1, Table 5 and Figure 1). A treatment shown to increase overall survival in a controlled clinical study is understood as prolonging the lives (i.e., increasing the life expectancies) of individual patients as compared to those patients receiving the control arm therapy from the clinical study. In other words, a finding of increased overall survival in a clinical study, as is true for the TROPIC study presented in the JEVTANA® label, demonstrates that the therapy will prolong the lives of individual patients. The JEVTANA® label therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '592 patent. (JEVTANA® label at §§ 1, 2, 14).

93. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians

to administer 20 mg/m^2 or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '592 patent.

94. The JEVTANA® label states that cabazitaxel is indicated in combination with prednisone. (JEVTANA® label at § 1). The JEVTANA® label therefore instructs and encourages physicians to administer cabazitaxel in combination with prednisone as recited in the '592 patent claims in accordance with the claimed methods of the '592 patent.

95. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: . . . antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the antihistamine, corticosteroid, and H_2 antagonist premedications recited in the '592 patent claims in accordance with the claimed methods of the '592 patent.

96. Physicians will direct and control every step of the claimed methods of the '592 patent such that each step is attributable to them. To the extent the physician does not infuse the cabazitaxel and premedications him- or herself, such infusion is attributable to the physician who directs the dose, timing, and administration of the medications, and the infusing healthcare provider is required to follow the direction of the physician. The physician also directs and controls the oral administration of prednisone by the patient. Physicians direct the dose, timing, and administration of prednisone, a prescription medication, and explain to patients the importance of prednisone to cabazitaxel treatment in accordance with the JEVTANA® label. The JEVTANA® Patient Information tells patients that "[i]t is important that you take prednisone exactly as

prescribed by your healthcare provider," and tells patients to inform their healthcare provider if they have not taken their prednisone as prescribed. Physicians will condition the benefit of cabazitaxel treatment for at least some patients on the patient taking prednisone as prescribed.

97. Thus, on information and belief, the use of Eugia's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one amended claim of the '592 patent under 35 U.S.C. § 271(a).

98. On information and belief, Eugia has actual knowledge of the '592 patent, as demonstrated by at least Eugia's 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) described in Eugia's Notice Letter, and will actively induce direct infringement of at least one claim of the '592 patent under 35 U.S.C. § 271(b) when its ANDA is approved and its Proposed ANDA Product is marketed, sold, distributed, and/or imported.

99. The foregoing acts by Eugia constitute and/or will constitute infringement of the '592 patent and/or active inducement of infringement of the '592 patent under 35 U.S.C. § 271(b).

100. If Eugia's infringement of the '592 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,927,592 UNDER 35 U.S.C. § 271(B)

101. Plaintiffs incorporate each of the preceding paragraphs 1 – 100 as if fully set forth herein.

102. On information and belief, Eugia 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 and prior

to the expiration of the '592 patent. Therefore, a case or controversy exists between Eugia and Plaintiffs as to infringement of the '592 patent.

103. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eugia's Proposed ANDA Product would infringe one or more amended claims of the '592 patent.

104. On information and belief, the proposed labeling for Eugia's Proposed ANDA Product will be substantially identical to the JEVTANA® label and instructs and encourages physicians to practice the claimed methods of the '592 patent.

105. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1).

106. The Dosage and Administration Section of the JEVTANA® label provides instructions on the recommended doses of JEVTANA®, which involve "the discretion of the treating healthcare provider" and refer such healthcare providers to the Clinical Studies Section of the label. (JEVTANA® label at § 2). The Clinical Studies Section of the JEVTANA® label describes, among other things, the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients. (JEVTANA® label at § 14). The Clinical Studies Section of the JEVTANA® label reports a difference in overall survival as the median time to death for the patients in the JEVTANA® + Prednisone arm vs. the Mitoxantrone + Prednisone arm of the TROPIC clinical study, provides a "p value" of <0.0001 for the difference, and reports a hazard ratio of 0.70, explicitly noting that it favors cabazitaxel. (JEVTANA® label at § 14.1, Table 5 and Figure 1). These data show a statistically significant increase in overall survival for the patients in the JEVTANA® + Prednisone arm, corresponding to a 30% reduction in risk of death.

(JEVTANA® label at § 14.1, Table 5 and Figure 1). A treatment shown to increase overall survival in a controlled clinical study is understood as prolonging the lives (i.e., increasing the life expectancies) of individual patients as compared to those patients receiving the control arm therapy from the clinical study. In other words, a finding of increased overall survival in a clinical study, as is true for the TROPIC study presented in the JEVTANA® label, demonstrates that the therapy will prolong the lives of individual patients. The JEVTANA® label therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '592 patent. (JEVTANA® label at §§ 1, 2, 14).

107. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 20 mg/m^2 or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '592 patent.

108. The JEVTANA® label states that cabazitaxel is indicated in combination with prednisone. (JEVTANA® label at § 1). The JEVTANA® label therefore instructs and encourages physicians to administer cabazitaxel in combination with prednisone as recited in the '592 patent claims in accordance with the claimed methods of the '592 patent.

109. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: . . . antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or

equivalent steroid), H_2 antagonist." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the antihistamine, corticosteroid, and H_2 antagonist premedications recited in the '592 patent claims in accordance with the claimed methods of the '592 patent.

110. Physicians will direct and control every step of the claimed methods of the '592 patent such that each step is attributable to them. To the extent the physician does not infuse the cabazitaxel and premedications him- or herself, such infusion is attributable to the physician who directs the dose, timing, and administration of the medications, and the infusing healthcare provider is required to follow the direction of the physician. The physician also directs and controls the oral administration of prednisone by the patient. Physicians direct the dose, timing, and administration of prednisone, a prescription medication, and explain to patients the importance of prednisone to cabazitaxel treatment in accordance with the JEVTANA® label. The JEVTANA® Patient Information tells patients that "[i]t is important that you take prednisone exactly as prescribed by your healthcare provider," and tells patients to inform their healthcare provider if they have not taken their prednisone as prescribed. Physicians will condition the benefit of cabazitaxel treatment for at least some patients on the patient taking prednisone as prescribed.

111. Thus, on information and belief, the use of Eugia's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one amended claim of the '592 patent under 35 U.S.C. § 271(a).

112. On information and belief, Eugia has actual knowledge of the '592 patent, as demonstrated by at least Eugia's 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) described in Eugia's Notice Letter, and will actively induce direct infringement of at least one claim of the '592 patent under 35 U.S.C.

§ 271(b) when its ANDA is approved and its Proposed ANDA Product is marketed, sold, distributed, and/or imported.

113. The foregoing acts by Eugia constitute and/or will constitute active inducement of infringement of the '592 patent under 35 U.S.C. §§ 271(b).

114. If Eugia's infringement of the '592 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 Eugia's submission and maintenance of its ANDA constituted an act of infringement of the '110 patent;

B. A judgment (or a declaration) that Eugia's making, using, offering to sell, or selling in the United States or importing into the United States of its respective Proposed ANDA Product will infringe the '110 patent;

C. A permanent injunction restraining and enjoining Eugia, its affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its respective Proposed ANDA Product until the expiration of the '110 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '110 patent are or become entitled;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Eugia's ANDA shall be a date that is not earlier than the expiration date of the '110 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '110 patent are or become entitled;

E. A judgment that Eugia's submission and maintenance of its ANDA constituted an act of infringement of the '777 patent;

F. A judgment (or a declaration) that Eugia's making, using, offering to sell, or selling in the United States or importing into the United States of its respective Proposed ANDA Product will infringe the '777 patent;

G. A permanent injunction restraining and enjoining Eugia, its affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its respective Proposed ANDA Product until the expiration of the '777 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '777 patent are or become entitled;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Eugia's ANDA shall be a date that is not earlier than the expiration date of the '777 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '777 patent are or become entitled;

I. A judgment that Eugia's submission and maintenance of its ANDA constituted an act of infringement of the '592 patent;

J. A judgment (or a declaration) that Eugia's making, using, offering to sell, or selling in the United States or importing into the United States of its respective Proposed ANDA Product will infringe the '592 patent;

K. A permanent injunction restraining and enjoining Eugia, its affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the

United States, or importation into the United States, of its respective Proposed ANDA Product until the expiration of the '592 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '592 patent are or become entitled;

L. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Eugia's ANDA shall be a date that is not earlier than the expiration date of the '592 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '592 patent are or become entitled;

M. Damages, including monetary and other relief, to Plaintiffs if Eugia engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed ANDA Product prior to the expiration date of the '110 patent, the '777 patent, and/or the '592 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

N. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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January 31, 2022