IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAIHO PHARMACEUTICAL CO., LTD. and TAIHO ONCOLOGY, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 19-02309-CFC
EUGIA PHARMA SPECIALITIES LTD., AUROBINDO PHARMA LTD., and AUROBINDO PHARMA U.S.A., INC.,	)	
Defendants.	)	

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant, Eugia Pharma Specialities Ltd. ("Eugia"), Aurobindo Pharma Ltd. ("Aurobindo Ltd."), and Aurobindo Pharma U.S.A., Inc. (Aurobindo USA") (collectively, "Eugia" or "Defendants"), by way of Answer to Plaintiffs' Complaint, state as follows:

Defendants deny each and every allegation contained in the Complaint, except as specifically admitted or explained herein. To the extent that the headings or any other non-numbered statements in the Complaint contain any allegations, Defendants deny each and every such allegation.

THE PARTIES

1. Plaintiff Taiho Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-27 Kandanishiki-cho, Chiyodaku, Tokyo 101-8444, Japan.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 and, therefore, deny them.

2. Plaintiff Taiho Oncology, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 101 Carnegie Center, Suite 101, Princeton, New Jersey 08540.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and, therefore, deny them.

3. Upon information and belief, defendant Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Plot #2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

ANSWER:

Admitted.

4. Upon information and belief, defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Plot #2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

ANSWER:

Admitted.

5. Upon information and belief, defendant Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

ANSWER:

Admitted.

6. Upon information and belief, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including the State of Delaware.

ANSWER:

Admitted that Eugia Pharma Specialities Ltd., and Aurobindo Pharma U.S.A., Inc. are in the business of manufacturing, importing and selling generic pharmaceutical products, and admitted that Aurobindo Pharma Ltd. is in the business of developing generic drug products; except as so expressly admitted, deny the allegations of Paragraph 6 of the Complaint

7. Upon information and belief, Aurobindo Pharma U.S.A., Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. and is the United States agent for Eugia Pharma Specialities Ltd.

ANSWER:

Admitted that Aurobindo Pharma U.S.A., Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd., and the United States agent for Eugia Pharma Specialities Ltd with respect to ANDA No. 213893, and except as so expressly admitted, deny the allegations of Paragraph 7 of the Complaint.

8. Upon information and belief, Eugia Pharma Specialities Ltd. is a subsidiary of Aurobindo Pharma Ltd.

ANSWER:

Admitted that Curepro Parenterals Limited owns 67.82% of Eugia Pharma Specialties Ltd., Curepro Parenterals Limited is a wholly owned subsidiary of Aurobindo Pharma Ltd., and except as so expressly admitted, deny the allegations of Paragraph 8 of the Complaint.

9. Upon information and belief, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. acted in concert to prepare and submit Eugia's Abbreviated New Drug Application ("ANDA") No. 213893 (trifluridine and tipiracil tablets) ("Eugia's ANDA Product") to the United States Food and Drug Administration ("FDA").

ANSWER:

Admitted that Aurobindo U.S.A., Inc. and Eugia Pharma Specialties Ltd. submitted ANDA No. 213893 to the FDA, and except as so expressly admitted, deny the allegations of Paragraph 9 of the Complaint.

10. Upon information and belief, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. are agents of each other and/or operate in concert as integrated parts of the same group, including with respect to Eugia's ANDA Product, and enter into agreements with each other that are nearer than arm's length.

ANSWER:

Denied.

11. Upon information and belief, Eugia Pharma Specialities Ltd. and Aurobindo Pharma Ltd. participated in, assisted, and cooperated with Aurobindo Pharma U.S.A., Inc. in the acts complained of herein.

ANSWER:

Denied.

12. Upon information and belief, following any FDA approval of Eugia's ANDA, Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc. will act in concert to manufacture, market, distribute, and/or sell Eugia's ANDA Product throughout the United States, including within Delaware.

ANSWER:

Admitted that Aurobindo U.S.A., Inc. and Eugia Pharma Specialties Ltd. plan to commercially manufacture and sell the ANDA product proposed in ANDA No. 213893 ("proposed ANDA product") at some time after approval by the FDA, and except as so expressly admitted, deny the allegations of Paragraph 12 of the Complaint.

NATURE OF THE ACTION

13. This is a civil action for infringement of U.S. Patent Nos. RE46,284 E ("the '284 patent") and 10,138,223 B2 ("the '223 patent") (collectively, "the patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code § 100, *et seq*., and in particular under U.S.C. § 271, as well as a civil action for declaratory judgment of patent infringement of the patents-in-suit under 28 U.S.C. §§ 2201-02. Taiho seeks declaratory relief, injunctive relief, attorneys' fees, and any other relief the Court deems just and proper.

ANSWER:

Admitted that the Complaint purports to bring an action for infringement of U.S. Patent Nos. RE46,284 E ("the '284 patent") and 10,138,223 B2 ("the '223 patent") (collectively, "the patents-in-suit") under the patent laws of the United States, 35 U.S.C. § 100, et seq., and purports to bring an action for declaratory judgment of patent infringement of the patents-in-suit under 28 U.S.C. §§ 2201-02, and except as so expressly admitted, deny the allegations of Paragraph 13 of the Complaint.

14. This action relates to ANDA No. 213893, which Eugia filed or caused to be filed under 21 U.S.C. § 355(j) with the FDA, for approval to manufacture, use, and/or offer for sale a generic copy of Taiho's Lonsurf® (trifluridine and tipiracil) tablets throughout the United States prior to the expiration of the patents-in-suit.

ANSWER:

Admitted that Eugia Pharma Specialties Limited submitted ANDA No. 213893 with the FDA, and except as so expressly admitted, deny the allegations of Paragraph 14 of the Complaint.

JURISDICTION AND VENUE

15. This is a civil action for infringement arising under the United States Patent Laws, including 35 U.S.C. § 271, as well as a civil action for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201-02.

ANSWER:

Admitted that the Complaint purports to bring an action for infringement under the patent laws of the United States, 35 U.S.C. § 100, et seq., and purports to bring an action for declaratory judgment of patent infringement of the patents-in-suit under 28 U.S.C. §§ 2201-02, and except as so expressly admitted, deny the allegations of Paragraph 15 of the Complaint.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201-02.

ANSWER:

Admitted that subject matter jurisdiction is appropriate only for claims under 35 U.S.C. § 271(e)(2)(A), and except as so expressly admitted, deny the allegations of Paragraph 16 of the Complaint.

17. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. and Eugia Pharma Specialties Ltd. do not contest venue in this Judicial District.

18. This Court has personal jurisdiction over Eugia Pharma Specialities Ltd. because, *inter alia*, Eugia Pharma Specialities Ltd., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware; (3) has corporate affiliates that are organized under the laws of the State of Delaware; (4) maintains a broad distribution network within the State of Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

ANSWER:

For the limited purposes of this action only, Eugia Pharma Specialties Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 18 of the Complaint.

19. Upon information and belief, Eugia Pharma Specialities Ltd. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

ANSWER:

For the limited purposes of this action only, Eugia Pharma Specialties Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 19 of the Complaint.

20. Upon information and belief, Eugia Pharma Specialities Ltd. has substantial, continuous, and systematic contacts with the State of Delaware including Eugia Pharma Specialities Ltd.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

ANSWER:

For the limited purposes of this action only, Eugia Pharma Specialties Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 20 of the Complaint.

21. Upon information and belief, Eugia Pharma Specialities Ltd., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Eugia's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

ANSWER:

For the limited purposes of this action only, Eugia Pharma Specialties Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 21 of the Complaint.

22. Upon information and belief, Eugia Pharma Specialities Ltd., and/or its subsidiaries, affiliates, or agents, intends to place Eugia's ANDA Product into the stream of

commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

ANSWER:

For the limited purposes of this action only, Eugia Pharma Specialties Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 22 of the Complaint.

23. Upon information and belief, Eugia Pharma Specialities Ltd. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

ANSWER:

For the limited purposes of this action only, Eugia Pharma Specialties Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 23 of the Complaint.

24. Eugia Pharma Specialities Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters, *inter alia*, of *Pfizer Inc. et al. v. Aurobindo Pharma, Ltd. et al.*, 19-cv-748 (D. Del.) and *Astellas Pharma Inc. v. Eugia Pharma Specialities Ltd. et al.*, 18-cv-757 (D. Del.).

ANSWER:

Admitted that Eugia Pharma Specialities Ltd. has been sued in this Court, consented to personal jurisdiction for the limited purposes of those lawsuits, and asserted counterclaims, and, for the limited purposes of this action only, Eugia Pharma Specialities Ltd.

consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of Paragraph 24 of the Complaint.

25. Upon information and belief, Eugia Pharma Specialities Ltd. participated in the preparation, development, and filing of ANDA No. 213893, and its underlying subject matter, with the intent to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Eugia Pharma Specialities Ltd.'s contact with the State of Delaware.

ANSWER:

Admitted that Eugia Pharma Specialties Ltd., submitted ANDA No. 213893 with the FDA, and for the limited purposes of this action only, Eugia Pharma Specialities Ltd. consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of Paragraph 25 of the Complaint

26. Venue is proper in this Judicial District as to Eugia Pharma Specialties Ltd. because, *inter alia*, Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this Judicial District.

ANSWER:

For purposes of this action only, Eugia Pharma Specialties Ltd. do not contest jurisdiction or venue in this Court, and except as so expressly admitted, deny the allegations of Paragraph 26 of the Complaint.

27. This Court has personal jurisdiction over Aurobindo Pharma Ltd. because, *inter alia*, Aurobindo Pharma Ltd., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware; (3) owns subsidiary companies that are organized under the laws of the State of Delaware; (4) maintains a broad distribution

network within the State of Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 27 of the Complaint.

28. Upon information and belief, Aurobindo Pharma Ltd. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 28 of the Complaint.

29. Upon information and belief, Aurobindo Pharma Ltd. has substantial, continuous, and systematic contacts with the State of Delaware including Aurobindo Pharma Ltd.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 29 of the Complaint.

30. Upon information and belief, Aurobindo Pharma Ltd., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Eugia's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 30 of the Complaint.

31. Upon information and belief, Aurobindo Pharma Ltd., and/or its subsidiaries, affiliates, or agents, intends to place Eugia's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 31 of the Complaint.

32. Upon information and belief, Aurobindo Pharma Ltd. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 32 of the Complaint.

33. Aurobindo Pharma Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters, *inter alia*, of *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-748 (D. Del.); *Genentech, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-103 (D. Del.); *Boehringer Ingelheim Pharma. Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 18-cv-1757 (D. Del.); *Kissei Pharma. Co. v. Aurobindo Pharma Ltd. et al.*, 17-cv-1161 (D. Del.); and *Amgen Inc. v. Aurobindo Pharma Ltd.*, 16-cv-853 (D. Del.).

ANSWER:

Admitted that Aurobindo Pharma Ltd. has been sued in this Court, consented to personal jurisdiction for the limited purposes of those lawsuits, and asserted counterclaims, and, for the limited purposes of this action only, Aurobindo Pharma Ltd. consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of Paragraph 33 of the Complaint.

34. Upon information and belief, Aurobindo Pharma Ltd. participated in the preparation, development, and filing of ANDA No. 213893, and its underlying subject matter, with the intent to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Aurobindo Pharma Ltd.'s contact with the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma Ltd. consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of Paragraph 34 of the Complaint

35. Venue is proper in this Judicial District as to Aurobindo Pharma, Ltd. because, *inter alia*, Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this Judicial District.

ANSWER:

For purposes of this action only, Aurobindo Pharma, Ltd. does not contest jurisdiction or venue in this Court. and except as so expressly admitted, deny the allegations of Paragraph 35 of the Complaint.

36. This Court has personal jurisdiction over Aurobindo Pharma U.S.A., Inc. because Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware. Aurobindo Pharma U.S.A., Inc. has a registered agent located at 251 Little Falls Drive, Wilmington, Delaware, 19808. This Court also has personal jurisdiction over Aurobindo Pharma U.S.A., Inc. because, *inter alia*, Aurobindo Pharma U.S.A., Inc., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware; (3) maintains a broad distribution network within the State of Delaware; and/or (4) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 36 of the Complaint.

37. Upon information and belief, Aurobindo Pharma U.S.A., Inc. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 37 of the Complaint.

38. Upon information and belief, Aurobindo Pharma U.S.A., Inc. has substantial, continuous, and systematic contacts with the State of Delaware including Aurobindo Pharma U.S.A., Inc.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 38 of the Complaint.

39. Upon information and belief, Aurobindo Pharma U.S.A., Inc., and/or its subsidiaries, affiliates, or agents intends to engage in the commercial manufacture and sale of Eugia's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 39 of the Complaint.

40. Upon information and belief, Aurobindo Pharma U.S.A., Inc., and/or its subsidiaries, affiliates, or agents, intends to place Eugia's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 40 of the Complaint.

41. Upon information and belief, Aurobindo Pharma U.S.A., Inc. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 41 of the Complaint.

42. Aurobindo Pharma U.S.A., Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters, *inter alia*, of *Pfizer Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-748 (D. Del.); *Genentech, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 19-cv-103 (D. Del.); *Boehringer Ingelheim Pharma. Inc. et al. v. Aurobindo Pharma Ltd. et al.*, 18-cv-1757 (D. Del.); *Biogen Int'l GmbH et al. v. Aurobindo Pharma U.S.A., Inc.*, 17-cv-824 (D. Del.); and *Amgen Inc. v. Aurobindo Pharma Ltd.*, 16-cv-853 (D. Del.).

ANSWER:

Admitted that Aurobindo Pharma U.S.A., Inc. has been sued in this Court, consented to personal jurisdiction for the limited purposes of those lawsuits, and asserted counterclaims, and, for the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc.

consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of Paragraph 42 of the Complaint.

43. Upon information and belief, Aurobindo Pharma U.S.A., Inc. participated in the preparation, development, and filing of ANDA No. 213893, and its underlying subject matter, with the intent to market, sell, and/or distribute Eugia's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Aurobindo Pharma U.S.A., Inc.'s contact with the State of Delaware.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma U.S.A., Inc. consents to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 43 of the Complaint.

44. Venue is proper in this Judicial District as to Aurobindo Pharma U.S.A., Inc. because, *inter alia*, Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this Judicial District.

ANSWER:

For purposes of this action only, Aurobindo Pharma U.S.A., Inc. does not contest jurisdiction or venue in this Court. and except as so expressly admitted, deny the allegations of Paragraph 44 of the Complaint.

LONSURF®

45. Plaintiff Taiho Oncology, Inc. is the holder of the New Drug Application ("NDA") No. 207981 for the manufacture and sale of trifluridine and tipiracil tablets, 15mg and 20 mg, and sells the product in the United States under the registered trademark Lonsurf®.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 and, therefore, deny them.

46. The FDA approved NDA No. 207981 for the 15mg and 20mg tablets on September 22, 2015.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 and, therefore, deny them.

47. Plaintiff Taiho Oncology, Inc. sells and distributes Lonsurf® throughout the United States pursuant to NDA No. 207981.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 and, therefore, deny them.

48. Lonsurf® is indicated for the treatment of metastatic colorectal cancer that has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy as well as the treatment of metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. A copy of the February 22, 2019 Lonsurf® Label is attached as Exhibit A.

ANSWER:

Admitted that the Complaint purports to attach a copy of the February 22, 2019 Lonsurf® Label as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 48 and, therefore, deny them.

PATENTS-IN-SUIT

49. The '284 patent, entitled "Method of Administrating an Anticancer Drug Containing α,α,α-Trifluorothymidine and Thymidine Phosphorylase Inhibitor" was duly and legally reissued by the United States Patent and Trademark Office ("USPTO") on January 24, 2017. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the '284 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '284 patent is attached as Exhibit B.

ANSWER:

Admitted that the Complaint purports to attach a certified copy of the '284 patent, which document is titled "Method of Administrating an Anticancer Drug Containing α,α,α-Trifluorothymidine and Thymidine Phosphorylase Inhibitor" on its face and was issued on January 24, 2017. Defendants deny the '284 patent was duly and legally reissued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 49 and, therefore, deny them.

50. Pursuant to Federal Food, Drug, and Cosmetic Act ("FFD&C Act"), 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Taiho has submitted information concerning the '284 patent to the FDA in connection with NDA No. 207981, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '284 patent has been listed in the FDA's Orange Book as covering Lonsurf® and methods for using it.

ANSWER:

Admitted that the '284 patent has been listed in the Orange book in connection with Lonsurf®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 50 and, therefore, deny them.

51. Claim 1 of the '284 patent is directed, *inter alia*, to a method for treating at least one of a digestive cancer and a breast cancer, comprising (i) orally administering a composition comprising α,α,α-trifluorothymidine ("FTD") and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ration of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, (ii) wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m2 is the human patient's body surface area.

ANSWER:

Admitted that Exhibit B recites claim 1 of the '284 patent. Defendants deny the remaining allegations asserted in Paragraph 51.

52. Claim 18 of the '284 patent is directed, *inter alia*, to a method for treating colorectal cancer comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area.

ANSWER:

Admitted that Exhibit B recites claim 18 of the '284 patent. Defendants deny the remaining allegations asserted in Paragraph 52.

53. The approved Lonsurf® product labeling instructs medical personnel and/or patients to perform the steps of at least one claim of the '284 patent.

ANSWER:

Admitted that what purports to be a copy of the February 22, 2019 Lonsurf® Label is attached as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 53 and, therefore, deny them.

54. The use of Lonsurf® by patients and/or medical personnel in accordance with its approved product labeling by medical personnel and/or patients necessarily results in the performance of each step of at least one claim of the '284 patent.

ANSWER:

Admitted that what purports to be a copy of the February 22, 2019 Lonsurf® Label is attached as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 54 and, therefore, deny them.

55. The '223 patent, entitled "Stable Crystal Form of Tipiracil Hydrochloride and Crystallization Method for the Same" was duly and legally issued by the USPTO on November, 27 2018. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the '223 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '223 patent is attached as Exhibit C.

ANSWER:

Admitted that the Complaint purports to attach a certified copy of the '223 patent, which document is titled "Stable Crystal Form of Tipiracil Hydrochloride and Crystallization Method for the Same" on its face and was issued on November 27, 2018. Defendants deny the '223 patent was duly and legally reissued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 55 and, therefore, deny them.

56. Claim 1 of the '223 patent is directed, inter alia, to a polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ ±0.2°) in powder X-ray diffraction.

ANSWER:

Admitted that Exhibit C recites claim 1 of the '223 patent. Defendants deny the remaining allegations asserted in Paragraph 56.

EUGIA'S ANDA PRODUCT

57. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. § 355(j), Eugia submitted ANDA No. 213893 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's ANDA Product within the United States prior to the expiration of the patents-in-suit.

Admitted that Eugia submitted ANDA No. 213893 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's ANDA Product within the United States at some time after approval by the FDA. Defendants deny the remaining allegations asserted in Paragraph 57.

58. Upon information and belief, Eugia's ANDA No. 213893 identified Taiho's Lonsurf® (trifluridine and tipiracil) tablets and included a written certification, as required by FFD&C Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the '284 patent and U.S. Patent No. 9,527,833 ("the '833 patent") are invalid or otherwise will not be infringed by Eugia's ANDA Product.

ANSWER:

Admitted that ANDA No. 213893 included a Paragraph IV certification; refer to the Paragraph IV certification for the contents therein and except as so expressly admitted, deny the allegations of Paragraph 58 of the Complaint.

59. On or about November 8, 2019, Taiho received a letter from Eugia purporting to be a written notice that Eugia had filed ANDA No. 213893 seeking approval to market Eugia's ANDA Product prior to the expiration of the '284 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV notice letter"). The Paragraph IV notice letter included notice of Eugia's allegations that the '284 patent is invalid and/or not infringed by Eugia's ANDA Product.

ANSWER:

Admitted that Taiho received the Paragraph IV notice letter on or about November 8, 2019; refer to the Paragraph IV notice letter for the contents therein and except as so expressly admitted, deny the allegations of Paragraph 59 of the Complaint.

60. Eugia's submission of ANDA No. 213893, including the Paragraph IV certification, to the FDA constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2).

ANSWER:

Paragraph 60 states a legal conclusion to which no response is required. Defendants deny it has infringed the patents-in-suit. Admitted that Eugia filed Eugia's ANDA for approval by FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 60 of the Complaint.

61. Eugia's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Eugia's ANDA Product upon approval of ANDA No. 213893 and before

expiration of the patents-in-suit will infringe at least claims 1 and 18 of the '284 patent and at least claim 1 of the '223 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER:

Denied.

62. Taiho commenced this action within 45 days of receiving Eugia's Paragraph IV notice letter.

ANSWER:

Admitted.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. RE46,284

63. Paragraphs 1-62 are incorporated by reference as though fully set forth herein.

ANSWER:

Defendants reallege the answers to Paragraphs 1-62 of the Complaint as if fully set forth herein.

64. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets according to the Lonsurf® product labeling satisfies at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

65. Upon information and belief, Eugia's ANDA Product has the same use as Lonsurf®, at least because Eugia's ANDA No. 213893 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 65.

66. Upon information and belief, the proposed product labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 66.

67. Upon information and belief, Eugia's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 67.

68. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

69. Eugia's submission of ANDA No. 213893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '284 patent constitutes infringement of at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(e)(2).

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny infringement of the '284 patent and the remaining allegations in Paragraph 69.

70. Claim 1 of the '284 patent recites "A method for treating at least one of a digestive cancer and a breast cancer, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area."

ANSWER:

Admitted that Exhibit B recites claim 1 of the '284 patent. Defendants deny the remaining allegations asserted in Paragraph 70.

71. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat a digestive cancer by orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of a digestive cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 71.

72. Claim 18 of the '284 patent recites "A method for treating colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area."

ANSWER:

Admitted that Exhibit B recites claim 18 of the '284 patent. Defendants deny the remaining allegations asserted in Paragraph 72.

73. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 73.

74. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(a)

by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

ANSWER:

Denied.

75. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '284 patent, with knowledge of said patent and said infringement.

ANSWER:

Denied.

76. Upon information and belief, the proposed product labeling for Eugia's ANDA will instruct medical personnel and/or patients to perform the steps of at least claims 1 and 18 of the '284 patent.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 76.

77. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

78. Upon information and belief, Eugia specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Eugia knows infringe at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

79. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(c) by selling or offering to sell Eugia's ANDA Product in the United States, with knowledge of the '284 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

ANSWER:

Denied.

80. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

81. Eugia's ANDA Product constitutes a material part of the invention covered by at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

82. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 213893 shall be no earlier than the date on which the '284 patent expires, including any patent term and regulatory extensions.

ANSWER:

Denied.

83. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Eugia's infringement of the '284 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

ANSWER:

Denied.

84. Upon information and belief, Eugia was aware of the '284 patent prior to Eugia submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without reasonable basis for a good faith belief that it would not be liable for infringing the '284 patent.

ANSWER:

Admitted that Eugia was aware of the '284 patent prior to Eugia submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Defendants deny the remaining allegations in Paragraph 84.

COUNT II – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT NO. RE46,284

85. Paragraphs 1-84 are incorporated by reference as though fully set forth herein.

ANSWER:

Defendants reallege the answers to Paragraphs 1-84 of the Complaint as if fully set forth herein.

86. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets according to the Lonsurf® product labeling satisfies at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

87. Upon information and belief, Eugia's ANDA Product has the same use as Lonsurf®, at least because Eugia's ANDA No. 213893 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 87.

88. Claim 1 of the '284 patent recites "A method for treating at least one of a digestive cancer and a breast cancer, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of at least one of a digestive cancer and a breast cancer, wherein the administration of a daily dose of said composition is in 2

portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area."

ANSWER:

Admitted that Exhibit B recites claim 1 of the '284 patent. Defendants deny the remaining allegations asserted in Paragraph 88.

89. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat a digestive cancer by orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 50 to 70 mg/m^2/day in terms of FTD in 2 divided portions per day to a human patient in need of treatment of a digestive cancer, wherein the administration of a daily dose of said composition is in 2 portions per day for 5 days followed by 2 days off treatment in the week on a one-week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 89.

90. Claim 18 of the '284 patent recites "A method for treating colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one-week dosing schedule wherein m^2 is the human patient's body surface area."

ANSWER:

Admitted that Exhibit B recites claim 18 of the '284 patent. Defendants deny the remaining allegations asserted in Paragraph 90.

91. Discovery will likely show that the product labeling for Eugia's ANDA Product will instruct medical personnel and/or patients to treat colorectal cancer in a human patient, comprising orally administering a composition comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-(1-(2-iminopyrrolidinyl)methyl)uracil hydrochloride in a molar ratio of 1:0.5 at a dose of 70 mg/m^2/day in terms of FTD in 2 divided portions per day at a dosing interval of 6 hours or more wherein the administration of said dose is for 5 days followed by 2 days off treatment in a one- week dosing schedule wherein m^2 is the human patient's body surface area. Discovery will also likely show that the proposed labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 91.

92. Upon information and belief, the proposed product labeling for Eugia's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 92.

93. Upon information and belief, Eugia's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 93.

94. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

95. Eugia's submission of ANDA No. 213893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '284 patent constitutes infringement of at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

96. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

ANSWER:

Denied.

97. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '284 patent, with knowledge of said patent and said infringement.

ANSWER:

Denied.

98. Upon information and belief, the proposed product labeling for Eugia's ANDA will instruct medical personnel and/or patients to perform the steps of at least claims 1 and 18 of the '284 patent.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 98.

99. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

100. Upon information and belief, Eugia specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Eugia knows infringe at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

101. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claims 1 and 18 of the '284 patent under 35 U.S.C. § 271(c) by selling or offering to sell Eugia's ANDA Product in the United States, with knowledge of the '284 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

ANSWER:

Denied.

102. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claims 1 and 18 of the '284 patent.

ANSWER:

Denied.

103. Upon information and belief, Eugia was aware of the '284 patent prior to Eugia submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95.

ANSWER:

Admitted that Eugia was aware of the '284 patent prior to Eugia submitting its Paragraph IV certification, and at least as early as September 23, 2019, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Defendants deny the remaining allegations in Paragraph 103.

104. Upon information and belief, Eugia acted, and upon the FDA's approval of ANDA No. 213893, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '284 patent.

ANSWER:

Denied.

105. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Eugia's making, using, offering to sell, selling and/or importing Eugia's ANDA Product, inducement therefor or contribution thereto, will infringe the '284 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

106. Pursuant to 28 U.S.C. § 2201 and 35 U.S.C. § 271(e)(4)(A), Taiho is entitled to a declaratory judgment that the effective date of any approval of ANDA No. 213893 shall be no earlier than the date on which the '284 patent expires, including any patent term and regulatory extensions.

ANSWER:

Denied.

107. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Eugia's ANDA Product with its proposed labeling, or any other Eugia drug that is covered by or whose use is covered by the '284 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '284 patent, and that the claims of the '284 patent are not invalid.

ANSWER:

Denied.

COUNT III –INFRINGEMENT OF U.S. PATENT NO. 10,138,223

108. Paragraphs 1-107 are incorporated by reference as though fully set forth herein.

ANSWER:

Defendants reallege the answers to Paragraphs 1-107 of the Complaint as if fully set forth herein.

109. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '223 patent.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 109 and, therefore, deny them.

110. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '223 patent.

ANSWER:

Denied.

111. Eugia's submission of ANDA No. 213893 seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '223 patent constitutes infringement of at least claim 1 of the '223 patent under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

112. Claim 1 of the '223 patent recites "A polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction."

ANSWER:

Admitted that Exhibit C recites claim 1 of the '223 patent. Defendants deny the remaining allegations asserted in Paragraph 112.

113. Eugia's ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Eugia's ANDA Product contains a polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 113.

114. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

ANSWER:

Denied.

115. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '223 patent, with knowledge of said patent and said infringement.

ANSWER:

Denied.

116. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '223 patent.

ANSWER:

Denied.

117. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(c) by selling and offering to sell Eugia's ANDA Product in the United States, with knowledge of the '223 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

ANSWER:

Denied.

118. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '223 patent.

ANSWER:

Denied.

119. Eugia's ANDA Product constitutes a material part of the invention covered by the claims of the '223 patent.

ANSWER:

Denied.

120. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Eugia's infringement of the '223 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

ANSWER:

Denied.

COUNT IV – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT NO. 10,138,223

121. Paragraphs 1-120 are incorporated by reference as though fully set forth herein.

ANSWER:

Defendants reallege the answers to paragraphs 1-120 of the Complaint as if fully set forth herein.

122. Taiho's Lonsurf® (trifluridine and tipiracil) tablets meet every limitation of at least claim 1 of the '223 patent.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 122 and, therefore, deny them.

123. Upon information and belief, Eugia's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '223 patent.

ANSWER:

Denied.

124. Claim 1 of the '223 patent recites "A polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction."

ANSWER:

Admitted that Exhibit C recites claim 1 of the '223 patent. Defendants deny the remaining allegations asserted in Paragraph 124.

125. Eugia's ANDA Product contains tipiracil HCl as one of its active ingredients. Discovery will likely show that Eugia's ANDA Product contains a polymorph, comprising a crystal of 5-chloro-6-(2-minopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a purity of 95% by mass or more, wherein the crystal exhibits peaks at two or more of 10.5°, 19.6°, 23.7°, 26.2°, and 31.2° which are characteristic peaks of Crystal III as a diffraction angle (2θ±0.2°) in powder X-ray diffraction.

ANSWER:

Admitted that Eugia filed ANDA No. 213893 for approval by the FDA of the matters recited therein. Defendants deny the remaining allegations in Paragraph 125.

126. Eugia's submission of ANDA No. 213893 seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Eugia's ANDA Product prior to the expiration of the '223 patent constitutes infringement of at least claim 1 of the '223 patent under 35 U.S.C. § 271(e)(2).

ANSWER:

Denied.

127. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Eugia's ANDA Product in the United States.

ANSWER:

Denied.

128. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '223 patent, with knowledge of said patent and said infringement.

ANSWER:

Denied.

129. Upon information and belief, the use of Eugia's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed

labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '223 patent.

ANSWER:

Denied.

130. Upon information and belief, upon the FDA's approval of ANDA No. 213893, Eugia will infringe at least claim 1 of the '223 patent under 35 U.S.C. § 271(c) by selling and offering to sell Eugia's ANDA Product in the United States, with knowledge of the '223 patent and that there is no substantial non-infringing use of Eugia's ANDA Product.

ANSWER:

Denied.

131. Upon information and belief, Eugia knows that Eugia's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '223 patent.

ANSWER:

Denied.

132. Upon information and belief, Eugia acted, and upon the FDA's approval of ANDA No. 213893, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '223 patent.

ANSWER:

Denied.

133. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Eugia's making, using, offering to sell, selling and/or importing Eugia's ANDA Product, inducement therefor or contribution thereto, will infringe the '223 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER:

Denied.

134. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Eugia's ANDA Product with its proposed labeling, or any other Eugia drug that is covered by or whose use is covered by the '223 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '223 patent, and that the claims of the '223 patent are not invalid.

ANSWER:

Denied.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

Defendants deny that Plaintiffs are entitled to the judgment or any of the relief sought in paragraphs (A) through (H) under the heading "REQUEST FOR RELIEF."B.

AFFIRMATIVE DEFENSES

Eugia alleges and asserts the following affirmative defenses in response to the allegations in the complaint. Eugia reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery.

FIRST AFFIRMATIVE DEFENSE

The manufacture, use or sale of the product that is the subject of ANDA No. 213893 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '284 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The claims of the '284 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs are estopped and/or precluded from asserting that the product described in Eugia's ANDA No. 213893 infringes the '284 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '284 patent.

FOURTH AFFIRMATIVE DEFENSE

The manufacture, use or sale of the product that is the subject of ANDA No. 213893 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '223 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

The claims of the '223 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are estopped and/or precluded from asserting that the product described in Eugia's ANDA No. 213893 infringes the '223 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '223 patent.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a proper claim for willful infringement or for this being an exceptional case justifying an award of attorney's fees.

EIGHTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSE

Eugia reserves the right to assert additional affirmative defenses that may be developed through discovery, or otherwise, in this action.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs, Defendants/Counterclaim-Plaintiffs Eugia Pharma Specialities Ltd. ("Eugia") and Aurobindo Pharma U.S.A., Inc. (Aurobindo USA") (collectively, "Eugia" or "Counterclaim-Plaintiffs") state as follows, without admitting any allegations of the Complaint not expressly admitted and without assuming the burden when such burden would otherwise be on Plaintiffs/Counterclaim-Defendants.

PARTIES

1. Aurobindo Pharma U.S.A., Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

2. Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Plot #2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

3. Upon information and belief, Plaintiff Taiho Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-27 Kandanishiki-cho, Chiyodaku, Tokyo 101-8444, Japan.

4. Upon information and belief, Plaintiff Taiho Oncology, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 101 Carnegie Center, Suite 101, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

5. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202.

7. Plaintiffs/Counterclaim-Defendants Taiho Pharmaceutical Co., Ltd., and Taiho Oncology, Inc. (collectively, "Taiho") are subject to personal jurisdiction in this Judicial District because Plaintiffs subjected themselves to the jurisdiction of this Court by filing their Complaint here. Plaintiffs Taiho are also subject to personal jurisdiction in this Judicial District

because: (i) Taiho Oncology, Inc. sells products here, including the Lonsurf® product that is the subject of this case; (ii) Taiho Pharmaceutical Co., Ltd. regularly practices business here; and, (iii) Plaintiffs Taiho have purposefully availed themselves of the benefits of jurisdiction in the State of Delaware.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim-Defendants' choice of forum in filing its Complaint against Eugia here.

9. As a consequence of Plaintiffs/Counterclaim-Defendants' complaint against Eugia, there is now an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity, and enforceability of the patents-in-suit.

THE CONTROVERSY

10. The United States Patent and Trademark Office ("USPTO") issued the '284 patent on January 24, 2017, naming Taiho Pharmaceutical Co., Ltd. as the assignee on the face of the patent.

11. The USPTO issued the '223 patent on November 27, 2018, naming Taiho Pharmaceutical Co., Ltd. as the assignee on the face of the patent.

12. Plaintiff Taiho Oncology, Inc. purports to be the holder of the New Drug Application ("NDA") No. 207981 for the manufacture and sale of trifluridine and tipiracil tablets, 15 mg and 20 mg, and sells the product in the United States under the registered trademark Lonsurf®.

13. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") must follow when determining whether to approve for marketing brand and generic drugs.

14. Under the FFDCA, an applicant seeking to market a new brand drug must prepare a NDA for review by the FDA. See 21 U.S.C. § 355.

15. An NDA may include the patent number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. See 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

16. An NDA holder is required to submit to the FDA the patent number of each patent relevant to the drug for which the NDA was submitted to the FDA. The FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the Orange Book.

17. Upon information and belief, Plaintiffs caused the '284 patent to be listed in the Orange Book in connection with NDA No. 207981.

18. Eugia submitted ANDA No. 213893 ("Eugia's ANDA) to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eugia's ANDA Product within the United States at some time after approval by the FDA and referenced NDA No. 207981. As part of Eugia's ANDA, Eugia submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly called a "paragraph IV certification," that the patents-in-suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Eugia's ANDA Product.

19. On or about November 7, 2019, Eugia sent Taiho written notice that Eugia had filed ANDA No. 213893 seeking approval to market Eugia's ANDA Product prior to the expiration of the '284 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "Paragraph

IV notice letter"). The Paragraph IV notice letter included Eugia's allegations that the '284 patent is invalid and/or not infringed by Eugia's ANDA Product.

20. On December 19, 2019, Plaintiffs/Counterclaim-Defendants Taiho sued Eugia, alleging infringement of the patents-in-suit. There has been and is now an actual and justiciable controversy between Eugia and Taiho as to whether the drug products described in ANDA No. 213893 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents-in-suit.

21. Eugia and Plaintiffs/Counterclaim-Defendants have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the patents-in-suit. The patents-in-suit effectively delay FDA approval of the drug products described in ANDA No. 213893.

COUNT I

(Declaratory Judgment of Non-Infringement of the '284 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '284 Patent)

22. Eugia repeats and incorporates by reference Paragraphs 1-21 of its Counterclaims as if fully set forth herein.

23. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '284 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Eugia's ANDA Product described by ANDA No. 213893 and that all claims of the '284 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one

or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

24. In Eugia's Paragraph IV notice letter, Eugia provided reasons sufficient to show that Eugia's ANDA Product described by ANDA No. 213893 does not infringe any valid claim of the '284 patent.

25. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Eugia's ANDA Product described by ANDA No. 213893 will infringe any valid and enforceable claim of the '284 patent.

26. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Eugia's ANDA Product described by ANDA No. 213893 will not infringe, directly or indirectly, any valid claim of the '284 patent.

COUNT II

(Declaratory Judgment of Non-Infringement of the '223 Patent by Eugia's ANDA Product and Declaratory Judgment of Invalidity of the '223 Patent)

27. Eugia repeats and incorporates by reference Paragraphs 1-26 of its Counterclaims as if fully set forth herein.

28. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '223 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Eugia's ANDA Product described by

ANDA No. 213893 and that all claims of the '223 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

29. Eugia's ANDA Product described by ANDA No. 213893 does not infringe any valid claim of the '223 patent, and that the claims of the '223 patent are invalid.

30. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Eugia's ANDA Product described by ANDA No. 213893 will infringe any valid and enforceable claim of the '223 patent.

31. Eugia is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Eugia's ANDA Product described by ANDA No. 213893 will not infringe, directly or indirectly, any valid claim of the '223 patent, and/or that all claims of the '223 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

PRAYER FOR RELIEF

WHEREFORE, Eugia respectfully requests the Court enter a Judgment and Order in its favor and against Counterclaim-Defendants to include:

(a) A declaration that Eugia's submission of ANDA No. 213893 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '284 patent does not, and will not, infringe, any valid and enforceable claim of the '284 patent;

(b) A declaration that Eugia's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Eugia's ANDA Product described by ANDA No. 213893 does not, and will not, infringe any valid and enforceable claim of the '284 patent;

(c) A declaration that the claims of the '284 patent are invalid;

(d) A declaration that Eugia's submission of ANDA No. 213893 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '223 patent does not, and will not, infringe, any valid and enforceable claim of the '223 patent;

(e) A declaration that Eugia's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Eugia's ANDA Product described by ANDA No. 213893 does not, and will not, infringe any valid and enforceable claim of the '223 patent;

(f) A declaration that the claims of the '223 patent are invalid;

(g) A declaration that Counterclaim-Defendants are entitled to no damages, interest, costs, or other relief from or against Eugia;

(h) A declaration that this case is exceptional in favor of Eugia and awarding attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the inherent power of the Court;

(i) An award of costs and expenses;

(j) A declaration that Counterclaim-Defendants are not entitled to injunctive relief; and

(k) Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Morris James, LLP

/s/ Kenneth L. Dorsney

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