UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AUROBINDO PHARMACEUTICALS LIMITED and AUROBINDO PHARMA INC., Plaintiff, v. DAIICI SANKYO, INC., and DAIICHI SANKYO CO., LTD., Defendants.	**Case No. 16-cv-4876**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Aurobindo Pharmaceuticals Limited and Aurobindo Pharma Inc. (sometimes collectively "Aurobindo" or "Plaintiffs"), by and through their undersigned counsel, hereby bring their Complaint for Declaratory Judgment against Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. (sometimes collectively "Daiichi" or "Defendants"), and allege as follows:

THE PARTIES

1. Aurobindo Pharmaceuticals Limited ("Aurobindo Pharmaceuticals") is an Indian corporation, having its principal place of business office at Maitri Vihar, Plot #2, Ameerpet, Hyderabad-500038, Telangana, India.

2. Aurobindo Pharma Inc. ("Aurobindo Pharma") is a corporation and existing under the laws of the state of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, NJ 08810.

3. Upon information and belief, Defendant Daiichi Sankyo, Inc. (sometimes "Daiichi Inc.") is a Delaware corporation with its principal place of business at Two Hilton Court, Parsippany, New Jersey 07054, with a registered agent for service of process in Illinois, National Registered Agents Inc., located at 208 S. LaSalle St., Ste. 814, Chicago, Illinois 60604.

4. Upon information and belief, Defendant Daiichi Sankyo Co., Ltd. ("Daiichi Ltd."), is a Japanese corporation having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan. Daiichi Ltd., which was formed as the result of a merger between Daiichi Pharmaceutical Co., Ltd. and Sankyo Co., Ltd, is the parent company of Defendant Daiichi Inc., and utilizes Daiichi Inc. as its U.S. headquarters.

NATURE OF THE ACTION

5. This is a declaratory judgment action in which Plaintiffs seek a declaration of non-infringement of United States Patent No. 6,878,703 (the "'703 patent") to enable Aurobindo to bring its generic drugs Olmesartan Medoxomil Tablets in dosages of 5 mg, 20 mg or 40 mg, and Olmesartan Medoxomil and Hydrochlorothiazide Combo Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg, to market at the earliest possible date under the applicable statutory and FDA regulatory provisions and to allow the public to enjoy the benefits of generic competition for these products.

6. This Complaint arises under the Patent Laws of the United States, Title 35 of the United States Code, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984 (codified as amended at 21 U.S.C. § 355)) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-

173, 17 Stat. 2066 (2003) (hereinafter "MMA"), based upon an actual controversy between the parties to declare that Aurobindo is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed Aurobindo's ANDA Products as described in ANDA 20-4798 and ANDA 20-5391 upon the expiration of United States Patent No. 5,616,599 ("the '599 patent") and any applicable pediatric exclusivity.

7. *Apotex, Inc. v. Daiichi Sankyo Inc. et al*., N.D. Ill., Case No. 12-cv-9295, 15-cv-3695 (Judge Coleman) is a nearly identical case to this one involving Apotex's generic Benicar® product (Olmesartan Medoxomil) and generic Benicar HCT® (olmesartan medoxomil plus hydrochlorothiazide) products. In that case, Judge Coleman issued an order on January 8, 2016 granting Apotex's summary judgment of non-infringement stating, "Non-infringement of the '703 patent follows as a matter of law from the fact that it has been formally disclaimed." (D.I. 66, p. 8) On March 2, 2016, Judge Coleman entered a final judgment in favor of Apotex.

8. Previous to Judge Coleman's order, the Court of Appeals for the Federal Circuit held that Apotex's complaint presented a justiciable case or controversy because "[u]nder the statute that governs marketing approval of generics, Apotex has a concrete, potentially high- value stake in obtaining the judgment it seeks." *Apotex, Inc. v. Daiichi Sankyo Inc.*, 781 F.3d 1356, 1358 (Fed. Cir. 2015). Certiorari was denied in the jurisdictional appeals. *Daiichi Sankyo, Inc. v. Apotex, Inc.*, 136 S. Ct. 481 (2015); *Mylan Pharmaceuticals Inc. v. Apotex Inc.*, 136 S. Ct. 485 (2015).

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28

U.S.C. §§ 1331, 1337, 1338(a), 2201, and 2202; and under 21 U.S.C. § 355(j)(5)(C).

10. Upon information and belief, Defendant Daiichi Inc. is the U.S. subsidiary of Defendant Daiichi Ltd., which subsidiary sells pharmaceutical drug products, including Olmesartan Medoxomil (Benicar®) and Olmesartan Medoxomil-Hydrochlorothiazide (Benicar HCT®) products, manufactured by Daiichi Ltd., in the U.S. and in this judicial district. (*See* internet website link of Daiichi Ltd. attached hereto as Exhibit A).

11. This Court has personal jurisdiction over Defendant Daiichi Inc. because it has designated an agent in this district for service of process. Additionally, upon information and belief, Daiichi Inc. also employs sales agents in Chicago to sell its pharmaceutical products in the Northern District of Illinois. (*See* internet website link of Daiichi Inc., attached hereto as Exhibit B.)

12. This Court has personal jurisdiction over both Defendants due to their continuous and systematic contacts with the state of Illinois, including their conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in Illinois including, but not limited to, the Olmesartan Medoxomil, and Olmesartan Medoxomil and Hydrochlorothiazide, products.

13. This Court has personal jurisdiction over Daiichi Inc. because, upon information and belief: (a) it directly or indirectly markets and sells pharmaceutical products throughout the United States and in this judicial district; (b) it has purposefully conducted and continues to conduct business in this judicial district; (c) this judicial district is a destination of Daiichi Inc.'s pharmaceutical products; and (d) it has previously submitted to the jurisdiction

of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction.

14. This Court has personal jurisdiction over Daiichi Ltd. because, upon information and belief: (a) it is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products and directly, or through its wholly-owned subsidiaries, including Daiichi Inc.; (b) it manufactures, markets and sells pharmaceutical drug products throughout the United States and in this judicial district; (c) derives substantial revenue from the sale of its products in this judicial district; (d) the preparation of the New Drug Applications ("NDA"s) for Olmesartan Medoxomil (Benicar®) and Olmesartan Medoxomil Hydrochlorothiazide (Benicar HCT®) and/or the subsequent marketing and selling of Benicar® and Benicar HCT® were done in this judicial district with the cooperation, participation, and/or assistance of Daiichi Ltd.; (d) Daiichi Ltd. so dominates Daiichi Inc. that Daiichi Inc. is a "mere instrumentality" for its parent company, Daiichi Ltd., to market and sell Olmesartan Medoxomil (Benicar®), and Olmesartan Medoxomil and Hydrochlorothiazide (Benicar HCT®), throughout the United States and in this judicial district; (e) Daiichi Ltd. benefits financially from the marketing, distribution, and sale of Benicar® and Benicar HCT® in the United States and in this judicial district and reports Daiichi Inc.'s earnings as part of Daiichi Ltd.'s consolidated financial statements; (f) Daiichi Inc., is a business unit of Daiichi Ltd., and the President of Commercial Operations at Daiichi Inc. reports to the CEO of Daiichi Ltd.; and (g) Daiichi Ltd., upon information and belief, has previously submitted to the jurisdiction of this Court and has further availed itself of this Court by filing suit in this jurisdiction.

15. Venue is proper in this District under 28 U.S.C. §§ 1391 (b), (c), 1400 (b) and/or 21 U.S.C. §355.

PATENT IN SUIT

16. On its face, U.S. Patent No. 6,878,703 entitled "Pharmaceutical Composition" indicates that it was issued by the United States Patent and Trademark Office on April 12, 2005. A copy of the '703 patent is attached hereto as Exhibit C.

17. According to the records at the United States Patent and Trademark Office, Sankyo Company, Limited is the assignee of the '703 patent.

18. Upon information and belief, Defendant Daiichi Ltd. was the successor in interest at the time to the '703 patent after the merger between Daiichi Pharmaceutical Co., Ltd. and Sankyo Co., Ltd.

19. On July 11, 2006, the term of every claim of the '703 patent was disclaimed. *See* Disclaimer, dated 11 July, 2006, attached hereto as Exhibit D.

BACKGROUND

20. In December 2003, Congress passed the Medicare Modernization Act of 2003 ("MMA"). Title XI of that Act entitled "Access to Affordable Pharmaceuticals," which included a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an "Orange Book"-listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

21. The MMA also added forfeiture provisions for the 180-day exclusivity to which a first generic ANDA filer might otherwise be entitled pursuant to the Hatch Waxman Act. 21 U.S.C. §355 (j)(5)(D). The forfeiture provision at issue here requires, *inter alia*, the entry of a judgment of non-infringement, unenforceability or invalidity with respect to the patents against which a first ANDA filer has filed a Paragraph IV certification, regardless of whether those patents are asserted against subsequent ANDA filers. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

22. Upon information and belief, Daiichi Inc. is the current holder of approved New Drug Applications ("NDA"s) No. 21-286 for Benicar® tablets containing Olmesartan Medoxomil in dosages of 5, mg, 20 mg, and 40 mg, and No. 21- 532 for Benicar HCT® tablets containing Olmesartan Medoxomil and Hydrochlorothiazide Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg tablets.

23. Daiichi Inc. identified the '703 patent along with the '599 patent to the Food and Drug Administration ("FDA") for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"), as patents 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" products containing Olmesartan Medoxomil in dosages of 5 mg, 20 mg, and 40 mg and ("Olmesartan products"), and Olmesartan Medoxomil and Hydrochlorothiazide Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg ("Olmesartan Medoxomil + Hydrochlorothiazide products").

24. The '599 and '703 patents remain listed in the Orange Book with respect to NDA No. 21-286 and NDA No. 21- 532 and Daiichi maintains and continues to represent to the public that the '703 patent claims the drug approved in NDA No. 21-286 and NDA 21-532 or a method of using that drug, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant who attempts to market a generic version of the drug prior to the delisting of the '703 patent. The FDA Orange Book also lists a six (6) month pediatric exclusivity for the '599 patent, which upon information and belief will prevent ANDA filers from obtaining final FDA marketing approval for a generic Olmesartan Medoxomil, or generic Olmesartan Medoxomil + Hydrochlorothiazide products, until six months after the expiration of the '599 patent.

25. According to Orange Book listing, Benicar®, or treatments using Benicar, and Benicar HCT®, or treatments using Benicar HCT®, are claimed in the '703 patent as well.

26. Aurobindo has submitted Abbreviated New Drug Application ("ANDA") No. 20-4798 for a proposed drug product containing Olmesartan Medoxomil Tablets in dosages of 5 mg, 20 mg, and 40 mg, and ANDA No. 20-5391 for a proposed drug product containing Olmesartan Medoxomil + Hydrochlorothiazide in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg tablets of Olmesartan Medoxomil + Hydrochlorothiazide (together "Aurobindo's ANDA Products"). Aurobindo's ANDAs seek FDA approval for the commercial manufacture, use, importation, offer for sale and sale of generic Olmesartan Medoxomil Tablets in dosages of 5 mg, 20 mg, and 40 mg, and Olmesartan Medoxomil + Hydrochlorothiazide Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg.

27. Aurobindo intends to market the Aurobindo ANDA Products as soon as the FDA approves its ANDAs. Subsequently, Aurobindo received tentative approvals from USFDA on 15 April 2016 (Olmesartan Medoxomil) and 30 March 2016 (Olmesartan Medoxomil + Hydrochlorothiazide) for its ANDA. The approvals are attached hereto as Exhibits E1 and E2, respectively.

28. Aurobindo filed certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification") to Daiichi's '599 patent certifying that Aurobindo will wait until the expiration of the '599 patent and any applicable pediatric exclusivity, *i.e.*, until October 25, 2016, to market Aurobindo's ANDA products.

29. Aurobindo filed certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") certifying that the '703 patent will not be infringed by the manufacture, use, or sale of Aurobindo's ANDA Products.

30. In accordance with 35 U.S.C. §§355(j)(2)(B) and 21 C.F.R. § 314.95, Aurobindo, in February 2013, served Daiichi with a notice letter (the "February Notice Letter") informing Daiichi of Aurobindo's ANDA which sought approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of the its Olmesartan Medoxomil ANDA Product before the expiration of the '703 patent. Daiichi received the February Notice Letter in February 2013. Aurobindo's February Notice Letter included a Paragraph IV certification that the '703 patent would not be infringed by the manufacture, use, or sale of Aurobindo's ANDA Product. Daiichi did not sue Aurobindo for patent infringement within 45 days of receiving notice of Aurobindo's paragraph IV certification (21 U.S.C. § 355(j)(5)(C)).

31. Also in accordance with 35 U.S.C. §§355(j)(2)(B) and 21 C.F.R. § 314.95, Aurobindo, in August 2013, served Daiichi with a notice letter (the "August Notice Letter") informing Daiichi of Aurobindo's ANDA which sought approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of the its Olmesartan Medoxomil + Hydrochlorothiazide ANDA Product before the expiration of the '703 patent. Daiichi received the August Notice Letter in September, 2013. Aurobindo's August Notice Letter again included a Paragraph IV certification that the '703 patent would not be infringed by the manufacture, use, or sale of Aurobindo's ANDA Product. Daiichi did not sue Aurobindo for patent infringement within 45 days of receiving notice of Aurobindo's paragraph IV certification (21 U.S.C. § 355(j)(5)(C)).

32. Aurobindo desires to bring its generic Olmesartan Medoxomil Tablets in dosages of 5 mg, 20 mg, and 40 mg and its generic Olmesartan Medoxomil + Hydrochlorothiazide Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg to market and to allow the public to enjoy the benefits of generic competition for these

products at the earliest possible date under the applicable statutory and FDA regulatory provisions.

33. Upon information and belief, the earliest possible date that Aurobindo can obtain final FDA marketing approval for its ANDA Products is upon the expiration of the '599 patent and any applicable pediatric exclusivity, on October 25, 2016. However, unless more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '703 patent is invalid or not infringed, Aurobindo will not be able to begin marketing its ANDA Products upon the expiration of the '599 patent and any applicable pediatric exclusivity.

34. Upon information and belief, Matrix Laboratories Limited ("Matrix"), now Mylan Laboratories Limited ("Mylan"), was the first generic ANDA applicant to have filed a Paragraph IV certification against both the '599 and '703 patents with respect to Olmesartan Medoxomil Tablets in dosages of 5 mg, 20 mg and 40 mg, and Olmesartan Medoxomil + Hydrochlorothiazide Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg, challenging, *inter alia*, the validity of both patents.

35. Daiichi filed suit against Matrix in the District of New Jersey for patent infringement, alleging that Matrix infringed the '599 patent, but on information and belief did not assert the '703 patent against Matrix in that lawsuit. Matrix failed in its Paragraph IV challenge to the validity of the '599 patent, and in 2010, the Federal Circuit affirmed the validity of the '599 patent in *Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010).

36. Because Matrix failed in its attempt to invalidate the '599 patent, Matrix's Paragraph IV certification with respect to that patent was converted to a Paragraph III certification, which requires Mylan to wait until the expiration of the '599 patent and any applicable pediatric exclusivity (now October 25, 2016) before it can market its generic Olmesartan and Olmesartan Medoxomil + Hydrochlorothiazide products.

37. Upon information and belief, despite Matrix's failure to invalidate the '599 patent, Mylan may retain a 180-day first generic applicant exclusivity by virtue of Matrix's Paragraph IV certification against the '703 patent. As such, the FDA will be prohibited from granting final approval to Aurobindo to market its Olmesartan Medoxomil Tablets in dosages of 5 mg, 20 mg, and 40 mg, and its Olmesartan Medoxomil + Hydrochlorothiazide Tablets in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg upon the expiration of the '599 patent and any applicable pediatric exclusivity, unless more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '703 patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

38. Accordingly, unless the Court first declares the '703 patent invalid, unenforceable or not infringed by Aurobindo's ANDA Product, Aurobindo will be prohibited from selling its products until 180 days after Mylan chooses to market its Olmesartan Medoxomil Tablet generic product in dosages of 5 mg, 20 mg and 40 mg, or its Olmesartan Medoxomil + Hydrochlorothiazide Tablet generic product in dosages of 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg, thereby injuring Aurobindo by depriving it of sales revenue for

that period of time and injuring the public by depriving the public of the benefit of the generic competition that would otherwise be provided by Aurobindo's ANDA products.

39. Upon information and belief, no court has entered "a final decision" identified in 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(AA) from which an appeal has been or can be taken that the '703 patent is invalid or not infringed nor has any court signed a "settlement order or consent decree" identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) that enters final judgment which includes a finding that the '703 patent is invalid or not infringed.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '703 PATENT

40. Aurobindo realleges and incorporates the allegations of paragraphs 1-39 of the Complaint as if fully set forth herein.

41. The '703 patent is not enforceable because every claim of that patent was disclaimed by Daiichi. Therefore, the manufacture, marketing, use, offer for sale, sale and/or importation of the product that is the subject of Aurobindo's ANDA No. 20-4798 will not directly infringe, induce or contribute to the infringement by others of the claims of the '703 patent, nor are the claims of the '703 patent infringed by the filing of Aurobindo's ANDA 20-4798.

41. The '703 patent is not enforceable because every claim of that patent was disclaimed by Daiichi. Therefore, the manufacture, marketing, use, offer for sale, sale and/or importation of the product that is the subject of Aurobindo's ANDA No. 20-5391 will not directly infringe, induce or contribute to the infringement by others of the claims of the '703 patent, nor are the claims of the '703 patent infringed by the filing of Aurobindo's ANDA 20-5391.

42. There is a substantial and continuing controversy between Daiichi and Aurobindo and a declaration of rights is both necessary and appropriate to establish that Aurobindo does not infringe any valid or enforceable claim of the '703 patent and allow it to bring its ANDA product to market upon the expiration of the '599 patent and any applicable pediatric exclusivity.

43. But-for Daiichi's decision to list the '703 patent in the Orange Book in the first place, FDA approval of Aurobindo's ANDA would not have been independently delayed by that patent. Aurobindo is being injured by Daiichi's actions of requesting the FDA to list the '703 patent

44. Aurobindo's injury can be redressed by the requested relief: a declaratory judgment of noninfringement that would trigger first applicant Mylan's 180-day exclusivity period, which otherwise will block final FDA marketing approval of Aurobindo's ANDA even after the expiration of the '599 patent and any applicable pediatric exclusivity. If Aurobindo is blocked by Mylan's first applicant exclusivity, Aurobindo will be monetarily harmed, as it will lose sales of its ANDA product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and be deprived of an economic opportunity to compete in the market for Olmesartan Medoxomil 5 mg, 20 mg, and 40 mg Tablets and Medoxomil + Hydrochlorothiazide 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg Tablets.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to enter judgment as follows:

A. Declaring that the claims of the '703 patent have not been infringed by the filing of Aurobindo's ANDA 20-4798;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Aurobindo ANDA 20-4798 have not infringed, do not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the '703 patent;

C. Declaring that the claims of the '703 patent have not been infringed by the filing of Aurobindo's ANDA 20-5391;

D. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Aurobindo ANDA 20-5391 have not infringed, do not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the '703 patent;

E. Declaring that the Food & Drug Administration may approve Aurobindo's Abbreviated New Drug Application (ANDA 20-4798 and ANDA 20-5391) with respect to Olmesartan Medoxomil 5 mg, 20 mg, and 40 mg Tablets and Medoxomil + Hydrochlorothiazide 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg Tablets whenever the application is otherwise in condition for approval, without awaiting any further order, judgment or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the patent in suit is not infringed pursuant to 21 U.S.C. 355(j)(5)(B)(iii)(I)(aa), and that any exclusivity periods to which Defendants might otherwise be entitled (including any pediatric exclusivity) with respect to the '703 patent are shortened to expire upon the date of entry of judgment in this case;

F. Awarding Plaintiffs their costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Awarding Plaintiffs such other relief that the Court deems just and proper under the circumstances.

H. Entering a final judgment under Fed. R. Civ. P. 58 that the Aurobindo ANDA products will not infringe the ‘703 patent.

I. Entering a final judgment under Fed. R. Civ. P. 58 that the ‘703 patent cannot be enforced.

J. Entering a final judgment on a separate paper or document under Fed. R. Civ. P. 58(a).

K. Entering a final judgment into the docket under Fed. R. Civ. P. 79(a).

L. Ordering the court clerk to enter a final judgment and notify the parties immediately and record such notification into the docket in compliance with Fed. R. Civ. P. 77.

Dated: May 2, 2016

THE PLAINTIFFS
AUROBINDO PHARMACEUTICALS LTD. and
AUROBINDO PHARMA, INC.

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