IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG and TAKEDA PHARMACEUTICALS AMERICA, INC.,	:	
Plaintiffs,	:	Civil Action No. 18-00753-LPS
v.	:	
CIPLA LIMITED and CIPLA USA INC.,	:	
Defendants.	:	

DEFENDANTS CIPLA LIMITED'S AND CIPLA USA INC.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Cipla Limited ("CL") and Cipla USA Inc. ("CipUSA") (collectively "Defendants"), by and through its undersigned attorneys, for its Answer, Affirmative Defenses, and Counterclaims to the Complaint of Plaintiffs H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Plaintiffs"), hereby responds as follows:

NATURE OF THE ACTION

1. Defendants admit that the Complaint purports to plead an action for patent infringement under the Patent Laws of the United States arising from Defendants' submission to the FDA of ANDA No. 211085 containing Paragraph IV certification to U.S. Patent No. 9,861,630 ("the '630 Patent"). Defendants deny that they are liable for any infringement of this patent and therefore deny any remaining allegations of Paragraph 1.

THE PARTIES

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

3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3 of the Complaint, and therefore deny them.

4. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint, and therefore deny them.

5. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint, and therefore deny them.

6. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint, and therefore deny them.

7. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the Complaint, and therefore deny them.

8. Admitted.

9. Admitted.

10. Denied.

11. Denied.

12. Defendants admit that CipUSA is CL's agent for filing ANDA No. 211085. Defendants deny the remaining allegations of paragraph 12.

13. Denied.

14. Defendants admit that CipUSA is the U.S. agent for CL for regulatory submissions to the FDA, but deny the remaining allegations of paragraph 14.

15. Admitted.

16. Defendants admit that CL, through its U.S. agent, CipUSA, submitted to the FDA and seeks FDA approval of ANDA No. 211085. Defendants deny the remaining allegations of paragraph 16.

17. Defendants are without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 17 since they relate to speculative future events, and therefore deny them.

18. Defendants admit that CipUSA markets, distributes, offers for sale and/or sells generic drugs in the U.S. market, including in the State of Delaware. Defendants are without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 18 since they relate to speculative future events, and therefore deny them.

JURISDICTION AND VENUE

19. Paragraph 19 states a legal conclusion to which no response is required. To the extent an answer is required, Defendants admit that the Complaint purports to plead an action arising under the Patent Laws of the United States, including 35 U.S.C. § 271, and purports to allege infringement of the ’630 Patent. Defendants deny the remaining allegations of paragraph 19.

20. Paragraph 20 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that the district courts, including this Court, have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States and arising under any Act of Congress relating to patents. Defendants deny the remaining allegations of paragraph 20.

21. Defendants admit that this Court has personal jurisdiction over CipUSA. Although this Court does not have general or specific jurisdiction over CL in this matter, without waiver of any rights, CL agrees to submit to the personal jurisdiction of this Court for the limited

purpose of this Action involving ANDA 211085, and the '630 Patent. Defendants deny the remaining allegations of paragraph 21.

22. Defendants admit that it previously stated in *H. Lundbeck A/S et al v. Cipla Limited et al*, 18-cv-00147-LPS, D.I. 11 (D. Del April 2, 2018) that this Court has personal jurisdiction over CipUSA and CL agrees to submit to the personal jurisdiction of this Court for the limited purpose of this Action involving ANDA 211085 and the '630 Patent. Defendants deny the remaining allegations of paragraph 22.

23. Admitted.

24. Defendants admit that CipUSA is in the business of marketing, importing, distributing and selling pharmaceutical drug products, including generic drug products, in the United States. Defendants admit that CL is in the business of manufacturing generic drug products. Defendants deny the remaining allegations of paragraph 24.

25. Defendants admit that they directly or indirectly sell generic pharmaceutical products in the State of Delaware. Defendants deny the remaining allegations of paragraph 25.

26. Defendants admit that CL sent a letter dated December 15, 2017 to Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B) (the "Notice Letter" or "First Notice Letter") and a letter dated April 2, 2018 pursuant to 21 U.S.C. § 355(j)(2)(B) (the "Second Notice Letter") (collectively, the "Notice Letters"). Defendants deny the remaining allegations of paragraph 26.

27. Defendants are without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 27 since they relate to speculative future events, and therefore, deny them.

28. Defendants are without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 28 since they relate to speculative future events, and therefore, deny them.

29. Defendants admit that CL and CipUSA have asserted counterclaims in *H. Lundbeck A/S et al v. Cipla Limited et al,* 18-cv-00147-LPS, D.I. 11 (D. Del April 2, 2018). Defendants admit that this Court has personal jurisdiction over CipUSA. Although this Court does not have general or specific jurisdiction over CL in this matter, without waiver of any rights, CL agrees to submit to the personal jurisdiction of this Court for the limited purpose of this Action involving ANDA 211085, and the '630 Patent. Defendants deny the remaining allegations of paragraph 29.

30. Defendants admit that they are named as defendants, and have asserted counterclaims in the following cases: *Alcon Research, Ltd. v. Cipla Limited et al*, 17-cv-01244, D.I. 9 (D. Del. Dec. 5, 2017); *Biogen International GmbH et al v. Cipla Limited et al*, 17-cv-00851, D.I. 10 (D. Del. Oct. 16, 2017); *Onyx Therapeutics, Inc. v. Cipla Limited et al.*, 1:16-cv-00988, D.I. 15 (D. Del. Jan. 25, 2017); *Amgen Inc. v. Cipla Limited et al.*, 1:16-cv-00880, D.I. 8 (D. Del. Oct. 26, 2016); *Bristol-Myers Squibb Company v. Cipla USA, Inc. et al.*, 1:16-cv-00074, D.I. 8 (D. Del. Mar. 4, 2016). Defendants admit that this Court has personal jurisdiction over CipUSA. Although this Court does not have general or specific jurisdiction over CL in this matter, without waiver of any rights, CL agrees to submit to the personal jurisdiction of this Court for the limited purpose of this Action involving ANDA 211085, and the '630 Patent. Defendants deny the remaining allegations of paragraph 30.

31. Paragraph 31 states a legal conclusion to which no response is required. To the extent a response is required, CL states that it does not contest personal jurisdiction or venue in this jurisdiction for the limited purpose of this Action only.

32. Defendants admit that in *H. Lundbeck A/S et al v. Cipla Limited et al,* 18-cv-00147-LPS, D.I. 11 (D. Del April 2, 2018) they stated that CL does not contest personal jurisdiction or venue in this jurisdiction for the limited purpose of this Action only. Defendants deny the remaining allegations of paragraph 32.

33. Paragraph 30 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

34. Defendants admit that in *H. Lundbeck A/S et al v. Cipla Limited et al,* 18-cv-00147-LPS, D.I. 11 (D. Del April 2, 2018) they admitted that venue is proper in this district for CipUSA pursuant to 28 U.S.C. §§ 1391 and 1400(b). Defendants deny the remaining allegations of paragraph 34.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

35. Admitted.

36. Defendants admit that the FDA approved NDA No. 204447 for treatment of Major Depressive Disorder (MDD). Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 36 of the Complaint, and therefore deny them.

37. Defendants admit that the '630 Patent is listed in the *Orange Book* for NDA No. 204447. Defendants deny the remaining allegations of paragraph 37.

38. Defendants admit that the '630 Patent indicates an issue date of January 9, 2018, and is entitled on its face "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound

with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment." Defendants deny the remaining allegations of paragraph 38.

DEFENDANTS' ANDA NO. 211085

39. Defendants admit that ANDA No. 211085 was submitted to the FDA under 21 U.S.C. §355(j). Defendants deny the remaining allegations of paragraph 39.

40. Admitted.

41. Defendants admit that the Second Notice Letter was sent to Lundbeck and Takeda informing Lundbeck and Takeda that a Paragraph IV certification to the '630 Patent was submitted to FDA in connection with ANDA No. 211085 ("Cipla ANDA"). Defendants deny the remaining allegations of paragraph 41.

42. Defendants admit that ANDA No. 211085 seeks approval for Vortioxetine Hydro bromide tablets, which contain 5 mg, 10 mg, 15 mg, and 20 mg of Vortioxetine Hydrobromide as the active ingredient. The remaining allegations state a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the remaining allegations of paragraph 42.

43. Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 43.

44. Defendants admit that the Second Notice Letter sent to Lundbeck and Takeda did not include an allegation that any claim of the '630 Patent is invalid or unenforceable, and the Second Notice Letter reserved the right to modify or supplement such position and to assert any other arguments or defenses related to noninfringement, invalidity, and/or unenforceability of the '630 Patent, including in the course of any future litigation.

45. Defendants admit the proposed labeling in the Cipla ANDA recites treatment of major depressive disorder. Defendants lack knowledge or information sufficient to form a belief

as to the truth of the remaining allegations contained in paragraph 45 of the Complaint, and therefore deny them.

46. Defendants deny that its ANDA Products will infringe the ’630 Patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 46 since they relate to speculative future events, and therefore, deny them.

47. Denied.

48. Defendants admit that the Complaint was filed within 45 days of Lundbeck’s and Takeda’s receipt of Defendant’s Second Notice Letter. The remaining allegations of paragraph 48 state legal conclusions, to which no answer is required. To the extent a response is required, Defendants deny the remaining allegations of paragraph 48.

CLAIM FOR RELIEF

49. Defendants incorporate by reference its responses to paragraphs 1-48 of the Complaint as if fully set forth herein.

50. Defendants admit that CL, through its U.S. agent, CipUSA, submitted to the FDA and seeks FDA approval of ANDA No. 211085. Defendants deny the remaining allegations of paragraph 50.

51. Defendants admit that CL, through its U.S. agent, CipUSA, submitted to the FDA a Paragraph IV certification for the ’630 Patent in ANDA No. 211085. Defendants deny the remaining allegations of paragraph 51.

52. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 52 of the Complaint, and therefore deny them.

53. Paragraph 53 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 53.

54. Defendants admit that the Second Notice Letter sent to Lundbeck and Takeda did not include an allegation that any claim of the '630 Patent is invalid or unenforceable, and reserved the right to modify or supplement its position and to assert any other arguments or defenses related to noninfringement, invalidity, and/or unenforceability of the '630 Patent, including in the course of any future litigation. The remaining allegations of paragraph 54 state legal conclusions, to which no answer is required. To the extent a response is required, Defendants deny the allegations of paragraph 54.

55. Defendants admit the current proposed labeling in ANDA No. 211085 recites treatment of major depressive disorder. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 55 of the Complaint, and therefore deny them.

56. Paragraph 56 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 56.

57. Paragraph 57 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 57.

58. The allegations in paragraph 58 state legal conclusions to which no answer is required. Defendants are without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 58 since they relate to speculative future events, and therefore deny them.

59. Defendants admit knowledge of the '630 Patent. The remaining allegations in paragraph 59 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations of paragraph 59.

60. Paragraph 60 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 60.

61. Paragraph 61 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 61

62. Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of paragraph 62.

ANSWER TO REQUEST FOR RELIEF

Defendants deny that Plaintiffs are entitled to any relief in this action as requested in paragraphs A-I of Plaintiffs' Complaint or otherwise.

Defendants deny each and every other allegation in Plaintiffs' Complaint not heretofore expressly admitted herein.

ADDITIONAL DEFENSES

Defendants allege and assert the following additional defenses in response to the allegations contained in Plaintiffs' Complaint. The inclusion of a defense among the below-listed additional defenses is not an admission that Defendants bear the burden of proof or persuasion on any claim or issue.

FIRST ADDITIONAL DEFENSE
Failure To State A Claim Upon Which Relief Can Be Granted

Each of Plaintiffs' allegations pertaining to infringement of the '630 Patent under 35 U.S.C. § 271 fails to state a claim upon which relief can be granted.

SECOND ADDITIONAL DEFENSE
Invalidity Of The '630 Patent

The claims of the '630 Patent are invalid under one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101 *et seq*.

THIRD ADDITIONAL DEFENSE
Noninfringement Of The '630 Patent

The manufacture, use, offer for sale, sale, marketing, or importation into the United States of the products described in the Cipla ANDA No. 211085 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '630 Patent.

FOURTH ADDITIONAL DEFENSE
Not An Exceptional Case

Defendant's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL DEFENSES

Defendants reserve the right to add additional defenses pending further investigation and discovery.

COUNTERCLAIMS FOR DECLARATORY JUDGEMENT

Defendants-Counterclaim Plaintiffs Cipla Limited ("CL") and Cipla USA Inc. ("CipUSA") (collectively "Counterclaim Plaintiffs"), by its attorneys, hereby states their counterclaims for declaratory relief against Plaintiff-Counterclaim Defendants H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Counterclaim Defendants"), as follows:

1. These Counterclaims seek, *inter alia*, a judgment declaring that the claims of U.S. Patent No. 9,861,630 ("the '630 Patent" or "the Patent-in-Suit") are not infringed by Counterclaim Plaintiffs.

THE PARTIES

2. CL is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

3. CipUSA is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, Florida 33323.

4. Upon information and belief, Counterclaim Defendant H. Lundbeck A/S ("Lundbeck") is incorporated and exists under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

5. Upon information and belief, Counterclaim Defendant Takeda Pharmaceutical Company Ltd. is incorporated and exists under the laws of Japan, with a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka 540-8645, Japan.

6. Upon information and belief, Counterclaim Defendant Takeda Pharmaceutical International AG is incorporated and exists under the laws of Switzerland, with a principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland.

7. Upon information and belief, Counterclaim Defendant Takeda Pharmaceutical U.S.A. is incorporated and exists under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

8. Upon information and belief, Counterclaim Defendant Takeda Pharmaceutical America, Inc. is incorporated and exists under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

NATURE OF THE ACTION

9. These Counterclaims arise 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. Counterclaim Plaintiffs seek a declaration that the '630 Patent is not and will not be infringed by the product described in Counterclaim Plaintiffs ANDA No. 211085.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over the counterclaims asserted herein pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. On May 17, 2018, Counterclaim Defendants filed a complaint for patent infringement in this Court, alleging that Counterclaim Plaintiffs infringe the '630 Patent, which is listed in the U.S. Food & Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("*Orange Book*") for TRINTELLIX®. By filing this Complaint, Counterclaim Defendants have consented to the personal jurisdiction of this Court.

12. Upon information and belief, Counterclaim Defendants regularly conduct business in this district.

13. Upon information and belief, and based upon Counterclaim Defendants' allegations in their Complaint, at least Takeda U.S.A. and Takeda America are corporations organized and existing under the laws of the State of Delaware.

14. Venue is proper in this judicial district based on 28 U.S.C. §§ 1400(a) and/or 1391(b), (c), and (d).

BACKGROUND

15. According to the *Orange Book*, Takeda U.S.A. is identified as the applicant of NDA No. N204447 for TRINTELLIX® Tablets.

16. Upon information and belief, and based on Counterclaim Defendants' allegations in their Complaint, the '630 Patent covers TRINTELLIX® Tablets, and that a claim of infringement has been made under the '630 Patent as it is listed in the *Orange Book* pursuant to 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53.

17. The '630 Patent, on its face, is titled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment" and displays an issue date of January 9, 2018.

18. Upon information and belief, and based on the Counterclaim Defendants' allegations in their Complaint, Lundbeck is the assignee and owner of the '630 Patent.

19. Upon information and belief, and based on the Counterclaim Defendants' allegations in their Complaint, Takeda Japan was granted an exclusive license to the '630 Patent.

20. Upon information and belief, and based on the Counterclaim Defendants' allegations in their Complaint, Takeda International has an exclusive sublicense from Takeda Japan to the '630 Patent.

21. Upon information and belief, and based on the Counterclaim Defendants' allegations in their Complaint, Takeda USA has an exclusive sublicense from Takeda International to the '630 Patent.

22. CL submitted an ANDA ("Cipla ANDA"), which seeks approval from the FDA for Vortioxetine Hydrobromide tablets, which contain 5 mg, 10 mg, 15 mg, and 20 mg of Vortioxetine Hydrobromide, the active ingredient related to TRINTELLIX® Tablets.

23. The FDA assigned the Cipla ANDA the application number 211085.

24. In its letter of April 2, 2018, CL provided notice to Counterclaim Defendants that it certified to the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. §

314.94(a)(12)(i)(A)(4) ("Paragraph IV Certification") that the '630 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in the Cipla ANDA.

25. In its letter of April 2, 2018, CL also included a detailed statement of its factual and legal bases for its Paragraph IV Certification.

26. CL's letter of April 2, 2018 also included an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95.

27. On May 17, 2018, Counterclaim Defendants filed a complaint in this judicial district alleging that the Cipla ANDA and products that would be manufactured thereunder ("Cipla ANDA Products"), infringe the '630 Patent.

CLAIM FOR RELIEF
Declaration Of Noninfringement Of The Patent-in-Suit

28. All of the foregoing allegations are restated and incorporated by reference as though fully set forth herein.

29. The manufacture, use, offer for sale, sale, marketing, or importation into the United States of the Cipla ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '630 Patent.

30. A definite and concrete, real and substantial, justiciable controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants concerning the alleged infringement by the Cipla ANDA Products of the '630 Patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

31. Pursuant to 28 U.S.C. §§ 2201-2202 and Federal Rule of Civil Procedure 57, Counterclaim Plaintiffs are entitled to a declaratory judgment that the Cipla ANDA Products do not infringe, and will not infringe, any valid and enforceable claim of the '630 Patent.

RELIEF REQUESTED

WHEREFORE, Counterclaim Plaintiffs requests the following relief:

A. An order dismissing Plaintiff's Complaint with prejudice, denying any relief requested by Plaintiffs, and granting Counterclaim Plaintiffs' additional defenses and counterclaims;

B. An order declaring all claims of the '630 Patent invalid;

C. An order declaring all claims of the '630 Patent not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, offer for sale, sale, marketing, or importation into the United States the Cipla ANDA Products;

D. An order declaring that Counterclaim Plaintiffs have the right to obtain FDA approval for the Cipla ANDA Products and to manufacture, use, offer to sell, sell, and/or import into the United States the Cipla ANDA Products.

E. An injunction preventing Plaintiffs and Counterclaim Defendants and/or any of their successors and attorneys, and all persons in active concert or participation with any of them, from directly or indirectly asserting infringement against, or instituting any further action for infringement of the '630 Patent against Counterclaim Plaintiffs, or any of its customers, agents, successors, and assigns;

F. An award to Counterclaim Plaintiffs of reasonable attorney fees and costs pursuant to 35 U.S.C. § 285, Fed. R. Civ. P. 11, and/or other applicable law;

G. Assessing the costs of this action against Counterclaim Defendants; and

H. Such other and further relief that this Court deems just and proper.

DATED: June 5, 2018

Of Counsel:

William L. Mentlik
Tedd W. Van Burskirk
Aaron S. Eckenthal
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, NJ 07090-1497
Tel: 908.654.5000
Fax: 908.654.7866
wmentlik@lernerdavid.com
tvanburskirk@lernerdavid.com
aeckenthal@lernerdavid.com

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

Karen L. Pascale (#2903)
Robert M. Vrana (# 5666)
Rodney Square
1000 North King Street
Wilmington, Delaware 19801
(302) 571-6600
kpascale@ycst.com
rvrana@ycst.com

Attorneys for Defendants Cipla Limited and Cipla USA Inc.

CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on June 5, 2018, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served upon the following counsel of record by e-mail:

For Plaintiffs:

Jack B. Blumenfeld — jblumenfeld@mnat.com
Maryellen Noreika — mnoreika@mnat.com
Megan Elizabeth Dellinger — mdellinger@mnat.com
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

George F. Pappas — gpappas@cov.com
Einar Stole — estole@cov.com
Christopher N. Sipes — csipes@cov.com
Brianne Bharkhda — bbharkhda@cov.com
Priscilla G. Dodson — pdodson@cov.com
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956

Yiye Fu — yfu@cov.com
COVINGTON & BURLING LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065-1418

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Karen L. Pascale

June 5, 2018

Karen L. Pascale (#2903) [kpascale@ycst.com]
Robert M. Vrana (# 5666) [rvrana@ycst.com]
Rodney Square
1000 North King Street
Wilmington, DE 19801
Telephone: (302) 571-6600
Attorneys for Defendants Cipla Limited and Cipla USA Inc.