

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

CYDEX PHARMACEUTICALS, INC.,

Plaintiff,

v.

LUPIN LIMITED and  
LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 19-cv-02043-LPS

**LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.’S ANSWER,  
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF’S COMPLAINT**

Defendants Lupin Limited (“Lupin Ltd.”) and Lupin Pharmaceuticals, Inc. (collectively, “Defendants”), by and through their counsel, hereby answer and respond to each of the allegations in the Complaint of Plaintiff CyDex Pharmaceuticals, Inc. (“Plaintiff”) (D.I. 1), and assert their separate defenses, and Lupin Ltd. asserts its separate counterclaims, as follows. Defendants deny all allegations not expressly admitted herein.

**NATURE OF THE ACTION**

1. Paragraph 1 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the Complaint purports to state claims for infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Defendants further admit that Lupin Ltd. submitted Abbreviated New Drug Application (“ANDA”) No. 213569 (hereinafter, “the Lupin ANDA”) with the U.S Food and Drug

Administration (“FDA”) seeking approval for Melphalan HCl for Injection, 50 mg/vial. Defendants 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 of Paragraph 2, and therefore deny them.

3. Defendants admit that Lupin Ltd. is an entity organized and existing under the laws of India, with a place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz East, Mumbai – 400055, India.

4. Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants further admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation with a place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action.

5. Paragraph 5 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 5.

6. Paragraph 6 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is

an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 6.

### **JURISDICTION AND VENUE**

7. Paragraph 7 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the Complaint purports to state claims for infringement under the patent laws of the United States, including 35 U.S.C. § 101, et seq. and § 271. Defendants deny that the Complaint states a proper claim for infringement and/or that such claim has any merit. Defendants admit that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2). Defendants do not contest venue over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 7.

8. Paragraph 8 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest venue over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 8.

9. Paragraph 9 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 9.

10. Paragraph 10 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal

jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 10.

11. Paragraph 11 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 11.

12. Paragraph 12 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 12.

13. Paragraph 13 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 13.

#### **THE PATENTS-IN-SUIT**

14. Defendants admit that Plaintiff purports to attach a copy of the '088 Patent to the Complaint as Exhibit A. Defendants admit that the face of the '088 Patent states that it issued on December 1, 2015. Defendants further admit that the '088 Patent is titled "Sulfoalkyl Ether Cyclodextrin Compositions." Defendants deny any remaining allegations of Paragraph 14, including any suggestion or implication that the '088 patent was duly and legally issued or is valid or enforceable.

15. Defendants admit that Plaintiff purports to attach a copy of the '582 Patent to the Complaint as Exhibit B. Defendants admit that the face of the '582 Patent states that it issued on

November 15, 2016. Defendants further admit that the '582 Patent is titled "Alkylated Cyclodextrin Compositions and Processes for Preparing and Using the Same." Defendants deny any remaining allegations of Paragraph 15, including any suggestion or implication that the '582 patent was duly and legally issued or is valid or enforceable.

16. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 16, and therefore deny them.

**EVOMELA®**

17. Upon information and belief, Defendants admit that the patents-in-suit are listed in the Orange Book as purportedly associated with EVOMELA®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 17, and therefore deny them.

**THE LUPIN ANDA**

18. Defendants admit that Lupin Ltd. sent a Notice Letter dated September 13, 2019 to Acrotech Biopharma, LLC and CyDex Pharmaceuticals, Inc. that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 213569 to the FDA seeking approval for its proposed Melphalan HCl for Injection; 50mg, which contained Paragraph IV certifications to U.S. Patent Nos. 8,410,077; 9,200,088; 9,493,582; and 10,040,872. Defendants state that the Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 18 to the extent they deviate from or otherwise do not accurately reflect or describe the Notice Letter or Lupin Ltd.'s proposed Melphalan HCl for Injection; 50 mg/vial. Defendants deny the remaining allegations of Paragraph 18.

19. Defendants admit that Lupin Ltd. sent a Notice Letter dated September 13, 2019 to Acrotech Biopharma, LLC and CyDex Pharmaceuticals, Inc. that notified them that Lupin Ltd., as

the sole applicant, submitted ANDA No. 213569 to the FDA seeking approval for its proposed Melphalan HCl for Injection; 50 mg/vial. Defendants deny the remaining allegations of Paragraph 19.

20. Paragraph 20 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. as the sole applicant, submitted ANDA No. 213569 to the FDA seeking approval for its proposed Melphalan HCl for Injection; 50 mg/vial, prior to the expiration of U.S. Patent Nos. 8,410,077; 9,200,088; 9,493,582; and 10,040,872. Defendants deny any remaining allegations of Paragraph 20.

21. Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 213569 to the FDA seeking approval for its proposed Melphalan HCl for Injection; 50 mg/vial. Defendants further state that ANDA No. 213569 speaks for itself. Defendants deny any remaining allegations of Paragraph 21.

**COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,200,088**

22. Defendants reassert and incorporate by reference their responses to paragraphs 1-21 in full herein.

23. Defendants deny the allegations of Paragraph 23.

24. Defendants deny the allegations of Paragraph 24.

25. Defendants deny the allegations of Paragraph 25.

26. Defendants deny the allegations of Paragraph 26.

27. Defendants deny the allegations of Paragraph 27.

28. Paragraph 28 states legal conclusions and allegations to which no answer is

required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 28.

29. Defendants deny the allegations of Paragraph 29.

**COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,493,582**

30. Defendants reassert and incorporate by reference their responses to paragraphs 1-29 in full herein.

31. Defendants deny the allegations of Paragraph 31.

32. Defendants deny the allegations of Paragraph 32.

33. Defendants deny the allegations of Paragraph 33.

34. Defendants deny the allegations of Paragraph 34.

35. Defendants deny the allegations of Paragraph 35.

36. Paragraph 36 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants deny the allegations of Paragraph 36.

37. Defendants deny the allegations of Paragraph 37.

**EXCEPTIONAL CASE**

38. Defendants deny the allegations of Paragraph 38.

**INJUNCTIVE RELIEF**

39. Defendants deny the allegations of Paragraph 39.

40. Defendants deny the allegations of Paragraph 40.

**RESPONSE TO PRAYER FOR RELIEF**

All remaining allegations not specifically admitted herein are denied. Defendants further deny that Plaintiff is entitled to any judgment or relief against Defendants and, therefore, specifically deny paragraphs A through K of Plaintiff's Prayer for Relief.

**GENERAL DENIAL**

Defendants deny all remaining allegations not specifically admitted herein. Defendants further deny that Plaintiff is entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever. Defendants respectfully request that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Defendants; (c) award Defendants the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Defendants such further relief as the Court deems just and appropriate.

**DEFENDANTS' AFFIRMATIVE DEFENSES**

Without prejudice to the responses and denials set forth in Defendants' Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff, Defendants assert the following separate defenses to the Complaint:

**First Affirmative Defense**

**(Failure to State a Claim)**

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

**Second Affirmative Defense**

**(Invalidity of the '088 Patent)**

The claims of the '088 Patent are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).



**Third Affirmative Defense**

**(Noninfringement of the '088 Patent)**

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '088 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Lupin Ltd.'s ANDA No. 213569 does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '088 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

**Fourth Affirmative Defense**

**(Invalidity of the '582 Patent)**

The claims of the '582 Patent are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

**Fifth Affirmative Defense**

**(Noninfringement of the '582 Patent)**

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '582 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Lupin Ltd.'s ANDA No. 213569 does not, has not, and will not infringe, literally or under the doctrine

of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '582 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

**Sixth Affirmative Defense**  
**(Prosecution History Estoppel)**

Plaintiff's cause of action is barred, in whole or in part, by the doctrine of prosecution history estoppel.

**Seventh Affirmative Defense**  
**(Limitation of Remedies)**

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit. The remedy of an injunction or other equitable relief sought by Plaintiff in the Complaint is unavailable to Plaintiff in this action.

**Eighth Affirmative Defense**  
**(Improper Party)**

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

**Ninth Affirmative Defense**  
**(Lack of Subject Matter Jurisdiction)**

This Court lacks subject matter jurisdiction over any and all claims asserted against Lupin Pharmaceuticals, Inc. and any and all claims asserted under 35 U.S.C. § 271(a), (b) or (c).

**Tenth Affirmative Defense**  
**(Failure to State a Claim for Exceptional Case and/or Willful Infringement)**

The Complaint fails to state a claim for exceptional case and/or willful infringement under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4).

### **Reservation of Rights**

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiff's Complaint, including, but not limited to, supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

### **COUNTERCLAIMS BY LUPIN LTD.**

Counterclaim-Plaintiff Lupin Ltd., for its Counterclaims against Plaintiff/Counterclaim Defendant CyDex Pharmaceuticals, Inc. ("CyDex"), allege as follows:

1. This is a counterclaim action for declaratory judgment of noninfringement and/or invalidity of one or more claims of U.S. Patent Nos. 8,410,077 ("the '077 patent"); 9,200,088 ("the '088 patent"); 9,493,582 ("the '582 patent"); and 10,040,872 ("the '872 patent").

### **THE PARTIES**

2. Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz East, Mumbai – 400055, India.

3. On information and belief, and based on the allegations in the Complaint, CyDex Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 3911 Sorrento Valley Boulevard, Suite 110, San Diego, CA 92121, and is the assignee and owner of the '077, '088, '582, and '872 patents.

### **JURISDICTION AND VENUE**

4. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

5. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271(e)(2).

6. This is an action based on an actual controversy between Lupin Ltd. and CyDex concerning the noninfringement and/or invalidity of the '077, '088, '582, and '872 patents arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and Lupin Ltd.'s right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 213569, and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the Melphalan HCl for Injection, 50 mg/vial that is the subject of Lupin Ltd.'s ANDA No. 213569 ("Lupin Ltd.'s ANDA Product").

7. The Court has personal jurisdiction over CyDex because, on information and belief, CyDex transacts business within the State of Delaware and/or has engaged in systematic and continuous business contacts within the State of Delaware. Further, CyDex has subjected itself to the jurisdiction of this Court by virtue of filing its Complaint.

8. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by CyDex's choice of forum.

### **BACKGROUND**

9. On information and belief, on or about April 2, 2013, the United States Patent and Trademark Office ("USPTO") issued the '077 patent, titled "Sulfoalkyl Ether Cyclodextrin Compositions." The '077 patent is attached as Exhibit A to Lupin Ltd.'s Answer and Counterclaims.

10. On information and belief, on or about December 1, 2015, the USPTO issued the '088 patent, titled "Sulfoalkyl Ether Cyclodextrin Compositions." The '088 patent is attached as Exhibit A to the Complaint.

11. On information and belief, on or about November 15, 2016, the USPTO issued the '582 patent, titled "Alkylated Cyclodextrin Compositions and Processes for Preparing and Using the Same." The '582 patent is attached as Exhibit B to the Complaint.

12. On information and belief, on or about August 7, 2018, the USPTO issued the '872 patent, titled "Alkylated Cyclodextrin Compositions and Processes for Preparing and Using the Same." The '872 patent is attached as Exhibit B to Lupin Ltd.'s Answer and Counterclaims.

13. On information and belief, the '077, '088, '582, and '872 patents are assigned to and owned by CyDex.

14. On information and belief, and according to the United States Food and Drugs Administration (FDA) publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"), CyDex caused the FDA to list the '077, '088, '582, and '872 patents in the Orange Book in connection with NDA No. 207155.

15. By maintaining the listing of the '077, '088, '582, and '872 patents in the Orange Book, CyDex represents that a claim of infringement of the '077, '088, '582, and '872 patents "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(G).

16. On information and belief, CyDex has not caused the FDA to remove the '077, '088, '582, and '872 patents from the Orange Book in connection with NDA No. 207155.

17. By Notice Letter dated September 13, 2019 (hereinafter, "Lupin Ltd.'s Notice Letter"), Lupin Ltd. timely notified CyDex that it had submitted ANDA No. 213569 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '077, '088, '582, and '872 patents. Lupin Ltd.'s Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Lupin Ltd.'s opinion that the claims of the '077, '088, '582, and '872 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or

importation of Lupin Ltd.'s ANDA Product. Lupin Ltd. incorporates by reference its Notice Letter.

18. On October 29, 2019, CyDex filed an infringement action against Lupin Ltd. alleging infringement of the '088 and '582 patents. CyDex did not file an infringement action against Lupin Ltd. alleging infringement of the '077 and '872 patents within 45 days of receipt of Lupin Ltd.'s notice of paragraph IV certification. In its Notice Letter, Lupin Ltd. granted CyDex an Offer of Confidential Access to Lupin Ltd.'s ANDA No. 213569 for the purpose of CyDex making a determination of whether an infringement action could be brought with respect to the '077, '088, '582, and '872 patents. As such, Lupin Ltd. is statutorily entitled to institute—and this Court has constitutional authority to adjudicate—a declaratory judgment action against CyDex for the '077, '088, '582 and '872 patents. 35 U.S.C. § 271(e)(5).

19. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Lupin Ltd. and CyDex having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the '077, '088, '582, and '872 patents, and as to Lupin Ltd.'s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product.

**COUNT I**  
**Declaratory Judgment of Noninfringement of the '077 Patent**

20. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-19 of its Counterclaims.

21. There is an actual, substantial, and continuing justiciable case or controversy between Lupin Ltd. and CyDex regarding, *inter alia*, non-infringement of the '077 patent.

22. Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '077 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

23. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '077 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

24. Lupin Ltd.'s ANDA Product will not infringe any valid and/or enforceable claim of the '077 patent, at least because Lupin Ltd.'s ANDA Product does not satisfy the claims of the '077 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

25. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '077 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

**COUNT II**  
**Declaratory Judgment of Invalidity of the '077 Patent**

26. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-25 of its Counterclaims.

27. The claims of the '077 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other

judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

28. The '077 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

29. The alleged invention of the '077 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '077 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '077 patent and would have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

30. The claims of the '077 patent are invalid at least under 35 U.S.C. § 102 based on the on-sale bar.

31. The claims of the '077 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: US Patent No. 6,153,746; Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Edition, 1986; International Publication No. WO 2006/071491 A1. The differences between the subject matter claimed in the '077 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having



knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

32. Lupin Ltd. is entitled to a judicial declaration that the claims of the '077 patent are invalid.

**COUNT III**  
**Declaratory Judgment of Noninfringement of the '088 Patent**

33. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-32 of its Counterclaims.

34. CyDex has accused Lupin Ltd. of infringing claims of the '088 patent in connection with ANDA No. 213569.

35. Lupin Ltd. denies infringement of any valid, enforceable, properly construed claim of the '088 patent and alleges that Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '088 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

36. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '088 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

37. Lupin Ltd.'s ANDA Product will not infringe any valid and/or enforceable claim of the '088 patent, at least because Lupin Ltd.'s ANDA Product does not satisfy the claims of the '088 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

38. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '088 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

**COUNT IV**  
**Declaratory Judgment of Invalidity of the '088 Patent**

39. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-38 of its Counterclaims.

40. The claims of the '088 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

41. The '088 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

42. The alleged invention of the '088 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '088 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '088 patent and would

have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

43. The claims of the '088 patent are invalid at least under 35 U.S.C. § 102 based on the on-sale bar.

44. The claims of the '088 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: US Patent No. 6,153,746; Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Edition, 1986; International Publication No. WO 2006/071491 A1. The differences between the subject matter claimed in the '088 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

45. Lupin Ltd. is entitled to a judicial declaration that the claims of the '088 patent are invalid.

**COUNT V**  
**Declaratory Judgment of Noninfringement of the '582 Patent**

46. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-45 of its Counterclaims.

47. CyDex has accused Lupin Ltd. of infringing claims of the '582 patent in connection with ANDA No. 213569.

48. Lupin Ltd. denies infringement of any valid, enforceable, properly construed claim of the '582 patent and alleges that Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily),

any valid, enforceable, properly construed claim of the '582 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

49. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '582 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

50. Lupin Ltd.'s ANDA Product will not infringe any valid and/or enforceable claim of the '582 patent, at least because Lupin Ltd.'s ANDA Product does not satisfy the claims of the '582 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

51. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '582 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

**COUNT VI**  
**Declaratory Judgment of Invalidity of the '582 Patent**

52. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-51 of its Counterclaims.

53. The claims of the '582 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

54. The '582 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

55. The alleged invention of the '582 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '582 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '582 patent and would have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

56. The claims of the '582 patent are invalid at least under 35 U.S.C. § 102 based on the on-sale bar.

57. The claims of the '582 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: US Patent No. 6,153,746; Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Edition, 1986; International Publication No. WO 2006/071491 A1 and U.S. Patent No. 7,635,773. The differences between the subject matter claimed in the '582 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

58. Lupin Ltd. is entitled to a judicial declaration that the claims of the '582 patent are invalid.

**COUNT VII**  
**Declaratory Judgment of Noninfringement of the '872 Patent**

59. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-58 of its Counterclaims.

60. There is an actual, substantial, and continuing justiciable case or controversy between Lupin Ltd. and CyDex regarding, *inter alia*, non-infringement of the '872 patent.

61. Lupin Ltd. has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '872 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

62. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '872 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

63. Lupin Ltd.'s ANDA Product will not infringe any valid and/or enforceable claim of the '872 patent, at least because Lupin Ltd.'s ANDA Product does not satisfy the claims of the '872 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

64. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed,

infringe any valid and/or enforceable claim of the '872 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

**COUNT VIII**  
**Declaratory Judgment of Invalidity of the '872 Patent**

65. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-64 of its Counterclaims.

66. The claims of the '872 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

67. The '872 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

68. The alleged invention of the '872 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '872 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '872 patent and would have had a reasonable expectation of success in doing so, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Notice Letter.

69. The claims of the '872 patent are invalid at least under 35 U.S.C. § 102 based on the on-sale bar.

70. The claims of the '872 patent are invalid at least under 35 U.S.C. § 103 in view of the prior art, including, but not limited to: US Patent No. 6,153,746; Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Edition, 1986; International Publication No. WO 2006/071491 A1 and U.S. Patent No. 7,635,773. The differences between the subject matter claimed in the '872 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

71. Lupin Ltd. is entitled to a judicial declaration that the claims of the '872 patent are invalid.

### **EXCEPTIONAL CASE**

This case is an exceptional one, and Lupin Ltd. is entitled to an award of its reasonable attorneys' fees, costs and expenses under 35 U.S.C. § 285.

### **PRAYER FOR RELIEF**

WHEREFORE, Lupin Ltd. prays that the Court enter judgment in its favor and against CyDex as follows:

- a) Dismissing the Complaint with prejudice and denying each request for relief made by CyDex therein;
- b) Declaring that the claims of the '077, '088, '582, and '872 patents are invalid;
- c) Declaring that the submission of Lupin Ltd.'s ANDA seeking FDA approval to market the Melphalan HCl for Injection, 50 mg/vial that is the subject of Lupin Ltd.'s ANDA No. 213569 prior to the expiration of the '077, '088, '582, and '872 patents has not infringed and will



not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '077, '088, '582, and '872 patents;

d) Declaring that the manufacture, use, sale, offer for sale, and/or importation of the Melphalan HCl for Injection, 50 mg/vial that is the subject of Lupin Ltd.'s ANDA No. 213569 will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '077, '088, '582, and '872 patents;

e) A declaration that Plaintiff/Counterclaim Defendant is not entitled to injunctive relief;

f) Granting Lupin Ltd. judgment in its favor on CyDex's claims;

g) Granting Lupin Ltd. judgment in its favor on its own Counterclaims;

h) Declaring that this is an exceptional case in favor of Lupin Ltd. pursuant to 35 U.S.C. § 285;

i) Declaring that Lupin Ltd. is the prevailing party and awarding costs, attorneys' fees, and expenses to Lupin Ltd.; and

(j) Awarding Lupin Ltd. such other and further relief to which it may be entitled.

Date: December 11, 2019

**PHILLIPS, GOLDMAN, McLAUGHLIN & HALL, P.A.**

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