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*Lupin Limited and Lupin Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

HORIZON ORPHAN LLC, HORIZON  
THERAPEUTICS USA, INC., and  
THE REGENTS OF THE UNIVERSITY OF  
CALIFORNIA,

Plaintiffs,

v.

LUPIN LIMITED and LUPIN  
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 20-cv-10339-MCA-LDW

*Document Filed Electronically*

**LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.'S  
ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., (collectively, “the Lupin Defendants”) hereby answer the Complaint of Horizon Orphan LLC (“Horizon Orphan”), Horizon

Therapeutics USA, Inc. (“Horizon USA”) (collectively, “Horizon”), and The Regents of the University of California (“UC”) (collectively, “Plaintiffs”), as follows.

### **GENERAL DENIAL**

Pursuant to Federal Rule of Civil Procedure 8(b)(3), the Lupin Defendants deny all allegations in Plaintiffs’ Complaint except those specifically admitted below.

### **THE PARTIES**

1. Horizon Orphan is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

**ANSWER:** Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations and, therefore, deny each and every allegation contained therein.

2. Horizon USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

**ANSWER:** Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations and, therefore, deny each and every allegation contained therein.

3. UC is a California non-profit constitutional corporation and the governing body of an educational institution, having its principal place of business at 1111 Franklin Street, Oakland, California 94607.

**ANSWER:** Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack sufficient knowledge or information

to form a belief as to the truth of the allegations and, therefore, deny each and every allegation contained therein.

4. Upon information and belief, defendant Lupin Ltd. is an Indian company, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India 107.

**ANSWER:** Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited is an Indian corporation having a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. The Lupin Defendants deny all remaining allegations of Paragraph 4.

5. Upon information and belief, LPI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, LPI is a wholly owned subsidiary of Lupin Ltd. and acts as its authorized agent in the United States.

**ANSWER:** Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants 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. The Lupin Defendants further admit that Lupin Pharmaceuticals, Inc. is an indirectly wholly-owned subsidiary of Lupin Limited. The Lupin Defendants deny all remaining allegations of Paragraph 5. The Lupin Defendants further deny that Lupin Pharmaceuticals, Inc. is a proper party to this action.

### **NATURE OF THE ACTION**

6. This is a civil action for infringement of United States Patent No. 8,026,284 (“the ’284 patent”), United States Patent No. 9,192,590 (“the ’590 patent”), United States Patent No. 9,198,882 (“the ’882 patent”), United States Patent No. 9,925,156 (“the ’156 patent”), United States Patent No. 9,925,157 (“the ’157 patent”), United States Patent No. 9,925,158 (“the ’158 patent”), United States Patent No. 9,173,851 (“the ’851 patent”), United States Patent No. 9,233,077 (“the ’077 patent”), United States Patent No. 10,143,665 (“the ’665 patent”), United States Patent No. 10,328,037 (“the ’037 patent”), and United States Patent No. 10,548,859 (“the ’859 patent”)

(collectively, “the patents-in-suit”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

**ANSWER:** Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the Complaint purports to state an action for alleged infringement of United States Patent No. 8,026,284 (“the ‘284 patent”), United States Patent No. 9,192,590 (“the ‘590 patent”), United States Patent No. 9,198,882 (“the ‘882 patent”), United States Patent No. 9,925,156 (“the ‘156 patent”), United States Patent No. 9,925,157 (“the ‘157 patent”), United States Patent No. 9,925,158 (“the ‘158 patent”), United States Patent No. 9,173,851 (“the ‘851 patent”), United States Patent No. 9,233,077 (“the ‘077 patent”), United States Patent No. 10,143,665 (“the ‘665 patent”), United States Patent No. 10,328,037 (“the ‘037 patent”), and United States Patent No. 10,548,859 (“the ‘859 patent”) under 35 U.S.C. §§ 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The Lupin Defendants deny that the Complaint states a proper claim for infringement and/or that such claims have any merit. The Lupin Defendants deny all remaining allegations of Paragraph 6.

### **JURISDICTION AND VENUE**

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

**ANSWER:** Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, the Lupin Defendants do not contest subject matter jurisdiction solely for claims directed against the Lupin Defendants under 35 U.S.C. § 271(e)(2), and solely for the limited purposes of this action only. The Lupin Defendants deny that subject matter jurisdiction is proper for any and all claims under 35 U.S.C. § 271(a), (b) or (c) asserted against any of the Lupin Defendants, and for any and all claims whatsoever asserted against Lupin Pharmaceuticals, Inc. The Lupin Defendants deny all remaining allegations of Paragraph 7.

8. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

**ANSWER:** Paragraph 8 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

9. This Court has personal jurisdiction over Lupin because, *inter alia*, Lupin has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including in New Jersey. Upon information and belief, following approval of Lupin's Abbreviated New Drug Application ("ANDA") No. 214400, Lupin will make, use, import, sell, and/or offer for sale its proposed generic versions of PROCYSBI® brand products in the United States, including in New Jersey, prior to the expiration of the patents-in-suit. This Court has personal jurisdiction over Lupin for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

**ANSWER:** Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

10. This Court also has personal jurisdiction over Lupin by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of the laws of New Jersey by engaging in systematic and continuous contacts with New Jersey. Upon information and belief, LPI, a wholly owned subsidiary of Lupin Ltd., maintains a physical presence in New Jersey with its manufacturing and research and development facility located in New Jersey, and is registered to do business in New Jersey. Upon information and belief, Lupin regularly and continuously transacts business within New Jersey, including by developing, manufacturing, marketing, and selling generic pharmaceutical products. Upon information and belief, Lupin derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

**ANSWER:** Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

11. Upon information and belief, Lupin Ltd. and LPI are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Lupin's proposed product that is the subject of ANDA No. 214400, for which Lupin has sought approval from the FDA.

**ANSWER:** Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

12. Upon information and belief, Lupin Ltd., alone and/or together with its affiliate and agent, LPI, filed or caused to be filed ANDA No. 214400 with the FDA.

**ANSWER:** Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted Abbreviated New Drug Application (“ANDA”) No. 214400 to the U.S. Food and Drug Administration (“FDA”). The Lupin Defendants deny all remaining allegations of Paragraph 12.

13. Upon information and belief, Lupin has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

**ANSWER:** Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

14. This Court also has personal jurisdiction over Lupin Ltd. and LPI because they have previously been sued numerous times in this Judicial District and have not challenged personal jurisdiction, and Lupin Ltd. has purposefully availed itself of the rights and benefits of the jurisdiction of this Court by filing counterclaims in this Judicial District. *See, e.g., Mitsubishi Tanabe Pharma Corp. v. Lupin Ltd.*, Civil Action No. 19-07165, D.I. 8 (D.N.J. Apr. 3, 2019) (Lupin Ltd. not contesting personal jurisdiction or venue and asserting counterclaims); *Sun Pharma Global FZE, et al. v. Lupin Ltd., et al.*, Civil Action No. 18-02213, D.I. 60 (D.N.J. Jan. 29, 2019) (Lupin Ltd. and LPI not contesting personal jurisdiction or venue and Lupin Ltd. asserting counterclaims); *Horizon Therapeutics, Inc. v. Lupin Ltd., et al.*, Civil Action No. 15-07624, D.I. 40 (D.N.J. Apr. 25, 2016) (Lupin Ltd. and LPI not contesting personal jurisdiction or venue and Lupin Ltd. asserting counterclaims); *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 14-00667, D.I. 7 (D.N.J. Mar. 27, 2014) (Lupin Ltd. and LPI not contesting personal jurisdiction or venue and Lupin Ltd. asserting counterclaims).

**ANSWER:** Paragraph 14 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited and/or Lupin Pharmaceuticals, Inc. were named defendants in separate and unrelated Civil Action Nos. 19-07165 (D.N.J.); 18-02213 (D.N.J.); 15-07624 (D.N.J.); and 14-00667 (D.N.J.). In further answering, solely to conserve the resources of the parties and the Court, the Lupin

Defendants do not contest personal jurisdiction in this judicial District for the limited purpose of this action only. The Lupin Defendants deny all remaining allegations of Paragraph 14.

15. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Lupin Ltd. in this action, this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, by submitting various ANDAs to the FDA and manufacturing and selling pharmaceutical products distributed throughout the United States such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

**ANSWER:** Paragraph 15 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, the Lupin Defendants do not contest personal jurisdiction over Lupin Limited in this judicial District solely for the limited purposes of this action only.

16. Venue is proper in this Judicial District as to Lupin pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Lupin has committed and will commit further acts of infringement in this Judicial District. Venue is also proper in this Judicial District as to Lupin because Lupin has a regular and established place of business in New Jersey, and for other reasons that will be presented to the Court if such venue is challenged.

**ANSWER:** Paragraph 16 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, the Lupin Defendants do not contest venue in this judicial District solely for the limited purposes of this action only.

### **THE PATENTS IN SUIT**

17. On September 27, 2011, the '284 patent, titled "Enterically Coated Cystamine, Cysteamine and derivatives thereof," was duly and legally issued. UC is the owner of the '284 patent. A copy of the '284 patent is attached as Exhibit A.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic

records of the United States Patent and Trademark Office (the “USPTO”), the ‘284 patent is titled “ENTERICALLY COATED CYSTAMINE, CYSTEAMINE AND DERIVATIVES THEREOF.” The Lupin Defendants further admit that the electronic records of the USPTO identify “The Regents of the University of California” as a purported “assignee” of the ‘284 patent. The Lupin Defendants deny that the ‘284 patent was “duly and legally issued,” and any suggestion or implication that the ‘284 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the ‘284 patent is attached as Exhibit A to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 17.

18. Horizon is an exclusive licensee of the ‘284 patent.

**ANSWER:** Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the ‘284 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 18.

19. On November 24, 2015, the ‘590 patent, titled “Enterically Coated Cysteamine, Cystamine and derivatives thereof,” was duly and legally issued. UC is the owner of the ‘590 patent. A copy of the ‘590 patent is attached as Exhibit B.

**ANSWER:** Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the ‘590 patent is titled “ENTERICALLY COATED CYSTEAMINE, CYSTAMINE AND DERIVATIVES THEREOF.” The Lupin Defendants further admit that the electronic records of the USPTO identify “The Regents of the University of California” as a purported “assignee” of the ‘590 patent. The Lupin Defendants deny that the ‘590 patent was “duly and legally issued,” and any suggestion or implication that the ‘590 patent is valid or

enforceable. The Lupin Defendants also admit that a purported copy of the '590 patent is attached as Exhibit B to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 19.

20. Horizon is an exclusive licensee of the '590 patent.

**ANSWER:** Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '590 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 20.

21. On December 1, 2015, the '882 patent, titled "Enterically Coated Cysteamine, Cystamine and derivatives thereof," was duly and legally issued. UC is the owner of the '882 patent. A copy of the '882 patent is attached as Exhibit C.

**ANSWER:** Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '882 patent is titled "ENTERICALLY COATED CYSTEAMINE, CYSTAMINE AND DERIVATIVES THEREOF." The Lupin Defendants further admit that the electronic records of the USPTO identify "The Regents of the University of California" as a purported "assignee" of the '882 patent. The Lupin Defendants deny that the '882 patent was "duly and legally issued," and any suggestion or implication that the '882 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the '882 patent is attached as Exhibit C to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 21.

22. Horizon is an exclusive licensee of the '882 patent.

**ANSWER:** Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '882 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 22.

23. On March 27, 2018, the '156 patent, titled "Enterically Coated Cysteamine, Cystamine and derivatives thereof," was duly and legally issued. UC is the owner of the '156 patent. A copy of the '156 patent is attached as Exhibit D.

**ANSWER:** Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '156 patent is titled "ENTERICALLY COATED CYSTEAMINE, CYSTAMINE AND DERIVATIVES THEREOF." The Lupin Defendants further admit that the electronic records of the USPTO identify "The Regents of the University of California" as a purported "assignee" of the '156 patent. The Lupin Defendants deny that the '156 patent was "duly and legally issued," and any suggestion or implication that the '156 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the '156 patent is attached as Exhibit D to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 23.

24. Horizon is an exclusive licensee of the '156 patent.

**ANSWER:** Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '156 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 24.

25. On March 27, 2018, the '157 patent, titled "Enterically Coated Cysteamine, Cystamine and derivatives thereof," was duly and legally issued. UC is the owner of the '157 patent. A copy of the '157 patent is attached as Exhibit E.

**ANSWER:** Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '157 patent is titled "ENTERICALLY COATED CYSTEAMINE, CYSTAMINE AND DERIVATIVES THEREOF." The Lupin Defendants further admit that the electronic records of the USPTO identify "The Regents of the University of California" as a purported "assignee" of the '157 patent. The Lupin Defendants deny that the '157 patent was "duly and legally issued," and any suggestion or implication that the '157 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the '157 patent is attached as Exhibit E to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 25.

26. Horizon is an exclusive licensee of the '157 patent.

**ANSWER:** Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '157 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 26.

27. On March 27, 2018, the '158 patent, titled "Enterically Coated Cysteamine, Cystamine and derivatives thereof," was duly and legally issued. UC is the owner of the '158 patent. A copy of the '158 patent is attached as Exhibit F.

**ANSWER:** Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '158 patent is titled "ENTERICALLY COATED CYSTEAMINE,

CYSTAMINE AND DERIVATIVES THEREOF.” The Lupin Defendants further admit that the electronic records of the USPTO identify “The Regents of the University of California” as a purported “assignee” of the ‘158 patent. The Lupin Defendants deny that the ‘158 patent was “duly and legally issued,” and any suggestion or implication that the ‘158 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the ‘158 patent is attached as Exhibit F to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 27.

28. Horizon is an exclusive licensee of the ‘158 patent.

**ANSWER:** Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the ‘158 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 28.

29. On November 3, 2015, the ‘851 patent, titled “Delayed Release Cysteamine Bead Formulation, and Methods of Making and Using Same,” was duly and legally issued. Horizon Orphan and UC are co-owners of the ‘851 patent. A copy of the ‘851 patent is attached as Exhibit G.

**ANSWER:** Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the ‘851 patent is titled “DELAYED RELEASE CYSTEAMINE BEAD FORMULATION, AND METHODS OF MAKING AND USING SAME.” The Lupin Defendants further admit that the electronic records of the USPTO identify “Horizon Orphan LLC” and “The Regents of the University of California” as purported “co-assignees” of the ‘851 patent. The Lupin Defendants deny that the ‘851 patent was “duly and legally issued,” and any suggestion or implication that the ‘851 patent is valid or enforceable. The Lupin Defendants also admit that

a purported copy of the '851 patent is attached as Exhibit G to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 29.

30. Horizon USA is an exclusive licensee of the '851 patent.

**ANSWER:** Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '851 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 30.

31. On January 12, 2016, the '077 patent, titled "Delayed Release Cysteamine Bead Formulation, and Methods of Making and Using Same," was duly and legally issued. Horizon Orphan and UC are co-owners of the '077 patent. A copy of the '077 patent is attached as Exhibit H.

**ANSWER:** Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '077 patent is titled "DELAYED RELEASE CYSTEAMINE BEAD FORMULATION, AND METHODS OF MAKING AND USING SAME." The Lupin Defendants further admit that the electronic records of the USPTO identify "Horizon Orphan LLC" and "The Regents of the University of California" as purported "co-assignees" of the '077 patent. The Lupin Defendants deny that the '077 patent was "duly and legally issued," and any suggestion or implication that the '077 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the '077 patent is attached as Exhibit H to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 31.

32. Horizon USA is an exclusive licensee of the '077 patent.

**ANSWER:** Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '077 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 32.

33. On December 4, 2018, the '665 patent, titled "Methods for Storing Cysteamine Formulations and Related Methods of Treatment," was duly and legally issued. Horizon Orphan is the owner of the '665 patent. A copy of the '665 patent is attached as Exhibit I.

**ANSWER:** Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '665 patent is titled "METHODS FOR STORING CYSTEAMINE FORMULATIONS AND RELATED METHODS OF TREATMENT." The Lupin Defendants further admit that the electronic records of the USPTO identify "Horizon Orphan LLC" as a purported "assignee" of the '665 patent. The Lupin Defendants deny that the '665 patent was "duly and legally issued," and any suggestion or implication that the '665 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the '665 patent is attached as Exhibit I to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 33.

34. Horizon USA is the exclusive licensee of the '665 patent.

**ANSWER:** Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '665 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 34.

35. On June 25, 2019, the '037 patent, titled "Methods for Storing Cysteamine Formulations and Related Methods of Treatment," was duly and legally issued. Horizon Orphan is the owner of the '037 patent. A copy of the '037 patent is attached as Exhibit J.

**ANSWER:** Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '037 patent is titled "METHODS FOR STORING CYSTEAMINE FORMULATIONS AND RELATED METHODS OF TREATMENT." The Lupin Defendants further admit that the electronic records of the USPTO identify "Horizon Orphan LLC" as a purported "assignee" of the '037 patent. The Lupin Defendants deny that the '037 patent was "duly and legally issued," and any suggestion or implication that the '037 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the '037 patent is attached as Exhibit J to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 35.

36. Horizon USA is the exclusive licensee of the '037 patent.

**ANSWER:** Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the '037 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 36.

37. On February 4, 2020, the '859 patent, titled "Methods for Storing Cysteamine Formulations and Related Methods of Treatment," was duly and legally issued. Horizon Orphan is the owner of the '859 patent. A copy of the '859 patent is attached as Exhibit K.

**ANSWER:** Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, according to the electronic records of the USPTO, the '859 patent is titled "METHODS FOR STORING CYSTEAMINE

FORMULATIONS AND RELATED METHODS OF TREATMENT.” The Lupin Defendants further admit that the electronic records of the USPTO identify “Horizon Orphan LLC” as a purported “assignee” of the ‘859 patent. The Lupin Defendants deny that the ‘859 patent was “duly and legally issued,” and any suggestion or implication that the ‘859 patent is valid or enforceable. The Lupin Defendants also admit that a purported copy of the ‘859 patent is attached as Exhibit K to the Complaint. The Lupin Defendants deny all remaining allegations of Paragraph 37.

38. Horizon USA is the exclusive licensee of the ‘859 patent.

**ANSWER:** Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation relating to the exclusive licensee of the ‘859 patent, and therefore deny the same. The Lupin Defendants deny all remaining allegations of Paragraph 38.

39. Horizon USA holds approved New Drug Application (“NDA”) No. 203389 for cysteamine bitartrate delayed release capsules, which it markets and sells in the United States under the brand name “PROCYSBI®.”

**ANSWER:** The Lupin Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39, and therefore deny the same.

40. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the United States Food and Drug Administration (“FDA”) publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (also known as the “Orange Book”) as covering PROCYSBI® brand cysteamine bitartrate delayed release capsules or their use.

**ANSWER:** Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that the Orange Book identifies the ‘284 patent, the ‘590 patent, the ‘882 patent, the ‘156 patent, the ‘157 patent, the ‘158 patent, the

‘851 patent, the ‘077 patent, the ‘665 patent, the ‘037 patent, and the ‘859 patent in connection with NDA No. 203389 for PROCYSBI® (cysteamine bitartrate) delayed release capsules. The Lupin Defendants deny all remaining allegations of Paragraph 40.

**ACTS GIVING RISE TO THIS ACTION**

**COUNT I – INFRINGEMENT  
OF THE ‘284 PATENT BY LUPIN’S ANDA**

41. Plaintiffs re-allege paragraphs 1-40 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-40, as if fully set forth herein.

42. Upon information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules (“the Lupin Generic Product”) prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. Upon information and belief, ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the ‘284 patent.

**ANSWER:** Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited’s ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, as amended (“FFDCA”), seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the ‘284 patent. The Lupin Defendants deny all remaining allegations of Paragraph 42.

43. Upon information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '284 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Lupin Generic Product.

**ANSWER:** Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification," in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '284 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 43.

44. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's written notification of ANDA No. 214400 and its accompanying § 505(j)(2)(A)(vii)(IV) certification, dated June 27, 2020 ("Lupin's Notice Letter").

**ANSWER:** Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 44.

45. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '284 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

46. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '284 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '284 patent.

**ANSWER:** Denied.

47. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '284 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

48. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

49. Upon information and belief, Lupin was aware of the existence of the '284 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '284 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '284 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 49.

**COUNT II – INFRINGEMENT  
OF THE '590 PATENT BY LUPIN'S ANDA**

50. Plaintiffs re-allege paragraphs 1-49 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-49, as if fully set forth herein.

51. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 21440 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '590 patent.

**ANSWER:** Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '590 patent. The Lupin Defendants deny all remaining allegations of Paragraph 51.

52. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '590 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Lupin Generic Product.

**ANSWER:** Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '590 patent is invalid, unenforceable, or will not be infringed by the

manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 52.

53. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 53.

54. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '590 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

55. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '590 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '590 patent.

**ANSWER:** Denied.

56. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '590 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

57. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

58. Upon information and belief, Lupin was aware of the existence of the '590 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '590 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '590 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 58.

**COUNT III – INFRINGEMENT  
OF THE '882 PATENT BY LUPIN'S ANDA**

59. Plaintiffs re-allege paragraphs 1-58 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-58, as if fully set forth herein.

60. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '882 patent.

**ANSWER:** Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '882 patent. The Lupin Defendants deny all remaining allegations of Paragraph 60.

61. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '882 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Lupin Generic Product.

**ANSWER:** Paragraph 61 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '882 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 61.

62. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's written notification of Lupin's Notice Letter.

**ANSWER:** Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 62.

63. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '882 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

64. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '882 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '882 patent.

**ANSWER:** Denied.

65. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '882 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

66. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

67. Upon information and belief, Lupin was aware of the existence of the '882 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '882 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '882 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 67.

#### **COUNT IV – INFRINGEMENT OF THE '156 PATENT BY LUPIN'S ANDA**

68. Plaintiffs re-allege paragraphs 1-67 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-67, as if fully set forth herein.

69. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '156 patent.

**ANSWER:** Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg

and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '156 patent. The Lupin Defendants deny all remaining allegations of Paragraph 69.

70. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '156 patent are invalid.

**ANSWER:** Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '156 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 70.

71. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for noninfringement of claims 1-6 of the '156 patent.

**ANSWER:** Denied.

72. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '156 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '156 patent.

**ANSWER:** Denied.

73. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 73.

74. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '156 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

75. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '156 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

76. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

77. Upon information and belief, Lupin was aware of the existence of the '156 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '156 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate)

delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '156 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 77.

**COUNT V – INFRINGEMENT  
OF THE '157 PATENT BY LUPIN'S ANDA**

78. Plaintiffs re-allege paragraphs 1-77 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-77, as if fully set forth herein.

79. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '157 patent.

**ANSWER:** Paragraph 79 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '157 patent. The Lupin Defendants deny all remaining allegations of Paragraph 79.

80. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '157 patent are invalid.

**ANSWER:** Paragraph 80 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400. The Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '157 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 80.

81. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for noninfringement of claims 1-3 of the '157 patent.

**ANSWER:** Denied.

82. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '157 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '157 patent.

**ANSWER:** Denied.

83. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 83 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 83.

84. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '157 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

85. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '157 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

86. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

87. Upon information and belief, Lupin was aware of the existence of the '157 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '157 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '157 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 87.

**COUNT VI – INFRINGEMENT  
OF THE '158 PATENT BY LUPIN'S ANDA**

88. Plaintiffs re-allege paragraphs 1-87 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-87, as if fully set forth herein.

89. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '158 patent.

**ANSWER:** Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '158 patent. The Lupin Defendants deny all remaining allegations of Paragraph 89.

90. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '158 patent are invalid.

**ANSWER:** Paragraph 90 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '158 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release

Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 90.

91. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for noninfringement of claim 1 of the '158 patent.

**ANSWER:** Denied.

92. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '158 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of certain additional claims of the '158 patent.

**ANSWER:** Denied.

93. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 93 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 93.

94. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '158 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

95. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '158 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

96. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

97. Upon information and belief, Lupin was aware of the existence of the '158 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '158 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '158 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 97.

**COUNT VII – INFRINGEMENT  
OF THE '851 PATENT BY LUPIN'S ANDA**

98. Plaintiffs re-allege paragraphs 1-97 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-97, as if fully set forth herein.

99. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400

specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '851 patent.

**ANSWER:** Paragraph 99 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '851 patent. The Lupin Defendants deny all remaining allegations of Paragraph 99.

100. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '851 patent are invalid.

**ANSWER:** Paragraph 100 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '851 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 100.

101. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for noninfringement of any claims of the '851 patent.

**ANSWER:** Denied.

102. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA,

prior to the expiration of the '851 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '851 patent.

**ANSWER:** Denied.

103. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 103 contains legal conclusions to which no answer is required.

To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 103.

104. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '851 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

105. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '851 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

106. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

107. Upon information and belief, Lupin was aware of the existence of the '851 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '851 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '851 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 107.

**COUNT VIII – INFRINGEMENT  
OF THE '077 PATENT BY LUPIN'S ANDA**

108. Plaintiffs re-allege paragraphs 1-107 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-107, as if fully set forth herein.

109. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '077 patent.

**ANSWER:** Paragraph 109 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval

for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '077 patent. The Lupin Defendants deny all remaining allegations of Paragraph 109.

110. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '077 patent are invalid.

**ANSWER:** Paragraph 110 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '077 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 110.

111. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for noninfringement of any claims of the '077 patent.

**ANSWER:** Denied.

112. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '077 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '077 patent.

**ANSWER:** Denied.

113. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 113 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc.,

Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 113.

114. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '077 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

115. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '077 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

116. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

117. Upon information and belief, Lupin was aware of the existence of the '077 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '077 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 117 contains legal conclusions to which no answer is required.

To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed

Release Capsules, 25 mg and 75 mg, prior to the expiration of the '077 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 117.

**COUNT IX – INFRINGEMENT  
OF THE '665 PATENT BY LUPIN'S ANDA**

118. Plaintiffs re-allege paragraphs 1-117 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-117, as if fully set forth herein.

119. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '665 patent.

**ANSWER:** Paragraph 119 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '665 patent. The Lupin Defendants deny all remaining allegations of Paragraph 119.

120. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '665 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Lupin Generic Product.

**ANSWER:** Paragraph 120 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No.

214400 contains a “Paragraph IV Patent Certification” in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited’s opinion and to the best of its knowledge, the ‘665 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited’s proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 120.

121. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the ‘665 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the ‘665 patent.

**ANSWER:** Denied.

122. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin’s Notice Letter.

**ANSWER:** Paragraph 122 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 122.

123. Lupin’s submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘665 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

124. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the

United States, and/or induces or contributes to such conduct, Lupin will infringe the '665 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

125. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

126. Upon information and belief, Lupin was aware of the existence of the '665 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '665 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 126 contains legal conclusions to which no answer is required.

To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '665 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 126.

**COUNT X – INFRINGEMENT  
OF THE '037 PATENT BY LUPIN'S ANDA**

127. Plaintiffs re-allege paragraphs 1-126 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-126, as if fully set forth herein.

128. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '037 patent.

**ANSWER:** Paragraph 128 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '037 patent. The Lupin Defendants deny all remaining allegations of Paragraph 128.

129. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '037 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Lupin Generic Product.

**ANSWER:** Paragraph 129 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '037 patent is invalid, unenforceable, or will not be infringed by the

manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 129.

130. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '037 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '037 patent.

**ANSWER:** Denied.

131. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 131 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 131.

132. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '037 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

133. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '037 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

134. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

135. Upon information and belief, Lupin was aware of the existence of the '037 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '037 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 135 contains legal conclusions to which no answer is required.

To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate) delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '037 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 135.

**COUNT XI – INFRINGEMENT  
OF THE '859 PATENT BY LUPIN'S ANDA**

136. Plaintiffs re-allege paragraphs 1-135 as if fully set forth herein.

**ANSWER:** The Lupin Defendants restate and incorporate by reference each of their answers to Paragraphs 1-135, as if fully set forth herein.

137. On information and belief, Lupin submitted ANDA No. 214400 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 214400 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of certain Orange Book-listed patents for the treatment of nephropathic cystinosis. ANDA No. 214400 specifically seeks FDA approval to market a generic version of PROCYSBI® brand 25 mg and 75 mg cysteamine bitartrate delayed release capsules prior to the expiration of the '859 patent.

**ANSWER:** Paragraph 137 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '859 patent. The Lupin Defendants deny all remaining allegations of Paragraph 137.

138. On information and belief, ANDA No. 214400 includes a Paragraph IV Certification that the claims of the '859 patent are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Lupin Generic Product.

**ANSWER:** Paragraph 138 contains legal conclusions to which no answer is required. To the extent an answer is required, the Lupin Defendants admit that Lupin Limited's ANDA No. 214400 contains a "Paragraph IV Patent Certification" in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94, stating that in Lupin Limited's opinion and to the best of its knowledge, the '859 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Lupin Limited's proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants deny all remaining allegations of Paragraph 138.

139. Upon information and belief, the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '859 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '859 patent.

**ANSWER:** Denied.

140. Plaintiffs commenced this action within 45 days of the date of receipt of Lupin's Notice Letter.

**ANSWER:** Paragraph 140 contains legal conclusions to which no answer is required.

To the extent an answer is required, the Lupin Defendants admit that in a Notification dated June 27, 2020, Lupin Limited provided requisite notice to, among others, Horizon Pharma USA, Inc., Horizon Orphan LLC, and The Regents of the University of California that Lupin Limited submitted ANDA No. 214400 to FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg. The Lupin Defendants further admit that Plaintiffs filed this action on August 11, 2020. The Lupin Defendants deny all remaining allegations of Paragraph 140.

141. Lupin's submission to the FDA of ANDA No. 214400, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '859 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

142. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells its proposed generic versions of PROCYSBI® brand products within the United States, imports its proposed generic versions of PROCYSBI® brand products into the United States, and/or induces or contributes to such conduct, Lupin will infringe the '859 patent under 35 U.S.C. § 271.

**ANSWER:** Denied.

143. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

144. Upon information and belief, Lupin was aware of the existence of the '859 patent and was aware that the filing of ANDA No. 214400 and the certification with respect to the '859 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 144 contains legal conclusions to which no answer is required.

To the extent an answer is required, the Lupin Defendants admit that, as required under Section 505(j)(2)(A)(vii) of the FFDCA, Lupin Limited included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, PROCYSBI® (cysteamine bitartrate)

delayed release capsules, NDA No. 203389 at the time of its ANDA submission. The Lupin Defendants further admit that Lupin Limited's ANDA contains certifications in accordance with Section 505(j)(2)(A)(vii)(IV) of the FFDCA, seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, prior to the expiration of the '859 patent, which was listed in the Orange Book at the time of that ANDA submission. The Lupin Defendants deny all remaining allegations of Paragraph 144.

\* \* \*

The Lupin Defendants deny that Plaintiffs are entitled to any of the relief prayed for in the Complaint or to any relief whatsoever, and further request that judgment be entered in favor of the Lupin Defendants, dismissing Plaintiffs' Complaint with prejudice, awarding the Lupin Defendants attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

## **SEPARATE DEFENSES**

Without prejudice to the denials set forth in their Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs Horizon Orphan LLC, Horizon Therapeutics USA, Inc., and The Regents of the University of California (collectively, “Plaintiffs”), Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, the “Lupin Defendants”) aver and assert the following defenses to the Complaint:

### **First Defense**

The claims of United States Patent No. 8,026,284 (“the ‘284 patent”), United States Patent No. 9,192,590 (“the ‘590 patent”), United States Patent No. 9,198,882 (“the ‘882 patent”), United States Patent No. 9,925,156 (“the ‘156 patent”), United States Patent No. 9,925,157 (“the ‘157 patent”), United States Patent No. 9,925,158 (“the ‘158 patent”), United States Patent No. 9,173,851 (“the ‘851 patent”), United States Patent No. 9,233,077 (“the ‘077 patent”), United States Patent No. 10,143,665 (“the ‘665 patent”), United States Patent No. 10,328,037 (“the ‘037 patent”), and United States Patent No. 10,548,859 (“the ‘859 patent”) (collectively, “the patents-in-suit”) are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

### **Second Defense**

The manufacture, use, sale, offer for sale or importation of the proposed Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg, that are the subject of Lupin Limited’s Abbreviated New Drug Application No. 214400, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents.

**Third Defense**

The Lupin Defendants have not induced, do not induce, and will not induce infringement of any valid and/or enforceable claim of the patents-in-suit.

**Fourth Defense**

The Lupin Defendants have not contributed, do not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the patents-in-suit.

**Fifth Defense**

The Court lacks subject matter jurisdiction over this action, including for any and all claims asserted under 35 U.S.C. § 271 (a), (b) or (c).

**Sixth Defense**

The Lupin Defendants are exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

**Seventh Defense**

The Complaint fails to state a claim for exceptional case or willful infringement.

**Eighth Defense**

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

**Ninth Defense**

Plaintiffs are barred from asserting infringement based on doctrine of equivalents in view of prosecution history estoppel, disclaimer, the disclosure-dedication rule, vitiation and/or ensnarement.

**Tenth Defense**

Any defense asserted in any other action in which any of the patents-in-suit are or were asserted.

**Eleventh Defense**

Any additional defenses or counterclaims that discovery may reveal, including unenforceability or inequitable conduct.

### **COUNTERCLAIMS**

Defendant/Counterclaim-Plaintiff Lupin Limited (“Lupin”), for its Counterclaims against Plaintiffs Horizon Orphan LLC (“Horizon Orphan”), Horizon Therapeutics USA, Inc. (“Horizon USA”), and The Regents of the University of California (“UC”) (collectively, “Plaintiffs/Counterclaim-Defendants”), alleges as follows:

#### **Parties**

1. Lupin Limited is an Indian corporation, having a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

2. On information and belief and according to the Complaint (D.I. 1 ¶ 1), Horizon Orphan LLC purports to be a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

3. On information and belief and according to the Complaint (D.I. 1 ¶ 2), Horizon Therapeutics USA, Inc. purports to be a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

4. On information and belief and according to the Complaint (D.I. 1 ¶ 3), The Regents of the University of California purports to be a California non-profit constitutional corporation and the governing body of an educational institution, having its principal place of business at 1111 Franklin Street, Oakland, California 94607.

#### **Jurisdiction and Venue**

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Lupin in this District, and, on information and belief, because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

8. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1400(b).

### **Background**

#### **A. FDA Approval of New Brand-Name Drugs.**

9. The Federal Food, Drug, and Cosmetic Act (“FFDCA”), 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) (commonly known as the “Hatch-Waxman Amendments” or “Hatch-Waxman”), and as further amended by Title XI of the MMA, sets forth the rules that the U.S. Food and Drug Administration (“FDA”) follows when considering whether to approve both brand-name and generic drugs.

10. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application (“NDA”) for consideration by FDA. *See* 21 U.S.C. § 355.

11. An NDA includes, among other things, the number of any patent that the NDA holder asserts claims the “drug” or a “method of using [the] drug” for which the NDA was

submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). The decision to submit patent information to FDA rests solely with the NDA holder.

12. Upon approval of the NDA, FDA publishes patent information for the approved drug in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” *See* 21 U.S.C. § 355(j)(7)(A)(iii).

**B. Generic Competition – Abbreviated New Drug Applications.**

13. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application (“ANDA”).

14. To receive approval of its ANDA, an applicant must, *inter alia*, show that its generic drug is “bioequivalent” to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

15. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant generally must also “certify” that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

16. When seeking FDA approval to market a drug product prior to patent expiration, an ANDA applicant generally submits a so-called “paragraph IV” certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

**C. Patents-in-Suit.**

**1. The ‘284 Patent.**

18. On or about September 27, 2011, according to the electronic records of the U.S. Patent and Trademark Office (the “USPTO”), U.S. Patent No. 8,026,284 (“the ‘284 patent”), titled “ENTERICALLY COATED CYSTAMINE, CYSTEAMINE AND DERIVATIVES THEREOF,” issued, on its face, to Ranjan Dohil and Jerry Schneider. Plaintiffs/Counterclaim-Defendants represented that a copy of the ‘284 patent was attached as Exhibit A to the Complaint (D.I. 1 ¶ 17).

19. According to the online records of the USPTO and the face of the patent, UC is purportedly a current assignee of the ‘284 patent. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 17) that “UC is the owner of the ‘284 patent.”

20. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 18) that “Horizon is an exclusive licensee of the ‘284 Patent.”

21. According to the online records of the FDA, “HORIZON PHARMA USA INC” is identified as the current purported holder of NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

22. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the ‘284 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the ‘284 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsule, EQ 25mg Base; EQ 75mg Base.

23. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the '284 patent under 35 U.S.C. § 271.

**2. The '590 Patent.**

24. On or about November 24, 2015, according to the electronic records of the USPTO, U.S. Patent No. 9,192,590 ("the '590 patent"), titled "Enterically Coated Cysteamine, Cystamine and derivatives thereof," issued, on its face, to Ranjan Dohil and Jerry Schneider. Plaintiffs/Counterclaim-Defendants represented that a copy of the '590 patent was attached as Exhibit B to the Complaint (D.I. 1 ¶ 19).

25. According to the online records of the USPTO and the face of the patent, UC is purportedly a current assignee of the '590 patent. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 19) that "UC is the owner of the '590 patent."

26. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 20) that "Horizon is an exclusive licensee of the '590 Patent."

27. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the '590 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the '590 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsule, EQ 25mg Base; EQ 75mg Base.

28. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the '590 patent under 35 U.S.C. § 271.

**3. The ‘882 Patent.**

29. On or about December 1, 2015, according to the electronic records of the USPTO, U.S. Patent No. 9,198,882 (“the ‘882 patent”), titled “Enterically Coated Cysteamine, Cystamine and derivatives thereof,” issued, on its face, to Ranjan Dohil and Jerry Schneider. Plaintiffs/Counterclaim-Defendants represented that a copy of the ‘882 patent was attached as Exhibit C to the Complaint (D.I. 1 ¶ 21).

30. According to the online records of the USPTO and the face of the patent, UC is purportedly a current assignee of the ‘882 patent. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 21) that “UC is the owner of the ‘882 patent.”

31. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 22) that “Horizon is an exclusive licensee of the ‘882 Patent.”

32. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the ‘882 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the ‘882 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

33. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ‘882 patent under 35 U.S.C. § 271.

**4. The ‘156 Patent.**

34. On or about March 27, 2018, according to the electronic records of the USPTO, U.S. Patent No. 9,925,156 (“the ‘156 patent”), titled “Enterically Coated Cysteamine, Cystamine and derivatives thereof,” issued, on its face, to Ranjan Dohil and Jerry Schneider. Plaintiffs/Counterclaim-Defendants represented that a copy of the ‘156 patent was attached as Exhibit D to the Complaint (D.I. 1 ¶ 23).

35. According to the online records of the USPTO and the face of the patent, UC is purportedly a current assignee of the '156 patent. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 23) that "UC is the owner of the '156 patent."

36. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 24) that "Horizon is an exclusive licensee of the '156 Patent."

37. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the '156 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the '156 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

38. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the '156 patent under 35 U.S.C. §§ 271.

#### **5. The '157 Patent.**

39. On or about March 27, 2018, according to the electronic records of the USPTO, U.S. Patent No. 9,925,157 ("the '157 patent"), titled "Enterically Coated Cysteamine, Cystamine and derivatives thereof," issued, on its face, to Ranjan Dohil and Jerry Schneider. Plaintiffs/Counterclaim-Defendants represented that a copy of the '157 patent was attached as Exhibit E to the Complaint (D.I. 1 ¶ 25).

40. According to the online records of the USPTO and the face of the patent, UC is purportedly a current assignee of the '157 patent. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 25) that "UC is the owner of the '157 patent."

41. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 26) that "Horizon is an exclusive licensee of the '157 Patent."

42. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the ‘157 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the ‘157 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

43. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ‘157 patent under 35 U.S.C. § 271.

**6. The ‘158 Patent.**

44. On or about March 27, 2018, according to the electronic records of the USPTO, U.S. Patent No. 9,925,158 (“the ‘158 patent”), titled “Enterically Coated Cysteamine, Cystamine and derivatives thereof,” issued, on its face, to Ranjan Dohil and Jerry Schneider. Plaintiffs/Counterclaim-Defendants represented that a copy of the ‘158 patent was attached as Exhibit F to the Complaint (D.I. 1 ¶ 27).

45. According to the online records of the USPTO and the face of the patent, UC is purportedly a current assignee of the ‘158 patent. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 27) that “UC is the owner of the ‘158 patent.”

46. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 28) that “Horizon is an exclusive licensee of the ‘158 Patent.”

47. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the ‘158 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the ‘158 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

48. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ‘158 patent under 35 U.S.C. § 271.

**7. The ‘851 Patent.**

49. On or about November 3, 2015, according to the electronic records of the USPTO, U.S. Patent No. 9,173,851 (“the ‘851 patent”), titled “Delayed Release Cysteamine Bead Formulation, and Methods of Making and Using Same,” issued, on its face, to Kathlene Powell, Ramesh Muttavarapu, and Ranjan Dohil. Plaintiffs/Counterclaim-Defendants represented that a copy of the ‘851 patent was attached as Exhibit G to the Complaint (D.I. 1 ¶ 29).

50. According to the face of the ‘851 patent, Raptor Pharmaceuticals Inc. is the purported assignee. According to USPTO electronic records, Raptor Pharmaceuticals Inc. changed its name to Horizon Orphan, and UC is a co-assignee. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 29) that “Horizon Orphan and UC are co-owners of the ‘851 patent.”

51. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 30) that “Horizon USA is an exclusive licensee of the ‘851 Patent.”

52. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the ‘851 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the ‘851 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

53. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ‘851 patent under 35 U.S.C. § 271.

**8. The ‘077 Patent.**

54. On or about January 12, 2016, according to the electronic records of the USPTO, U.S. Patent No. 9,233,077 (“the ‘077 patent”), titled “Delayed Release Cysteamine Bead Formulation, and Methods of Making and Using Same,” issued, on its face, to Kathlene Powell,

Ramesh Muttavarapu, and Ranjan Dohil. Plaintiffs/Counterclaim-Defendants represented that a copy of the '077 patent was attached as Exhibit H to the Complaint (D.I. 1 ¶ 31).

55. According to the face of the '077 patent, Raptor Pharmaceuticals Inc. is the purported assignee. According to USPTO electronic records, Raptor Pharmaceuticals Inc. changed its name to Horizon Orphan, and UC is a co-assignee. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 31) that "Horizon Orphan and UC are co-owners of the '077 patent."

56. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 32) that "Horizon USA is an exclusive licensee of the '077 Patent."

57. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the '077 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the '077 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

58. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the '077 patent under 35 U.S.C. § 271.

## **9. The '665 Patent.**

59. On or about December 4, 2018, according to the electronic records of the USPTO, U.S. Patent No. 10,143,665 ("the '665 patent"), titled "Methods for Storing Cysteamine Formulations and Related Methods of Treatment," issued, on its face, to Michael DesJardin and Mark Johnson. Plaintiffs/Counterclaim-Defendants represented that a copy of the '665 patent was attached as Exhibit I to the Complaint (D.I. 1 ¶ 33).

60. According to the online records of the USPTO and the face of the patent, Horizon Orphan is the purported assignee. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 33) that “Horizon Orphan is the owner of the ’665 patent.”

61. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 34) that “Horizon USA is the exclusive licensee of the ’665 Patent.”

62. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the ’665 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the ’665 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

63. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ’665 patent under 35 U.S.C. § 271.

#### **10. The ’037 Patent.**

64. On or about June 25, 2019, according to the electronic records of the USPTO, U.S. Patent No. 10,328,037 (“the ’037 patent”), titled “Methods for Storing Cysteamine Formulations and Related Methods of Treatment,” issued, on its face, to Michael DesJardin and Mark Johnson. Plaintiffs/Counterclaim-Defendants represented that a copy of the ’037 patent was attached as Exhibit J to the Complaint (D.I. 1 ¶ 35).

65. According to the online records of the USPTO and the face of the patent, Horizon Orphan is the purported assignee. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 35) that “Horizon Orphan is the owner of the ’037 patent.”

66. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 36) that “Horizon USA is the exclusive licensee of the ’037 Patent.”

67. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the '037 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the '037 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

68. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the '037 patent under 35 U.S.C. §§ 271.

#### **11. The '859 Patent.**

69. On or about February 4, 2020, according to the electronic records of the USPTO, U.S. Patent No. 10,548,859 ("the '859 patent"), titled "Methods for Storing Cysteamine Formulations and Related Methods of Treatment," issued, on its face, to Michael DesJardin and Mark Johnson. Plaintiffs/Counterclaim-Defendants represented that a copy of the '665 patent was attached as Exhibit K to the Complaint (D.I. 1 ¶ 37).

70. According to the online records of the USPTO and the face of the patent, Horizon Orphan is the purported assignee. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 37) that "Horizon Orphan is the owner of the '859 patent."

71. Plaintiffs/Counterclaim-Defendants allege in the Complaint (D.I. 1 ¶ 38) that "Horizon USA is the exclusive licensee of the '859 Patent."

72. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted the '859 patent to the FDA for listing in the Orange Book. By virtue of this submission, FDA listed the '859 patent in the Orange Book in connection with NDA No. 203389 for PROCYSBI® (Cysteamine Bitartrate) Delayed Release Capsules, EQ 25mg Base; EQ 75mg Base.

73. On or about August 11, 2020, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the '859 patent under 35 U.S.C. § 271.

**D. Lupin Limited's Cysteamine Bitartrate Delayed Release Capsules.**

74. Lupin Limited filed an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval for Cysteamine Bitartrate Delayed Release Capsules, 25 mg and 75 mg (“Lupin Limited’s ANDA Product”).

75. FDA assigned Lupin Limited’s ANDA No. 214400.

76. Because Lupin seeks approval to market its ANDA Product prior to the expiration of the ‘284 patent, the ‘590 patent, the ‘882 patent, the ‘156 patent, the ‘157 patent, the ‘158 patent, the ‘851 patent, the ‘077 patent, the ‘665 patent, the ‘037 patent, and the ‘859 patent (collectively, “the patents-in-suit”) Lupin Limited included so-called “paragraph IV” certifications in its ANDA.

77. Lupin Limited provided proper and timely notice of its paragraph IV certifications to the purported patent holder(s) and NDA holder(s) of record, as required under 21 U.S.C. § 355(j)(2)(B), by Notification dated June 27, 2020 (the “Notice Letter”).

78. The manufacture, use, sale, offer for sale and/or importation of Lupin Limited’s ANDA Product does not and will not infringe any valid and/or enforceable claim of the patents-in-suit.

79. The claims of the patents-in-suit are invalid.

**COUNT I**  
**(Declaratory Judgment of Non-Infringement of the ‘284 Patent)**

80. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

81. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product would infringe any valid and/or enforceable claim of the ‘284 patent.

82. Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '284 patent for at least the reasons set forth in the Notice Letter because the claims of the '284 patent are invalid and/or unenforceable, *see Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971) for proposition that "invalidity operates as a complete defense to infringement for any product, forever").

83. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '284 patent.

**COUNT II**  
**(Declaratory Judgment of Invalidity of the '284 Patent)**

84. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

85. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '284 patent.

86. One or more claims of the '284 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

87. For example, and not by way of limitation, one or more claims of the '284 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '284 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '284 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

88. There is no objective evidence of non-obviousness of the claims of the '284 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '284 patent or outweigh the evidence in support of obviousness.

89. For example, and not by way of limitation, one or more claims of the '284 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement; (2) failing to comply with the "enablement" requirement; (3) failing to comply with the "definiteness" requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The '284 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '284 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The '284 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '284 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '284 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the '284 patent would not understand with reasonable certainty the full scope of the '284 patent claims when read in light of the specification.

90. The Lupin Defendants are entitled to a judicial declaration that the claims of the '284 patent are invalid.

**COUNT III**  
**(Declaratory Judgment of Non-Infringement of the ‘590 Patent)**

91. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

92. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product would infringe any valid and/or enforceable claim of the ‘590 patent.

93. Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘590 patent for at least the reasons set forth in the Notice Letter because the claims of the ‘590 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

94. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘590 patent.

**COUNT IV**  
**(Declaratory Judgment of Invalidity of the ‘590 Patent)**

95. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

96. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘590 patent.

97. One or more claims of the ‘590 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including

§§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

98. For example, and not by way of limitation, one or more claims of the ‘590 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘590 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘590 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

99. There is no objective evidence of non-obviousness of the claims of the ‘590 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘590 patent or outweigh the evidence in support of obviousness.

100. For example, and not by way of limitation, one or more claims of the ‘590 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘590 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘590 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘590 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘590 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘590 patent claims do not satisfy the

definiteness requirement at least because those of ordinary skill in the art as relevant to the ‘590 patent would not understand with reasonable certainty the full scope of the ‘590 patent claims when read in light of the specification.

101. The Lupin Defendants are entitled to a judicial declaration that the claims of the ‘590 patent are invalid.

**COUNT V**  
**(Declaratory Judgment of Non-Infringement of the ‘882 Patent)**

102. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

103. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product would infringe any valid and/or enforceable claim of the ‘882 patent.

104. Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘882 patent for at least the reasons set forth in the Notice Letter because the claims of the ‘882 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

105. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘882 patent.

**COUNT VI**  
**(Declaratory Judgment of Invalidity of the ‘882 Patent)**

106. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

107. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘882 patent.

108. One or more claims of the ‘882 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

109. For example, and not by way of limitation, one or more claims of the ‘882 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘882 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘882 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

110. There is no objective evidence of non-obviousness of the claims of the ‘882 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘882 patent or outweigh the evidence in support of obviousness.

111. For example, and not by way of limitation, one or more claims of the ‘882 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘882 patent claims do not satisfy the written description

requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '882 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The '882 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '882 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '882 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the '882 patent would not understand with reasonable certainty the full scope of the '882 patent claims when read in light of the specification.

112. The Lupin Defendants are entitled to a judicial declaration that the claims of the '882 patent are invalid.

**COUNT VII**  
**(Declaratory Judgment of Non-Infringement of the '156 Patent)**

113. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

114. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product would infringe any valid and/or enforceable claim of the '156 patent.

115. Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '156 patent for at least the reasons set forth in the Notice Letter because the claims of the '156 patent are invalid and/or unenforceable,

*see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

116. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘156 patent.

**COUNT VIII**  
**(Declaratory Judgment of Invalidity of the ‘156 Patent)**

117. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

118. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘156 patent.

119. One or more claims of the ‘156 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

120. For example, and not by way of limitation, one or more claims of the ‘156 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘156 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘156 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

121. There is no objective evidence of non-obviousness of the claims of the ‘156 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘156 patent or outweigh the evidence in support of obviousness.

122. For example, and not by way of limitation, one or more claims of the ‘156 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘156 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘156 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘156 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘156 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘156 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the ‘156 patent would not understand with reasonable certainty the full scope of the ‘156 patent claims when read in light of the specification.

123. The Lupin Defendants are entitled to a judicial declaration that the claims of the ‘156 patent are invalid.

**COUNT IX**  
**(Declaratory Judgment of Non-Infringement of the ‘157 Patent)**

124. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

125. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use,

offer for sale, sale or importation of Lupin Limited's ANDA Product would infringe any valid and/or enforceable claim of the '157 patent.

126. Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '157 patent for at least the reasons set forth in the Notice Letter because the claims of the '157 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that "invalidity operates as a complete defense to infringement for any product, forever").

127. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '157 patent.

**COUNT X**  
**(Declaratory Judgment of Invalidity of the '157 Patent)**

128. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

129. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '157 patent.

130. One or more claims of the '157 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

131. For example, and not by way of limitation, one or more claims of the '157 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '157 patent would have been motivated, and would have had a reasonable expectation of

success, to prepare the alleged invention disclosed in the claims of the ‘157 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

132. There is no objective evidence of non-obviousness of the claims of the ‘157 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘157 patent or outweigh the evidence in support of obviousness.

133. For example, and not by way of limitation, one or more claims of the ‘157 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘157 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘157 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘157 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘157 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘157 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the ‘157 patent would not understand with reasonable certainty the full scope of the ‘157 patent claims when read in light of the specification.

134. The Lupin Defendants are entitled to a judicial declaration that the claims of the ‘157 patent are invalid.

**COUNT XI**  
**(Declaratory Judgment of Non-Infringement of the ‘158 Patent)**

135. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

136. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product would infringe any valid and/or enforceable claim of the ‘158 patent.

137. Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘158 patent for at least the reasons set forth in the Notice Letter because the claims of the ‘158 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

138. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘158 patent.

**COUNT XII**  
**(Declaratory Judgment of Invalidity of the ‘158 Patent)**

139. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

140. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘158 patent.

141. One or more claims of the ‘158 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including

§§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

142. For example, and not by way of limitation, one or more claims of the ‘158 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘158 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘158 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

143. There is no objective evidence of non-obviousness of the claims of the ‘158 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘158 patent or outweigh the evidence in support of obviousness.

144. For example, and not by way of limitation, one or more claims of the ‘158 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘158 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘158 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘158 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘158 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘158 patent claims do not satisfy the

definiteness requirement at least because those of ordinary skill in the art as relevant to the ‘158 patent would not understand with reasonable certainty the full scope of the ‘158 patent claims when read in light of the specification.

145. The Lupin Defendants are entitled to a judicial declaration that the claims of the ‘158 patent are invalid.

**COUNT XIII**  
**(Declaratory Judgment of Non-Infringement of the ‘851 Patent)**

146. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

147. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product would infringe any valid and/or enforceable claim of the ‘851 patent.

148. Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘851 patent for at least the reasons set forth in the Notice Letter because the claims of the ‘851 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

149. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘851 patent.

**COUNT XIV**  
**(Declaratory Judgment of Invalidity of the ‘851 Patent)**

150. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

151. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘851 patent.

152. One or more claims of the ‘851 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter. For example, and not by way of limitation, one or more claims of the ‘851 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘851 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘851 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

153. There is no objective evidence of non-obviousness of the claims of the ‘851 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘851 patent or outweigh the evidence in support of obviousness.

154. For example, and not by way of limitation, one or more claims of the ‘851 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘851 patent claims do not satisfy the written description

requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '851 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The '851 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '851 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '851 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the '851 patent would not understand with reasonable certainty the full scope of the '851 patent claims when read in light of the specification.

155. The Lupin Defendants are entitled to a judicial declaration that the claims of the '851 patent are invalid.

**COUNT XV**  
**(Declaratory Judgment of Non-Infringement of the '077 Patent)**

156. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

157. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product would infringe any valid and/or enforceable claim of the '077 patent.

158. Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '077 patent for at least the reasons set forth in the Notice Letter because the claims of the '077 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for

proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

159. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘077 patent.

**COUNT XVI**  
**(Declaratory Judgment of Invalidity of the ‘077 Patent)**

160. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

161. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘077 patent.

162. One or more claims of the ‘077 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

163. For example, and not by way of limitation, one or more claims of the ‘077 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘077 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘077 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

164. There is no objective evidence of non-obviousness of the claims of the ‘077 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘077 patent or outweigh the evidence in support of obviousness.

165. For example, and not by way of limitation, one or more claims of the ‘077 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘077 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘077 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘077 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘077 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘077 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the ‘077 patent would not understand with reasonable certainty the full scope of the ‘077 patent claims when read in light of the specification.

166. The Lupin Defendants are entitled to a judicial declaration that the claims of the ‘077 patent are invalid.

**COUNT XVII**  
**(Declaratory Judgment of Non-Infringement of the ‘665 Patent)**

167. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

168. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use,

offer for sale, sale or importation of Lupin Limited's ANDA Product would infringe any valid and/or enforceable claim of the '665 patent.

169. Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '665 patent for at least the reasons set forth in the Notice Letter because the claims of the '665 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that "invalidity operates as a complete defense to infringement for any product, forever").

170. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '665 patent.

**COUNT XVIII**  
**(Declaratory Judgment of Invalidity of the '665 Patent)**

171. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

172. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '665 patent.

173. One or more claims of the '665 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

174. For example, and not by way of limitation, one or more claims of the '665 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '665 patent would have been motivated, and would have had a reasonable expectation of

success, to prepare the alleged invention disclosed in the claims of the ‘665 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

175. There is no objective evidence of non-obviousness of the claims of the ‘665 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘665 patent or outweigh the evidence in support of obviousness.

176. For example, and not by way of limitation, one or more claims of the ‘665 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘665 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘665 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘665 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘665 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘665 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the ‘665 patent would not understand with reasonable certainty the full scope of the ‘665 patent claims when read in light of the specification.

177. The Lupin Defendants are entitled to a judicial declaration that the claims of the ‘665 patent are invalid.

**COUNT XIX**

**(Declaratory Judgment of Non-Infringement of the ‘037 Patent)**

178. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

179. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product would infringe any valid and/or enforceable claim of the ‘037 patent.

180. Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘037 patent for at least the reasons set forth in the Notice Letter because the claims of the ‘037 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that “invalidity operates as a complete defense to infringement for any product, forever”).

181. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited’s ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘037 patent.

**COUNT XX**

**(Declaratory Judgment of Invalidity of the ‘037 Patent)**

182. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

183. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘037 patent.

184. One or more claims of the ‘037 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including

§§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

185. For example, and not by way of limitation, one or more claims of the ‘037 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘037 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘037 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

186. There is no objective evidence of non-obviousness of the claims of the ‘037 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘037 patent or outweigh the evidence in support of obviousness.

187. For example, and not by way of limitation, one or more claims of the ‘037 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘037 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the ‘037 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The ‘037 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the ‘037 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The ‘037 patent claims do not satisfy the

definiteness requirement at least because those of ordinary skill in the art as relevant to the '037 patent would not understand with reasonable certainty the full scope of the '037 patent claims when read in light of the specification.

188. The Lupin Defendants are entitled to a judicial declaration that the claims of the '037 patent are invalid.

**COUNT XXI**  
**(Declaratory Judgment of Non-Infringement of the '859 Patent)**

189. The Lupin Defendants re-assert and re-allege each of the foregoing Paragraphs as if fully set forth herein.

190. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product would infringe any valid and/or enforceable claim of the '859 patent.

191. Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '859 patent for at least the reasons set forth in the Notice Letter because the claims of the '859 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue*, 402 U.S. 313 for proposition that "invalidity operates as a complete defense to infringement for any product, forever").

192. Lupin is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Lupin Limited's ANDA Product has not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '859 patent.

**COUNT XXII**  
**(Declaratory Judgment of Invalidity of the ‘859 Patent)**

193. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

194. There is an actual, substantial and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the ‘859 patent.

195. One or more claims of the ‘859 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability, for at least the reasons set forth in the Notice Letter.

196. For example, and not by way of limitation, one or more claims of the ‘859 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the ‘859 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the ‘859 patent, including in view of at least (but not necessarily limited to) the references disclosed in the Notice Letter.

197. There is no objective evidence of non-obviousness of the claims of the ‘859 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘859 patent or outweigh the evidence in support of obviousness.

198. For example, and not by way of limitation, one or more claims of the ‘859 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the “written description” requirement; (2) failing to comply with the “enablement” requirement; (3) failing to comply with the “definiteness” requirement; and/or (4) because one or more dependent claims do not incorporate by reference all limitations of the claim to which they refer and then specify a further limitation of the subject matter. The ‘859 patent claims do not satisfy the written description

requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '859 patent can conclude that the inventor(s) were in possession of the claimed invention as of the filing date. The '859 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '859 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '859 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the '859 patent would not understand with reasonable certainty the full scope of the '859 patent claims when read in light of the specification.

199. The Lupin Defendants are entitled to a judicial declaration that the claims of the '859 patent are invalid.

### **PRAYER FOR RELIEF**

WHEREFORE, Lupin respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

- (a) Declaring that the manufacture, use, sale, offer for sale or importation of Lupin Limited's ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '284 patent, the '590 patent, the '882 patent, the '156 patent, the '157 patent, the '158 patent, the '851 patent, the '077 patent, the '665 patent, the '037 patent, or the '859 patent;
- (b) Declaring that the claims of the '284 patent, the '590 patent, the '882 patent, the '156 patent, the '157 patent, the '158 patent, the '851 patent, the '077 patent, the '665 patent, the '037 patent, or the '859 patent are invalid;

- (c) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of the Lupin Defendants;
- (d) Declaring this case exceptional and awarding the Lupin Defendants their reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and
- (e) Awarding the Lupin Defendants such other and further relief as the Court may deem just and proper.

Dated: October 16, 2020

Respectfully submitted,

/s/ Karen A. Confoy

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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Under Local Civil Rule 11.2, the undersigned counsel for Defendants hereby certifies that this matter is not the subject of any other action asserted by Defendants in any court, or of any pending arbitration or administrative proceeding.

Dated: October 16, 2020

Respectfully submitted,

/s/ Karen A. Confoy

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**LOCAL CIVIL RULE 201.1 CERTIFICATION**

Under Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that Defendants seek declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 16, 2020

Respectfully submitted,

/s/ Karen A. Confoy

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