

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

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INTERCEPT PHARMACEUTICALS, INC. and	)	
INTERCEPT PHARMA EUROPE LTD.,	)	
	)	
Plaintiffs/Counterclaim	)	
Defendants,	)	
	)	C.A. No. 21-35 (MN)
v.	)	
	)	
DR. REDDY'S LABORATORIES, INC. and DR.	)	
REDDY'S LABORATORIES, LTD.,	)	
	)	
Defendants/Counterclaim	)	
Plaintiffs.	)	
	)	

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**DEFENDANTS DR. REDDY'S LABORATORIES, INC. & DR. REDDY'S  
LABORATORIES, LTD.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFFS'  
COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), by and through their undersigned attorneys, submit their answer, affirmative defenses, and Counterclaims to Plaintiffs Intercept Pharmaceuticals, Inc. and Intercept Pharma Europe Ltd.'s (collectively, "Intercept" or "Plaintiffs") Complaint for Patent Infringement ("Complaint") as follows:

Pursuant to Fed. R. Civ. P. 8(b)(3), DRL denies all allegations in Plaintiffs' Complaint, except those expressly admitted below. This pleading is based upon DRL's knowledge of its own activities, and upon information and belief as to the activities of others.

**NATURE OF THE ACTION**

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271, arises from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 214899 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to market a generic version of the pharmaceutical product OCALIVA® (obeticholic acid, 5 and 10 mg) prior to the expiration of U.S. Patent Nos. RE 48,286 (filed June 21, 2019) ("the

RE286 Patent"); 9,238,673 (filed June 17, 2013) ("the '673 Patent"); 10,047,117 (filed Nov. 20, 2015) ("the '117 Patent"); 10,052,337 (filed Apr. 26, 2016) ("the '337 Patent"); 10,174,073 (filed Apr. 25, 2017) ("the '073 Patent"); 10,751,349 (filed Jan. 15, 2019) ("the '349 Patent"); and 10,758,549 (filed Feb. 11, 2020) ("the '549 Patent") (collectively the "patents-in-suit"). Plaintiffs seek injunctive relief prohibiting infringement, attorneys' fees, and any other relief the Court deems just and proper.

**RESPONSE:** DRL admits that Plaintiffs' Complaint against DRL is for alleged infringement of United States Patent Nos. RE 48,286 ("the RE286 Patent"); 9,238,673 ("the '673 Patent"); 10,047,117 ("the '117 Patent"); 10,052,337 ("the '337 Patent"); 10,174,073 ("the '073 Patent"); 10,751,349 ("the '349 Patent"); and 10,758,549 ("the '549 Patent") (collectively, the "patents-in-suit") arising under the Patent Laws of the United States, 35 U.S.C. § 271, but denies that Plaintiffs are entitled to any such relief. DRL states that the filing dates of the patents-in-suit speak for themselves.

DRL further admits that Dr. Reddy's Laboratories, Ltd. submitted an Abbreviated New Drug Application ("ANDA") No. 214899 seeking U.S. Food and Drug Administration ("FDA") approval to market a generic obeticholic acid product ("DRL's ANDA product"), which Plaintiffs market as a product called OCALIVA®, prior to the expiration of the patents-in-suit. DRL denies any remaining allegations in this paragraph.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271.

**RESPONSE:** DRL admits that Plaintiffs' Complaint against DRL is for a declaratory judgment of patent infringement of the patents-in-suit arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. DRL denies any remaining allegations in this paragraph.

**THE PARTIES**

3. Plaintiff Intercept Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Hudson Yards, 37th Floor, New York, New York 10001.

**RESPONSE:** On information and belief, DRL admits that Plaintiff Intercept Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

4. Plaintiff IPEL is a limited corporation organized under the laws of the United Kingdom, having a principal place of business at One Glass Wharf, Bristol, BS2 0ZX United Kingdom.

**RESPONSE:** On information and belief, DRL admits that Plaintiff Intercept Pharmaceutical Europe Limited is a corporation organized under the laws of the United Kingdom. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

5. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, Telangana, India.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, Telangana, India.

6. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having an address at 107 College Road East, Princeton, New Jersey 08540.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, and has an address at 107 College Road East, Princeton, New Jersey 08540.

7. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

8. On information and belief, Dr. Reddy's Laboratories, Ltd. is the holder of FDA Drug Master File No. 31977 for obeticholic acid.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. is the holder of FDA Drug Master File No. 31977 for obeticholic acid.

9. On information and belief, Dr. Reddy's Laboratories, Inc. acts at the direction, and for the benefit, of Dr. Reddy's Laboratories, Ltd., and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

**RESPONSE:** DRL denies the allegations in this paragraph.

10. On further information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

11. On information and belief, Dr. Reddy's Laboratories, Inc. acts as the U.S. agent for Dr. Reddy's Laboratories, Ltd. for purposes of regulatory submissions to the FDA in seeking approval for generic drugs.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Inc. is the U.S. Agent for Dr. Reddy's Laboratories, Ltd. for purposes of regulatory submissions to the FDA with respect to ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

12. On information and belief, Defendants prepared and submitted ANDA No. 214899 (the "DRL ANDA") and continue to seek FDA approval of that application.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. is the listed applicant for ANDA No. 214899. DRL further admits that Dr. Reddy's Laboratories, Inc. is the U.S. Agent for Dr. Reddy's Laboratories, Ltd. for purposes of regulatory submissions to the FDA with respect to ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

13. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the products described in the DRL ANDA (the "DRL ANDA Products" or "ANDA Products") throughout the United States, including in the State of Delaware, in the event the FDA approves the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

#### **JURISDICTION AND VENUE**

14. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that Plaintiffs' Complaint is for a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. DRL admits that this Court has jurisdiction over patent infringement cases pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-02.

15. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with Delaware, regularly conduct business in Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in Delaware, and intend to sell the DRL ANDA Products in Delaware upon approval of the DRL ANDA.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest that this Court has personal jurisdiction over DRL for the purposes of this action only. DRL denies any remaining allegations contained in this paragraph.

16. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Defendants manufacture, distribute, market and/or sell throughout the United States and in this judicial district.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

17. On information and belief, Dr. Reddy's Laboratories, Inc. is registered as a pharmacy wholesaler under license No. A-4-0002524 and as a controlled substances distributor/manufacturer under license No. DM-0013148 with the Delaware Division of Professional Regulation.

**RESPONSE:** DRL denies the allegations in this paragraph.

18. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated November 30, 2020 sent by DRL to Intercept Pharmaceuticals pursuant to 21 U.S.C. § 355(j)(2)(b), Defendants prepared and filed the DRL ANDA with the intention of seeking to market the DRL ANDA Products nationwide, including within this judicial district.

**RESPONSE:** DRL admits that DRL sent a Paragraph IV Notice Letter to Intercept Pharmaceuticals, Inc. on November 30, 2020 pursuant to 21 U.S.C. § 355(j)(2)(b) to notify Intercept that Dr. Reddy's Laboratories, Ltd. had filed ANDA No. 214899. This letter speaks for itself. DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. The remainder of this paragraph contains conclusions

of law for which no response is required. To the extent a response is required, DRL denies the remaining allegations in this paragraph.

19. On information and belief, Defendants plan to sell the DRL ANDA Products in Delaware, list the DRL ANDA Products on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the DRL ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

20. On information and belief, Defendants know and intend that the DRL ANDA Products will be distributed and sold in Delaware and will thereby displace sales of OCALIVA®, causing injury to Plaintiffs. Defendants intend to take advantage of their established channels of distribution in Delaware for the sale of the DRL ANDA Products.

**RESPONSE:** DRL denies the allegations in this paragraph.

21. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See, e.g., Abbvie Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 20-968 (LPS) (D. Del. Oct. 19, 2020); *Bial - Portela & CA S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 20-784 (CFC) (D. Del. Aug. 11, 2020); *Takeda Pharmaceuticals U.S.A., Inc. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 20-845 (RGA) (D. Del. July 29, 2020); *Merck Sharp & Dohme Corp. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 20-847 (RGA) (D. Del. July 23, 2020); *Sanofi-Aventis U.S. LLC, et al. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 20-804 (RGA) (D. Del. July 20, 2020); *Genzyme Corp., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 19-2045 (CFC) (D. Del. Nov. 20, 2019).

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required from DRL, DRL does not contest that this Court has personal jurisdiction over DRL for the purposes of this action only. DRL denies any remaining allegations contained in this paragraph.

22. Additionally, this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Intercept's claims arise under federal law; (b) Dr. Reddy's Laboratories, Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Dr. Reddy's Laboratories, Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the DRL ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Dr. Reddy's Laboratories, Ltd. satisfies due process.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required from DRL, DRL does not contest that this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. for the purposes of this action only. DRL denies any remaining allegations contained in this paragraph.

23. Venue is proper in this district for Dr. Reddy's Laboratories, Ltd. pursuant to 28 U.S.C. § 13391(c)(3) because, inter alia, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required from DRL, DRL does not contest that this Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and DRL does not contest venue over Dr. Reddy's Laboratories, Ltd. for the purposes of this action only. DRL admits that Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India. DRL denies any remaining allegations contained in this paragraph.

24. Venue is further proper against Dr. Reddy's Laboratories, Inc. as it is the agent or alter ego of Dr. Reddy's Laboratories, Ltd. (which is also subject to venue in this Judicial District) in connection with the submission of DRL's ANDA. Moreover, Dr. Reddy's Laboratories, Inc. has litigated other Hatch-Waxman patent infringement disputes in this judicial district. In addition, counsel for DRL has advised counsel for Plaintiffs that DRL would not contest venue in this judicial district for purposes of this action.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required from DRL, DRL does not contest that this Court has

personal jurisdiction over Dr. Reddy's Laboratories, Inc. and DRL does not contest venue over Dr. Reddy's Laboratories, Inc. for the purposes of this action only, and has told Plaintiffs' counsel the same. DRL denies any remaining allegations contained in this paragraph.

**INTERCEPT'S APPROVED OCALIVA® DRUG PRODUCT AND PATENTS**

25. Intercept makes and sells OCALIVA®, a product used in the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. The active ingredient in OCALIVA® is obeticholic acid. OCALIVA® is available in two strengths, 5 mg and 10 mg. A true and correct copy of the prescribing label for OCALIVA® is attached as Exhibit A.

**RESPONSE:** Upon information and belief, DRL admits that Intercept makes and sells OCALIVA®, which is indicated to treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Further, upon information and belief, DRL admits that the active ingredient in OCALIVA® is obeticholic acid, and OCALIVA® is available in two strengths, 5 mg and 10 mg. DRL admits that a purported copy of the OCALIVA® prescribing label was attached to Plaintiffs' Complaint as Exhibit A. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies those allegations.

26. Intercept Pharmaceuticals is the holder of New Drug Application ("NDA") No. 207999 for OCALIVA® and the owner of the patents-in-suit. The FDA approved NDA No. 207999 for OCALIVA® on May 27, 2016, and granted OCALIVA® five years of regulatory exclusivity for a new chemical entity pursuant to 21 C.F.R. § 314.108, which expires on May 27, 2021. The FDA also granted OCALIVA® orphan drug exclusivity pursuant to 21 C.F.R. § 316.31, which expires on May 27, 2023.

**RESPONSE:** Upon information and belief, DRL admits that Intercept Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 207999 for OCALIVA® and purports to be the owner of the patents-in-suit. DRL admits that, according to information available on the

FDA's website, OCALIVA® was approved on May 27, 2016, and OCALIVA® was granted a five-year new chemical entity, which expires on May 27, 2021. DRL admits that, according to information available on the FDA's website, OCALIVA® was granted an orphan drug exclusivity, which expires on May 27, 2023. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of any remaining allegations of this paragraph and, therefore, denies those allegations.

27. IPEL is the exclusive licensee of the patents-in-suit, which are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for OCALIVA®.

**RESPONSE:** DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

28. The RE286 Patent entitled, "Steroids as Agonists for FXR," was duly and lawfully issued by the USPTO on October 27, 2020. A true and correct copy of the RE286 Patent is attached as Exhibit B. RE286 is a reissue of U.S. Patent No. 7,138,390 ("the '390 Patent").

**RESPONSE:** DRL admits that, on its face, the RE286 patent is entitled "Steroids as Agonists for FXR." DRL admits that the USPTO issued the RE286 patent on October 27, 2020 as a reissue of the '390 patent, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the RE286 patent was attached to Plaintiffs' Complaint as Exhibit B.

29. The '673 Patent entitled, "Preparations and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on January 19, 2016. A true and correct copy of the '673 Patent is attached as Exhibit C.

**RESPONSE:** DRL admits that, on its face, the '673 Patent is entitled "Preparations and Uses of Obeticholic Acid." DRL admits that the USPTO issued the '673 Patent on January 19,

2016, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the '673 Patent was attached to Plaintiffs' Complaint as Exhibit C.

30. The '117 Patent entitled, "Preparations and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on August 14, 2018. A true and correct copy of the '117 Patent is attached as Exhibit D.

**RESPONSE:** DRL admits that, on its face, the '117 patent is entitled "Preparations and Uses of Obeticholic Acid." DRL admits that the USPTO issued the '117 patent on August 14, 2018, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the '117 patent was attached to Plaintiffs' Complaint as Exhibit D.

31. The '337 Patent entitled, "Compositions of Obeticholic Acid and Methods of Use," was duly and lawfully issued by the USPTO on August 21, 2018. A true and correct copy of the '337 Patent is attached as Exhibit E.

**RESPONSE:** DRL admits that, on its face, the '337 patent is entitled "Compositions of Obeticholic Acid and Methods of Use." DRL admits that the USPTO issued the '337 patent on August 21, 2018, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the '337 patent was attached to Plaintiffs' Complaint as Exhibit E.

32. The '073 Patent entitled, "Preparations and Uses of Obeticholic Acid," was duly and lawfully issued by the USPTO on January 8, 2019. A true and correct copy of the '073 Patent is attached as Exhibit F.

**RESPONSE:** DRL admits that, on its face, the '073 patent is entitled "Preparations and Uses of Obeticholic Acid." DRL admits that the USPTO issued the '073 patent on January 8, 2019, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the '073 patent was attached to Plaintiffs' Complaint as Exhibit F.

33. The '349 Patent entitled, "Compositions of Obeticholic Acid and Methods of Use," was duly and lawfully issued by the USPTO on August 25, 2020. A true and correct copy of the '349 Patent is attached as Exhibit G.

**RESPONSE:** DRL admits that, on its face, the '349 patent is entitled "Compositions of Obeticholic Acid and Methods of Use." DRL admits that the USPTO issued the '349 patent on August 25, 2020, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the '349 patent was attached to Plaintiffs' Complaint as Exhibit G.

34. The '549 Patent entitled, "Compositions of Obeticholic Acid and Methods of Use," was duly and lawfully issued by the USPTO on September 1, 2020. A true and correct copy of the '549 Patent is attached as Exhibit H.

**RESPONSE:** DRL admits that, on its face, the '549 patent is entitled "Compositions of Obeticholic Acid and Methods of Use." DRL admits that the USPTO issued the '549 patent on September 1, 2020, but specifically denies that the patent was duly and legally issued. DRL admits that a purported copy of the '549 patent was attached to Plaintiffs' Complaint as Exhibit H.

#### **DRL'S ANDA**

35. On information and belief, DRL has submitted or caused to be submitted ANDA No. 214899 to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of obeticholic acid tablets, as a purported generic version of OCALIVA®, prior to the expiration of the patents-in-suit.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. submitted ANDA No. 214899 to the FDA under 21 U.S.C. § 355(j). DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations contained in this paragraph.

36. On information and belief, on or about November 30, 2020, DRL mailed a letter to Intercept Pharmaceuticals regarding "Notification Pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95) Concerning ANDA No. 214899 and Ocaliva® (Obeticholic Acid Oral Tablets)" (the "Notice Letter"). The Notice Letter represented that DRL had submitted to the FDA the DRL ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the DRL ANDA before the expiration of patents listed in the Orange Book for OCALIVA®. Hence, DRL's purpose in submitting the DRL ANDA is to manufacture and market the ANDA Products before the expiration of the patents-in-suit.

**RESPONSE:** DRL admits to having sent a Notice Letter dated November 30, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. DRL states that the letter speaks for itself and no further answer is required. To the extent an answer is required, DRL admits that Dr. Reddy's Laboratories, Ltd. submitted ANDA No. 214899 to the FDA with a Paragraph IV certification. DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations contained in this paragraph.

37. DRL's Notice Letter stated that the Paragraph IV certification in the DRL ANDA alleges that the RE286, '673, '117, '337, '073, '349, and '549 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.<sup>1</sup>

**RESPONSE:** DRL admits to having sent a Notice Letter dated November 30, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. DRL states that the letter speaks for itself and no further answer is required. To the extent a response is required, DRL admits that its ANDA No. 214899 included a Paragraph IV certification with respect to the RE286, '673, '117, '337, '073, '349, and '549 Patents, alleging that the patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer or sale, or sale of the DRL ANDA product that is the subject of ANDA 214899. DRL denies any remaining allegations contained in this paragraph.

38. DRL's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Detailed Statement").

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<sup>1</sup> The Notice Letter also stated that the Paragraph IV certification in the DRL ANDA alleges that the '390 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products. The '390 Patent has been reissued as the RE286 Patent, which is asserted in this action.

**RESPONSE:** DRL admits to having sent a Notice Letter dated November 30, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. DRL states that the letter speaks for itself and no further answer is required. To the extent a response is required, DRL admits that its Notice Letter contained a detailed statement of the factual and legal basis of non-infringement and/or invalidity for the RE286, '673, '117, '337, '073, '349, and '549 Patents. DRL denies any remaining allegations contained in this paragraph.

39. On information and belief, Defendants have participated in the preparation and submission of the DRL ANDA, have provided material support to the preparation and submission of the DRL ANDA, and intend to support the further prosecution of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. submitted ANDA No. 214899 with the FDA and is seeking FDA approval of that application. DRL admits that Dr. Reddy's Laboratories, Inc. is the U.S. Agent for Dr. Reddy's Laboratories, Ltd. for purposes of regulatory submissions to the FDA with respect to ANDA No. 214899. DRL denies the remaining allegations in this paragraph.

40. On information and belief, if the FDA approves the DRL ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products within the United States, including within Delaware, or will import the ANDA Products into the United States, including Delaware.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies the remaining allegations in this paragraph.

41. Alternatively, on information and belief, if the FDA approves the DRL ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies the remaining allegations in this paragraph.

42. This action was filed within forty-five days of Intercept Pharmaceuticals' receipt of the Notice Letter.

**RESPONSE:** DRL admits the allegations in this paragraph.

**COUNT I**  
**INFRINGEMENT OF THE RE286 PATENT**

43. Plaintiffs incorporate by reference paragraphs 1–42 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–42 as if fully set forth herein.

44. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

45. Defendants have infringed the RE286 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the RE286 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

46. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the RE286 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

47. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the RE286 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the RE286 Patent and knowledge that they are encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

48. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the RE286 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

49. Defendants had actual knowledge of the RE286 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the RE286 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the RE286 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

50. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the RE286 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT II**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE RE286 PATENT**

51. Plaintiffs incorporate by reference paragraphs 1–50 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–50 as if fully set forth herein.

52. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

53. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

54. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

55. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the RE286 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the RE286 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

56. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the RE286 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding alleged infringement of the RE286 Patent. DRL denies the remaining allegations in this paragraph.

57. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

58. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT III**  
**INFRINGEMENT OF THE '673 PATENT**

59. Plaintiffs incorporate by reference paragraphs 1–58 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–58 as if fully set forth herein.

60. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

61. Defendants have infringed the '673 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '673 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

62. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '673 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

63. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '673 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '673 Patent and knowledge that they are encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

64. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '673 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

65. Defendants had actual knowledge of the '673 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '673 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '673 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

66. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '673 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT IV**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '673 PATENT**

67. Plaintiffs incorporate by reference paragraphs 1–66 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1-66 as if fully set forth herein.

68. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

69. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

70. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

71. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '673 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '673 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

72. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '673 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding alleged infringement of the '673 Patent. DRL denies the remaining allegations in this paragraph.

73. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

74. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT V**  
**INFRINGEMENT OF THE '117 PATENT**

75. Plaintiffs incorporate by reference paragraphs 1–74 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–74 as if fully set forth herein.

76. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

77. Defendants have infringed the '117 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '117 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

78. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '117 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

79. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '117 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '117 Patent and knowledge that they are encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

80. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '117 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

81. Defendants had actual knowledge of the '117 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '117 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '117 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

82. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '117 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT VI**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '117 PATENT**

83. Plaintiffs incorporate by reference paragraphs 1–82 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1-82 as if fully set forth herein.

84. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

85. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

86. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

87. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '117 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '117 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

88. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '117 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding alleged infringement of the '117 Patent. DRL denies the remaining allegations in this paragraph.

89. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

90. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT VII**  
**INFRINGEMENT OF THE '337 PATENT**

91. Plaintiffs incorporate by reference paragraphs 1–90 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1-90 as if fully set forth herein.

92. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

93. Defendants have infringed the '337 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '337 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

94. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '337 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

95. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '337 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '337 Patent and knowledge that they are encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

96. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '337 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

97. Defendants had actual knowledge of the '337 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '337 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '337 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

98. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '337 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT VIII**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '337 PATENT**

99. Plaintiffs incorporate by reference paragraphs 1–98 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1-98 as if fully set forth herein.

100. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

101. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

102. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

103. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '337 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '337 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

104. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '337 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding infringement of the '337 patent. DRL denies the remaining allegations in this paragraph.

105. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

106. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT IX**  
**INFRINGEMENT OF THE '073 PATENT**

107. Plaintiffs incorporate by reference paragraphs 1–106 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–106 as if fully set forth herein.

108. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval to offer from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

109. Defendants have infringed the '073 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '073 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

110. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '073 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

111. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '073 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '073 Patent and knowledge that it is encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

112. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '073 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

113. Defendants had actual knowledge of the '073 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '073 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '073 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

114. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '073 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT X**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '073 PATENT**

115. Plaintiffs incorporate by reference paragraphs 1–114 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–114 as if fully set forth herein.

116. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

117. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

118. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

119. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '073 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '073 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

120. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '073 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding alleged infringement of the '073 Patent. DRL denies the remaining allegations in this paragraph.

121. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

122. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT XI**  
**INFRINGEMENT OF THE '349 PATENT**

123. Plaintiffs incorporate by reference paragraphs 1–122 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–122 as if fully set forth herein.

124. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

125. Defendants have infringed the '349 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '349 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

126. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '349 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

127. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '349 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '349 Patent and knowledge that it is encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

128. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '349 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '349 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

129. Defendants had actual knowledge of the '349 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '349 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '349 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

130. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '349 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT XII**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '349 PATENT**

131. Plaintiffs incorporate by reference paragraphs 1–130 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–130 as if fully set forth herein.

132. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

133. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

134. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '349 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

135. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '349 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '349 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

136. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '349 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding alleged infringement of the '349 Patent. DRL denies the remaining allegations in this paragraph.

137. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

138. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT XIII**  
**INFRINGEMENT OF THE '549 PATENT**

139. Plaintiffs incorporate by reference paragraphs 1–138 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–138 as if fully set forth herein.

140. On information and belief, Defendants have submitted or caused the submission of the DRL ANDA to the FDA and continue to seek FDA approval of the DRL ANDA.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

141. Defendants have infringed the '549 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the DRL ANDA with a Paragraph IV certification and seeking FDA approval of the DRL ANDA prior to the expiration of the '549 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

142. On information and belief, if the DRL ANDA is approved, Defendants and their affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Products in the United States, directly infringing the '549 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

143. On information and belief, upon FDA approval of the DRL ANDA, Defendants will market and distribute the DRL ANDA Products to resellers, pharmacies, health care professionals, and end users of the DRL ANDA Products. Accompanying the DRL ANDA Products, Defendants will also knowingly and intentionally include a product label and insert

containing instructions for administering the DRL ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the DRL ANDA Products to directly infringe one or more claims of the '549 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '549 Patent and knowledge that it is encouraging infringement.

**RESPONSE:** DRL denies the allegations in this paragraph.

144. Defendants' commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Products would actively induce and/or contribute to infringement of the '549 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 214899, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent.

**RESPONSE:** DRL denies the allegations in this paragraph.

145. Defendants had actual knowledge of the '549 Patent prior to filing the DRL ANDA. Defendants filed the DRL ANDA without a reasonable basis for asserting the '549 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '549 Patent renders this case "exceptional" under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

146. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing and from actively inducing or contributing to the infringement of the '549 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

**RESPONSE:** DRL denies the allegations in this paragraph.

**COUNT XIV**  
**DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '549 PATENT**

147. Plaintiffs incorporate by reference paragraphs 1–146 as if fully set forth herein.

**RESPONSE:** DRL repeats and incorporates by reference its responses to paragraphs 1–146 as if fully set forth herein.

148. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**RESPONSE:** DRL denies the allegations in this paragraph.

149. On information and belief, if the DRL ANDA is approved, the ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, by or through Defendants and their affiliates.

**RESPONSE:** DRL admits that Dr. Reddy's Laboratories, Ltd. seeks approval to offer from FDA for the product that is the subject of ANDA No. 214899. DRL denies any remaining allegations in this paragraph.

150. On information and belief, Defendants know that health care professionals or patients will use the ANDA Products in accordance with the labeling sought by the DRL ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

151. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Products complained of herein will begin immediately after the FDA approves the DRL ANDA. Any such conduct before the '549 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '549 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

**RESPONSE:** DRL denies the allegations in this paragraph.

152. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '549 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

**RESPONSE:** This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that a justiciable controversy exists between Plaintiffs and DRL regarding alleged infringement of the '549 Patent. DRL denies the remaining allegations in this paragraph.

153. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**RESPONSE:** DRL denies the allegations in this paragraph.

154. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**RESPONSE:** DRL denies the allegations in this paragraph.

**RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF**

DRL denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or to any relief whatsoever, including any such relief specifically requested as against DRL.

**DRL'S AFFIRMATIVE DEFENSES**

Further answering the Complaint, DRL asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. DRL reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. DRL asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

**FIRST AFFIRMATIVE DEFENSE**  
**(Invalidity)**

The RE286, '673, '117, '337, '073, '349, and '549 Patents and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**SECOND AFFIRMATIVE DEFENSE**  
**(No Direct Infringement)**

DRL does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE286, '673, '117, '337, '073, '349, and '549 Patents. If the product that is the subject of ANDA No. 214899 were marketed, DRL would not infringe any valid and enforceable claim of the RE286, '673, '117, '337, '073, '349, and '549 Patents.

**THIRD AFFIRMATIVE DEFENSE**  
**(No Indirect Infringement)**

DRL has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the RE286, '673, '117, '337, '073, '349, and

'549 Patents. If the product that is the subject of ANDA No. 214899 were marketed, DRL would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the RE286, '673, '117, '337, '073, '349, and '549 Patents.

**FOURTH AFFIRMATIVE DEFENSE**  
**(Failure to State a Claim)**

The Complaint fails to state a claim for relief against DRL.

**FIFTH AFFIRMATIVE DEFENSE**  
**(No Exceptional Case)**

The Complaint fails to state a claim for relief against DRL for an exceptional case under 35 U.S.C. § 285.

**SIXTH AFFIRMATIVE DEFENSE**  
**(Additional Defenses)**

Any additional defenses that discovery may reveal.

WHEREFORE, DRL respectfully requests that Plaintiffs take nothing by way of their Complaint, that judgment be entered in favor of DRL, that DRL be awarded its attorneys' fees and costs, and all other just and proper relief.

**DR. REDDY'S LABORATORIES, INC. & DR. REDDY'S LABORATORIES, LTD.'S  
COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

For its Counterclaims against Intercept Pharmaceuticals, Inc. and Intercept Pharma Europe Ltd. (collectively, "Intercept"), Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL" or "Counterclaim Plaintiffs") state as follows:

**THE PARTIES**

1. Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having an address at 107 College Road East, Princeton, New Jersey 08540.

2. Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, Telangana, India.

3. On information and belief, Intercept Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Hudson Yards, 37th Floor, New York, New York 10001.

4. On information and belief, Intercept Pharma Europe Ltd. is a limited corporation organized under the laws of the United Kingdom, having a principal place of business at One Glass Wharf, Bristol, BS2 0ZX United Kingdom.

**JURISDICTION AND VENUE**

5. These Counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Intercept on the basis of, *inter alia*, its contacts with Delaware relating to the subject matter of this action, including having filed this suit.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

8. Upon information and belief, Intercept holds approved New Drug Application (“NDA”) No. 207999 for OCALIVA®, a product used in the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. The active ingredient in OCALIVA® is obeticholic acid. OCALIVA® is available in two strengths, 5 mg and 10 mg.

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

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

11. U.S. Patent No. RE48,286 (“the RE286 patent”), entitled “Steroids as Agonists for FXR,” was reissued by the United States Patent & Trademark Office (“USPTO”) on October 27, 2020.

12. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the RE286 patent.

13. U.S. Patent No. 9,238,673 (“the ’673 patent”), entitled “Preparations and Uses of Obeticholic Acid,” was issued by the USPTO on January 19, 2016.

14. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the ’673 patent.

15. U.S. Patent No. 10,047,117 (“the ’117 patent”), entitled “Preparations and Uses of Obeticholic Acid,” was issued by the USPTO on August 14, 2018.

16. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the ’117 patent.

17. U.S. Patent No. 10,052,337 (“the ’337 patent”), entitled “Compositions of Obeticholic Acid and Methods of Use,” was issued by the USPTO on August 21, 2018.

18. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the ’337 patent.

19. U.S. Patent No. 10,174,073 (“the ’073 patent”), entitled “Preparations and Uses of Obeticholic Acid,” was issued by the USPTO on January 8, 2019.

20. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the ’073 patent.

21. U.S. Patent No. 10,751,349 (“the ’349 patent”), entitled “Compositions of Obeticholic Acid and Methods of Use,” was issued by the USPTO on August 25, 2020.

22. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the ’349 patent.

23. U.S. Patent No. 10,758,549 (“the ’549 patent”), entitled “Compositions of Obeticholic Acid and Methods of Use,” was issued by the USPTO on September 1, 2020.

24. Upon information and belief, Intercept purports to be the owner of all right, title, and interests in the '549 patent.

25. Upon information and belief, Intercept caused the RE286, '673, '117, '337, '073, '349, and '549 patents to be listed in the Orange Book in connection with OCALIVA®.

26. Dr. Reddy's Laboratories, Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 214899 to obtain FDA approval to engage in the commercial manufacture, use, and sale of oral tablets containing 5 mg or 10 mg of obeticholic acid ("DRL's ANDA Product") prior to the expiration of the RE286, '673, '117, '337, '073, '349, and '549 patents.

27. DRL's ANDA No. 214899 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the RE286, '673, '117, '337, '073, '349, and '549 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Product.

28. By a letter dated November 30, 2020 (the "Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, DRL notified Intercept that ANDA No. 214899 includes a Paragraph IV certification with respect to the RE286, '673, '117, '337, '073, '349, and '549 patents. DRL's Notice Letter, which is hereby incorporated by reference as if fully set forth herein, contained a detailed statement of the factual and legal bases for DRL's Paragraph IV certification that the claims of the RE286, '673, '117, '337, '073, '349, and '549 patents are invalid, unenforceable, and/or will not be infringed by DRL's ANDA Product.

29. On January 13, 2021, Intercept filed this instant lawsuit alleging infringement of the RE286, '673, '117, '337, '073, '349, and '549 patents.

30. Intercept's conduct impairs DRL's ability to market DRL's ANDA Product. DRL thus seeks a declaratory judgment that DRL's ANDA Product does not infringe the RE286, '673, '117, '337, '073, '349, and '549 patents and/or that the patents are invalid and/or unenforceable.

**COUNT I**  
**(Declaratory Judgment of Non-Infringement of the RE286 Patent)**

31. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-30 of its Counterclaims as if fully set forth herein.

32. Intercept alleges ownership of the RE286 patent, and Intercept has brought claims against DRL alleging infringement of the RE286 patent.

33. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the RE286 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

34. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the RE286 patent.

35. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the RE286 patent and is not liable for such infringement.

36. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the RE286 patent.

**COUNT II**

**(Declaratory Judgment of Invalidity or Unenforceability of the RE286 Patent)**

37. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-36 of its Counterclaims as if fully set forth herein.

38. Intercept alleges ownership of the RE286 patent, and Intercept has brought claims against DRL alleging infringement of the RE286 patent.

39. One or more claims of the RE286 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

40. By way of example and not limitation, one or more claims of the RE286 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

41. The alleged invention of the RE286 patent does no more than combine familiar elements according to known compounds, formulas, and methods to yield predictable results. Any alleged improvement over the prior art set forth in the RE286 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the RE286 patent and would have had a reasonable expectation of success in doing so.

42. The subject matter claimed in the RE286 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

43. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

44. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the RE286 patent.

45. DRL is entitled to a declaration that all claims of the RE286 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**COUNT III**  
**(Declaratory Judgment of Non-Infringement of the '673 Patent)**

46. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-45 of its Counterclaims as if fully set forth herein.

47. Intercept alleges ownership of the '673 patent, and Intercept has brought claims against DRL alleging infringement of the '673 patent.

48. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '673 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

49. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '673 patent.

50. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '673 patent and is not liable for such infringement.

51. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '673 patent.

**COUNT IV**  
**(Declaratory Judgment of Invalidity or Unenforceability of the '673 Patent)**

52. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-51 of its Counterclaims as if fully set forth herein.

53. Intercept alleges ownership of the '673 patent, and Intercept has brought claims against DRL alleging infringement of the '673 patent.

54. One or more claims of the '673 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

55. By way of example and not limitation, one or more claims of the '673 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

56. The alleged invention of the '673 patent does no more than combine familiar elements according to known compositions to yield predictable results. Any alleged improvement over the prior art set forth in the '673 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '673 patent and would have had a reasonable expectation of success in doing so.

57. The subject matter claimed in the '673 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

58. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

59. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '673 patent.

60. DRL is entitled to a declaration that all claims of the '673 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**COUNT V**  
**(Declaratory Judgment of Non-Infringement of the '117 Patent)**

61. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-60 of its Counterclaims as if fully set forth herein.

62. Intercept alleges ownership of the '117 patent, and Intercept has brought claims against DRL alleging infringement of the '117 patent.

63. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '117 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

64. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '117 patent.

65. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '117 patent and is not liable for such infringement.

66. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '117 patent.

**COUNT VI**  
**(Declaratory Judgment of Invalidity or Unenforceability of the '117 Patent)**

67. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-66 of its Counterclaims, as if fully set forth herein.

68. Intercept alleges ownership of the '117 patent, and Intercept has brought claims against DRL alleging infringement of the '117 patent.

69. One or more claims of the '117 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

70. By way of example and not limitation, one or more claims of the '117 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

71. The alleged invention of the '117 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '117 patent is not more than the predictable use of prior art elements

according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '117 patent and would have had a reasonable expectation of success in doing so.

72. The subject matter claimed in the '117 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

73. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

74. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '117 patent.

75. DRL is entitled to a declaration that all claims of the '117 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**COUNT VII**  
**(Declaratory Judgment of Non-Infringement of the '337 Patent)**

76. DRL repeats, re-alleges and incorporates by reference the allegations in paragraphs 1-75 of its Counterclaims as if fully set forth herein.

77. Intercept alleges ownership of the '337 patent, and Intercept has brought claims against DRL alleging infringement of the '337 patent.

78. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '337 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

79. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '337 patent.

80. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '337 patent and is not liable for such infringement.

81. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '337 patent.

**COUNT VIII**  
**(Declaratory Judgment of Invalidity or Unenforceability of the '337 Patent)**

82. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-81 of its Counterclaims as if fully set forth herein.

83. Intercept alleges ownership of the '337 patent, and Intercept has brought claims against DRL alleging infringement of the '337 patent.

84. One or more claims of the '337 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

85. By way of example and not limitation, one or more claims of the '337 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

86. The alleged invention of the '337 patent does no more than combine familiar elements according to known compositions to yield predictable results. Any alleged improvement over the prior art set forth in the '337 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '337 patent and would have had a reasonable expectation of success in doing so.

87. The subject matter claimed in the '337 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

88. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

89. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '337 patent.

90. DRL is entitled to a declaration that all claims of the '337 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**COUNT IX**  
**(Declaratory Judgment of Non-Infringement of the '073 Patent)**

91. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-90 of its Counterclaims.

92. Intercept alleges ownership of the '073 patent, and Intercept has brought claims against DRL alleging infringement of the '073 patent.

93. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '073 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

94. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '073 patent.

95. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '073 patent and is not liable for such infringement.

96. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '073 patent.

**COUNT X**  
**(Declaratory Judgment of Invalidity or Unenforceability of the '073 Patent)**

97. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-96 of its Counterclaims as if fully set forth herein.

98. Intercept alleges ownership of the '073 patent, and Intercept has brought claims against DRL alleging infringement of the '073 patent.

99. One or more claims of the '073 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

100. By way of example and not limitation, one or more claims of the '073 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

101. The alleged invention of the '073 patent does no more than combine familiar elements according to known compositions to yield predictable results. Any alleged improvement over the prior art set forth in the '073 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '073 patent and would have had a reasonable expectation of success in doing so.

102. The subject matter claimed in the '073 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

103. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

104. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '073 patent.

105. DRL is entitled to a declaration that all claims of the '073 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**COUNT XI**  
**(Declaratory Judgment of Non-Infringement of the '349 Patent)**

106. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-105 of its Counterclaims.

107. Intercept alleges ownership of the '349 patent, and Intercept has brought claims against DRL alleging infringement of the '349 patent.

108. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '349 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

109. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '349 patent.

110. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '349 patent and is not liable for such infringement.

111. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '349 patent.

**COUNT XII**  
**(Declaratory Judgment of Invalidity or Unenforceability of the '349 Patent)**

112. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-111 of its Counterclaims as if fully set forth herein.

113. Intercept alleges ownership of the '349 patent, and Intercept has brought claims against DRL alleging infringement of the '349 patent.

114. One or more claims of the '349 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

115. By way of example and not limitation, one or more claims of the '349 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

116. The alleged invention of the '349 patent does no more than combine familiar elements according to known compositions to yield predictable results. Any alleged improvement over the prior art set forth in the '349 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '349 patent and would have had a reasonable expectation of success in doing so.

117. The subject matter claimed in the '349 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was

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

118. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

119. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '349 patent.

120. DRL is entitled to a declaration that all claims of the '349 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**COUNT XIII**  
**(Declaratory Judgment of Non-Infringement of the '549 Patent)**

121. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-120 of its Counterclaims.

122. Intercept alleges ownership of the '549 patent, and Intercept has brought claims against DRL alleging infringement of the '549 patent.

123. The manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '549 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

124. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use,

offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '549 patent.

125. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '549 patent and is not liable for such infringement.

126. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's ANDA Product would not infringe any valid or enforceable claim of the '549 patent.

**COUNT XIV**  
**(Declaratory Judgment of Invalidity or Unenforceability of the '549 Patent)**

127. DRL repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-126 of its Counterclaims as if fully set forth herein.

128. Intercept alleges ownership of the '549 patent, and Intercept has brought claims against DRL alleging infringement of the '549 patent.

129. One or more claims of the '549 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

130. By way of example and not limitation, one or more claims of the '549 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in DRL's Notice Letter that Intercept received.

131. The alleged invention of the '549 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '549 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to

combine the teachings of the prior art to achieve the alleged invention of the '549 patent and would have had a reasonable expectation of success in doing so.

132. The subject matter claimed in the '549 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

133. DRL reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

134. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of DRL's ANDA No. 214899 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '549 patent.

135. DRL is entitled to a declaration that all claims of the '549 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

**PRAAYER FOR RELIEF**

WHEREFORE, DRL respectfully requests judgment in its favor and against Plaintiffs/Counterclaim Defendants as follows:

- a. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the RE286 patent;
- b. declaring that the claims of the RE286 patent are invalid;

- c. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the '673 patent;
- d. declaring that the claims of the '673 patent are invalid;
- e. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the '117 patent;
- f. declaring that the claims of the '117 patent are invalid;
- g. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the '337 patent;
- h. declaring that the claims of the '337 patent are invalid;
- i. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the '073 patent;
- j. declaring that the claims of the '073 patent are invalid;
- k. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the '349 patent;
- l. declaring that the claims of the '349 patent are invalid;
- m. declaring that DRL has not infringed and will not infringe any valid and enforceable claim of the '549 patent;
- n. declaring that the claims of the '549 patent are invalid;
- o. declaring this case exceptional and awarding DRL its attorneys' fees, costs, and expenses in this action under 35 U.S.C § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

p. awarding such other and further relief as this Court deems just and proper.

Dated: February 5, 2021

YOUNG CONAWAY STARGATT &  
TAYLOR, LLP

*OF COUNSEL:*

George C. Lombardi  
Maureen L. Rurka  
Kevin E. Warner  
Bryce A. Cooper  
Alison M. Heydorn  
WINSTON & STRAWN LLP  
35 West Wacker Drive  
Chicago, IL 60601  
(312) 558-5600  
GLombard@winston.com  
MRurka@winston.com  
KWarner@winston.com  
BCooper@winston.com  
AHeydorn@winston.com

/s/ Anne Shea Gaza  
Anne Shea Gaza (No. 4093)  
Samantha G. Wilson (No. 5816)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
agaza@ycst.com  
swilson@ycst.com

*Attorneys for Defendants/Counterclaim  
Plaintiffs Dr. Reddy's Laboratories, Inc. and  
Dr. Reddy's Laboratories, Ltd.*

Jovial Wong  
Claire A. Fundakowski  
WINSTON & STRAWN LLP  
1901 L Street, N.W.  
Washington, D.C. 20006  
(202) 282-5000  
JWong@winston.com  
CFundakowski@winston.com

**CERTIFICATE OF SERVICE**

I, Anne Shea Gaza, Esquire, hereby certify that on February 5, 2021, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered participants.

I further certify that on February 5, 2021, I caused the foregoing document to be served by e-mail on the following counsel of record:

Jack B. Blumenfeld  
Jeremy A. Tigan  
Andrew M. Moshos  
MORRIS, NICHOLS, ARSHT  
& TUNNELL LLP  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
[jblumenfeld@mnat.com](mailto:jblumenfeld@mnat.com)  
[jtigan@mnat.com](mailto:jtigan@mnat.com)  
[amoshos@mnat.com](mailto:amoshos@mnat.com)

Christopher Sipes  
Jeffrey Elikan  
Megan Keane  
Jeremy Cobb  
Laura Dolbow  
Mary Swears  
COVINGTON & BURLING LLP  
One CityCenter  
850 Tenth Street NW  
Washington, DC 20001-4956  
[csipes@cov.com](mailto:csipes@cov.com)  
[jelikan@cov.com](mailto:jelikan@cov.com)  
[mkeane@cov.com](mailto:mkeane@cov.com)  
[jcobb@cov.com](mailto:jcobb@cov.com)  
[ldolbow@cov.com](mailto:ldolbow@cov.com)  
[mswears@cov.com](mailto:mswears@cov.com)

*Attorneys for Plaintiffs*

Dated: February 5, 2021

YOUNG CONAWAY STARGATT  
& TAYLOR, LLP

/s/ Anne Shea Gaza

Anne Shea Gaza (No. 4093)  
Samantha G. Wilson (No. 5816)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
[agaza@ycst.com](mailto:agaza@ycst.com)  
[swilson@ycst.com](mailto:swilson@ycst.com)

*Attorneys for Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.*