IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC. and INTERCEPT PHARMA EUROPE LTD.,	)	
Plaintiffs/Counterclaim Defendants,	)	
v.	)	C.A. No. 20-1154 (MN)
AMNEAL EU, LIMITED and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,	)	
Defendants/Counterclaim Plaintiffs.	)	

DEFENDANTS AMNEAL EU, LIMITED AND AMNEAL PHARMACEUTICALS OF NEW YORK, LLC'S ANSWER AND COUNTERCLAIMS TO PLAINTIFFS' FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants Amneal EU, Limited and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal"), 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") First Amended Complaint for Patent Infringement ("Complaint") as follows:

Pursuant to Fed. R. Civ. P. 8(b)(3), Amneal denies all allegations in Plaintiffs' Complaint, except those expressly admitted below. This pleading is based upon Amneal'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. 214810 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. 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: Amneal admits that Plaintiffs' Complaint against Amneal is for infringement of United States Patent Nos. 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. Amneal states that the filing dates of the patents-in-suit speak for themselves.

Amneal further admits that Amneal EU, Limited submitted an Abbreviated New Drug Application ("ANDA") No. 214810 seeking U.S. Food and Drug Administration ("FDA") approval to market a generic obeticholic acid product, which Plaintiffs market as a product called OCALIVA®, prior to the expiration of the patents-in-suit. Amneal 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: Amneal admits that Plaintiffs' Complaint against Amneal 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. Amneal 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, Amneal admits that Plaintiff Intercept Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware. Amneal 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, Amneal admits that Plaintiff Intercept Pharmaceutical Europe Limited is a corporation organized under the laws of the United Kingdom. Amneal 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 Amneal EU, Limited is a limited corporation organized and existing under the laws of Ireland, having its principal place of business at 70 Sir John Rogerson's Quay, D02 R296 Dublin, Ireland.

RESPONSE: Amneal admits Amneal EU, Limited is a limited corporation organized and existing under the laws of Ireland, having its principal place of business at 70 Sir John Rogerson's Quay, D02 R296 Dublin, Ireland.

6. On information and belief, defendant Amneal Pharmaceuticals of New York, LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. On information and belief, Amneal Pharmaceuticals of New York, LLC is the U.S. agent for Amneal EU, Limited.

RESPONSE: Amneal admits Amneal Pharmaceuticals of New York, LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Amneal further

admits that Amneal Pharmaceuticals of New York, LLC is the U.S. agent for Amneal EU, Limited for purposes of ANDA No. 214810.

7. On information and belief, Amneal Pharmaceuticals of New York, LLC acts at the direction and for the benefit of Amneal EU, Limited and is controlled and/or dominated by Amneal EU, Limited.

RESPONSE: Amneal admits that Amneal EU, Limited, and Amneal Pharmaceuticals of New York, LLC are both direct or indirect subsidiaries of Amneal Pharmaceuticals LLC. Amneal admits that Amneal Pharmaceuticals of New York, LLC is the U.S. agent for Amneal EU, Limited for purposes of ANDA No. 214810. Amneal denies any remaining allegations in this paragraph.

8. On further information and belief, Amneal EU, Limited and Amneal Pharmaceuticals of New York, LLC 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: Amneal admits that Amneal EU, Limited, and Amneal Pharmaceuticals of New York, LLC are both direct or indirect subsidiaries of Amneal Pharmaceuticals LLC. Amneal further admits that Amneal Pharmaceuticals of New York, LLC is the U.S. agent for Amneal EU, Limited for purposes of ANDA No. 214810. Amneal denies any remaining allegations in this paragraph.

9. On information and belief, Defendants prepared and submitted ANDA No. 214810 (the "Amneal ANDA") and continue to seek FDA approval of that application.

RESPONSE: Amneal admits that Amneal EU, Limited submitted ANDA No. 214810 to the FDA and is seeking FDA approval of that application. Amneal further admits that Amneal Pharmaceuticals of New York, LLC is the U.S. agent for Amneal EU, Limited for purposes of ANDA No. 214810. Amneal denies any remaining allegations in this paragraph.

10. On information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell the products described in the Amneal ANDA (the "Amneal ANDA

Products" or "ANDA Products") throughout the United States, including in the State of Delaware, in the event the FDA approves the Amneal ANDA.

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

11. 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, Amneal 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. Amneal admits that this Court has jurisdiction over patent infringement cases pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-02.

12. 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 Amneal ANDA Products in Delaware upon approval of the Amneal ANDA.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Amneal does not contest that this Court has personal jurisdiction over Amneal for the purposes of this action only. Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations contained in this paragraph.

13. 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal 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.

14. Amneal Pharmaceuticals of New York, LLC is a limited liability company organized and existing under the laws of the State of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Amneal does not contest that this Court has personal jurisdiction for the purposes of this action only. Amneal admits Amneal Pharmaceuticals of New York, LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Amneal denies any remaining allegations contained in this paragraph.

15. On information and belief, Amneal Pharmaceuticals of New York, LLC is licensed to sell generic and proprietary pharmaceutical products in Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal 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.

16. On information and belief, Amneal Pharmaceuticals of New York, LLC holds a current and valid "Pharmacy-Wholesale" License in Delaware.

RESPONSE: Amneal admits that Amneal Pharmaceuticals of New York, LLC holds a current and valid "Pharmacy-Wholesale" License in Delaware. Amneal denies any remaining allegations contained in this paragraph.

17. 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 July 17, 2020 sent by Amneal Pharmaceuticals of New York, LLC to Intercept Pharmaceuticals pursuant to 21 U.S.C. § 355(j)(2)(b), Defendants prepared and filed the Amneal ANDA with the intention of seeking to market the Amneal ANDA Products nationwide, including within this judicial district.

RESPONSE: Amneal admits that Amneal Pharmaceuticals of New York, LLC sent a Paragraph IV Notice Letter to Intercept Pharmaceuticals, Inc. on July 17, 2020 pursuant to 21 U.S.C. § 355(j)(2)(b) to notify Intercept that Amneal had filed ANDA No. 214810. Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. The remainder of this paragraph contains conclusions of law for which no response is required. To the extent a response is required, Amneal denies the remaining allegations in this paragraph.

18. On information and belief, Defendants plan to sell the Amneal ANDA Products in Delaware, list the Amneal ANDA Products on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal 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.

19. On information and belief, Defendants know and intend that the Amneal 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 Amneal ANDA Products.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Amneal denies Plaintiffs will suffer any injury. Amneal otherwise 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. Defendants 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., Otsuka Pharmaceutical Co., Ltd. et al. v. Amneal Pharmaceuticals LLC et al.*, No. 19-1952 (LPS) (D. Del. Mar. 16, 2020); *Par Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals Company GmbH et al.*, No. 19-712 (CFC) (D. Del. June 12, 2019); *Genentech, Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, No. 19-190 (RGA) (D. Del. Mar. 22, 2019); *H. Lundbeck A/S et al. v. Amneal Pharmaceuticals LLC et al*., No. 18-175 (LPS) (D. Del. Apr. 6, 2018); *Amgen Inc. v. Amneal Pharmaceuticals LLC et al*., No. 16-925 (GMS) (D. Del. Dec. 2, 2016).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Amneal does not contest that this Court has personal jurisdiction over Amneal for the purposes of this action only. Amneal admits that it has engaged in patent litigation concerning FDA-approved drug products in this judicial district. Amneal denies any remaining allegations contained in this paragraph.

21. Additionally, this Court has personal jurisdiction over Amneal EU, Limited 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) Amneal EU, Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Amneal EU, Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the Amneal 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 Amneal EU, Limited satisfies due process.

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

22. Venue is proper in this district for Amneal EU, Limited pursuant to 28 U.S.C. §§ 1391(c)(3) because, *inter alia*, Amneal EU, Limited is a corporation organized and existing under the laws of Ireland 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, Amneal does not contest that this Court has personal jurisdiction over Amneal EU, Limited and Amneal does not contest venue over Amneal EU,

Limited for the purposes of this action only. Amneal admits that Amneal EU, Limited is a private limited corporation organized and existing under the laws of Ireland. Amneal denies any remaining allegations contained in this paragraph.

23. Venue is proper in this district for Amneal Pharmaceuticals of New York, LLC pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Amneal Pharmaceuticals of New York, LLC is a limited liability company organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Amneal does not contest that this Court has personal jurisdiction over Amneal Pharmaceuticals of New York, LLC and Amneal does not contest venue over Amneal Pharmaceuticals of New York, LLC for the purposes of this action only. Amneal admits that Amneal Pharmaceuticals of New York, LLC is a private limited corporation organized and existing under the laws of the State of Delaware. Amneal denies any remaining allegations contained in this paragraph.

INTERCEPT'S APPROVED OCALIVA® DRUG PRODUCT AND PATENTS

24. 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, Amneal 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, Amneal admits that the active ingredient in OCALIVA® is obeticholic acid, and OCALIVA® is available in two strengths, 5 mg and 10 mg. Amneal admits that a purported copy of the OCALIVA® prescribing label was attached to Plaintiffs' Complaint as Exhibit A. Amneal 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.

25. 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, Amneal 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. Amneal 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. Amneal admits that, according to information available on the FDA's website, OCALIVA® was granted an orphan drug exclusivity, which expires on May 27, 2023. Amneal 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. 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: Amneal 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.

27. 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 B.

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

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

28. 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 C.

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

29. 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 D.

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

30. 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 E.

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

31. 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 F.

RESPONSE: Amneal admits that, on its face, the '349 patent is entitled "Compositions of Obeticholic Acid and Methods of Use." Amneal admits that the USPTO issued the '349 patent

on August 25, 2020, but specifically denies that the patent was duly and legally issued. Amneal admits that a purported copy of the '349 patent was attached to Plaintiffs' Complaint as Exhibit F.

32. 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 G.

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

AMNEAL'S ANDA

33. On information and belief, Amneal has submitted or caused to be submitted ANDA No. 214810 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: Amneal admits that Amneal EU, Limited submitted ANDA No. 214810 to the FDA under 21 U.S.C. § 355(j). Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's obeticholic acid ANDA product that is the subject of ANDA No. 214810. Amneal denies any remaining allegations contained in this paragraph.

34. On information and belief, on or about July 17, 2020, Amneal Pharmaceuticals of New York, LLC mailed a letter to Intercept Pharmaceuticals regarding "Notice of Paragraph IV Certification of U.S. Patent Nos. 9,238,673; 10,047,117; 10,052,337; and 10,174,073 Concerning ANDA No. 214810 for Obeticholic Acid tablets, 5 mg and 10 mg" (the "First Notice Letter"). The First Notice Letter represented that Amneal had submitted to the FDA the Amneal 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 Amneal ANDA before the expiration of patents listed in the Orange Book for OCALIVA®. Hence, Amneal's purpose in submitting the Amneal ANDA is to manufacture and market the ANDA Products before the expiration of the patents-in-suit.

RESPONSE: Amneal admits to having sent a Notice Letter dated July 17, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Amneal states that the letter speaks for itself and no further answer is required. To the extent an answer is required, Amneal admits that

Amneal EU, Limited submitted ANDA No. 214810 to the FDA with a Paragraph IV certification. Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's obeticholic acid ANDA product that is the subject of ANDA No. 214810. Amneal denies any remaining allegations contained in this paragraph.

35. Amneal's First Notice Letter stated that the Paragraph IV certification in the Amneal ANDA alleges that the '673, '117, '337, and '073 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

RESPONSE: Amneal admits to having sent a Notice Letter dated July 17, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Amneal states that the letter speaks for itself and no further answer is required. To the extent a response is required, Amneal admits that its ANDA No. 214810 included a Paragraph IV certification with respect to the '673, '117, '337, and '073 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 Amneal ANDA product that is the subject of ANDA 214810. Amneal denies any remaining allegations contained in this paragraph.

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

RESPONSE: Amneal admits to having sent a Notice Letter dated July 17, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Amneal states that the letter speaks for itself and no further answer is required. To the extent a response is required, Amneal admits that its Notice Letter contained a detailed statement of the factual and legal basis of non-infringement and/or invalidity for the '673 patent, '117 patent, '337 patent, and '073 patent. Amneal denies any remaining allegations contained in this paragraph.

37. On information and belief, Defendants have participated in the preparation and submission of the Amneal ANDA, have provided material support to the preparation and

submission of the Amneal ANDA, and intend to support the further prosecution of the Amneal ANDA.

RESPONSE: Amneal admits that Amneal EU, Limited submitted ANDA No. 214810 with the FDA and is seeking FDA approval of that application. Amneal admits that Amneal Pharmaceuticals New York, LLC acts as the U.S. agent for Amneal EU, Limited for purposes of regulatory submissions to the FDA with respect to ANDA No. 214810. Amneal 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.

38. On information and belief, on or about October 9, 2020, Defendants mailed a letter to Intercept Pharmaceuticals regarding a purported "Notice of Paragraph IV Certification of U.S. Patent Nos. 10,751,349 and 10,758,549 Concerning ANDA No. 214810 for Obeticholic Acid tablets, 5 mg and 10 mg" (the "Second Notice Letter"). The Second Notice Letter represented that Amneal had submitted to the FDA a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Amneal ANDA before the expiration of patents listed in the Orange Book for OCALIVA®, the '349 and '549 Patents. Hence, Amneal's purpose in submitting the Amneal ANDA is to manufacture and market the ANDA Products before the expiration of the '349 and '549 Patents.

RESPONSE: Amneal admits to having sent a Notice Letter dated October 9, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Amneal states that the letter speaks for itself and no further answer is required. To the extent an answer is required, Amneal admits that Amneal EU, Limited submitted ANDA No. 214810 to the FDA with a Paragraph IV certification. Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's obeticholic acid ANDA product that is the subject of ANDA No. 214810. Amneal denies any remaining allegations contained in this paragraph.

39. Amneal's Second Notice Letter stated that the Paragraph IV certification in the Amneal ANDA alleges that the '349 and '549 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

RESPONSE: Amneal admits to having sent a Notice Letter dated October 9, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Amneal states that the letter

speaks for itself and no further answer is required. To the extent a response is required, Amneal admits that its ANDA No. 214810 included a Paragraph IV certification with respect to the '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 Amneal ANDA product that is the subject of ANDA 214810. Amneal denies any remaining allegations contained in this paragraph.

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

RESPONSE: Amneal admits to having sent a Notice Letter dated October 9, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Amneal states that the letter speaks for itself and no further answer is required. To the extent a response is required, Amneal admits that its Notice Letter contained a detailed statement of the factual and legal basis of non-infringement and/or invalidity for the '349 patent and '549 patent. Amneal denies any remaining allegations contained in this paragraph.

41. On information and belief, if the FDA approves the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal specifically denies that the manufacture, use, offer for sale, sale, or importation of Amneal's ANDA product that is the subject of ANDA No. 214810 will directly infringe any valid claim of the patents-in-suit.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal specifically denies that the manufacture, use, offer for sale, sale, or importation of Amneal's ANDA product that is the subject of ANDA No. 214810 will actively induce and/or contribute to its alleged infringement of the patents-in-suit.

43. This action was filed within forty-five days of Intercept Pharmaceuticals' receipt of the First Notice Letter. This First Amended Complaint is being filed within forty-five days of receipt of the Second Notice Letter.

RESPONSE: Amneal admits that its first Notice Letter was dated July 17, 2020, which is 42 days before the filing date of Intercept's original complaint in this action. Amneal further admits that its second Notice Letter was dated October 9, 2020, which is 38 days before the filing date of Intercept's First Amended Complaint in this action.

COUNT I
[ALLEGED] INFRINGEMENT OF THE '673 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-43 as if fully set forth herein.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

47. On information and belief, if the Amneal 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: Amneal denies the allegations in this paragraph.

48. On information and belief, upon FDA approval of the Amneal ANDA, Defendants will market and distribute the Amneal ANDA Products to resellers, pharmacies, health care professionals, and end users of the Amneal ANDA Products. Accompanying the Amneal ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Amneal ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal 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: Amneal denies the allegations in this paragraph.

49. 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. 214810, 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: Amneal denies the allegations in this paragraph.

50. Defendants had actual knowledge of the '673 Patent prior to filing the Amneal ANDA. Defendants filed the Amneal 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: Amneal denies the allegations in this paragraph.

51. 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: Amneal denies the allegations in this paragraph.

COUNT II
DECLARATORY JUDGMENT OF [ALLEGED] INFRINGEMENT
OF THE '673 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-51 as if fully set forth herein.

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

RESPONSE: Amneal denies the allegations in this paragraph.

54. On information and belief, if the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

55. 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 Amneal 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: Amneal denies the allegations in this paragraph.

56. 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 Amneal 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: Amneal denies the allegations in this paragraph.

57. 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, Amneal admits that a justiciable controversy exists between Plaintiffs and Amneal regarding infringement of the '673 patent.

58. 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: Amneal denies the allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

COUNT III
[ALLEGED] INFRINGEMENT OF THE '117 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-59 as if fully set forth herein.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

63. On information and belief, if the Amneal 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: Amneal denies the allegations in this paragraph.

64. On information and belief, upon FDA approval of the Amneal ANDA, Defendants will market and distribute the Amneal ANDA Products to resellers, pharmacies, health care professionals, and end users of the Amneal ANDA Products. Accompanying the Amneal ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Amneal ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal 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: Amneal denies the allegations in this paragraph.

65. 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. 214810, 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: Amneal denies the allegations in this paragraph.

66. Defendants had actual knowledge of the '117 Patent prior to filing the Amneal ANDA. Defendants filed the Amneal 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: Amneal denies the allegations in this paragraph.

67. 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: Amneal denies the allegations in this paragraph.

COUNT IV
DECLARATORY JUDGMENT OF [ALLEGED] INFRINGEMENT
OF THE '117 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-67 as if fully set forth herein.

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

RESPONSE: Amneal denies the allegations in this paragraph.

70. On information and belief, if the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

71. 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 Amneal 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: Amneal denies the allegations in this paragraph.

72. 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 Amneal 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: Amneal denies the allegations in this paragraph.

73. 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, Amneal admits that a justiciable controversy exists between Plaintiffs and Amneal regarding infringement of the '117 patent.

74. 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: Amneal denies the allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

COUNT V
[ALLEGED] INFRINGEMENT OF THE '337 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-75 as if fully set forth herein.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

79. On information and belief, if the Amneal 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: Amneal denies the allegations in this paragraph.

80. On information and belief, upon FDA approval of the Amneal ANDA, Defendants will market and distribute the Amneal ANDA Products to resellers, pharmacies, health care professionals, and end users of the Amneal ANDA Products. Accompanying the Amneal ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Amneal ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal 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: Amneal denies the allegations in this paragraph.

81. 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. 214810, 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: Amneal denies the allegations in this paragraph.

82. Defendants had actual knowledge of the '337 Patent prior to filing the Amneal ANDA. Defendants filed the Amneal 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: Amneal denies the allegations in this paragraph.

83. 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: Amneal denies the allegations in this paragraph.

COUNT VI
DECLARATORY JUDGMENT OF [ALLEGED] INFRINGEMENT
OF THE '337 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-83 as if fully set forth herein.

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

RESPONSE: Amneal denies the allegations in this paragraph.

86. On information and belief, if the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

87. 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 Amneal 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: Amneal denies the allegations in this paragraph.

88. 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 Amneal 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: Amneal denies the allegations in this paragraph.

89. 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, Amneal admits that a justiciable controversy exists between Plaintiffs and Amneal regarding infringement of the '337 patent.

90. 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: Amneal denies the allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

COUNT VII
[ALLEGED] INFRINGEMENT OF THE '073 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-91 as if fully set forth herein.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

95. On information and belief, if the Amneal 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: Amneal denies the allegations in this paragraph.

96. On information and belief, upon FDA approval of the Amneal ANDA, Defendants will market and distribute the Amneal ANDA Products to resellers, pharmacies, health care professionals, and end users of the Amneal ANDA Products. Accompanying the Amneal ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Amneal ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal 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: Amneal denies the allegations in this paragraph.

97. 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. 214810, 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: Amneal denies the allegations in this paragraph.

98. Defendants had actual knowledge of the '073 Patent prior to filing the Amneal ANDA. Defendants filed the Amneal 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: Amneal denies the allegations in this paragraph.

99. 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: Amneal denies the allegations in this paragraph.

COUNT VIII
DECLARATORY JUDGMENT OF [ALLEGED] INFRINGEMENT
OF THE '073 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-99 as if fully set forth herein.

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

RESPONSE: Amneal denies the allegations in this paragraph.

102. On information and belief, if the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

103. 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 Amneal 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: Amneal denies the allegations in this paragraph.

104. 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 Amneal 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: Amneal denies the allegations in this paragraph.

105. 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, Amneal admits that a justiciable controversy exists between Plaintiffs and Amneal regarding infringement of the '073 patent.

106. 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: Amneal denies the allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

COUNT IX
[ALLEGED] INFRINGEMENT OF THE '349 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-107 as if fully set forth herein.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

111. On information and belief, if the Amneal 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: Amneal denies the allegations in this paragraph.

112. On information and belief, upon FDA approval of the Amneal ANDA, Defendants will market and distribute the Amneal ANDA Products to resellers, pharmacies, health care professionals, and end users of the Amneal ANDA Products. Accompanying the Amneal ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Amneal ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal 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: Amneal denies the allegations in this paragraph.

113. 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. 214810, 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: Amneal denies the allegations in this paragraph.

114. Defendants had actual knowledge of the '349 Patent prior to filing the Paragraph IV certification to the Amneal ANDA, and were aware that submitting a Paragraph IV certification requesting FDA approval prior to the expiration of the '349 Patent would constitute an act of infringement of the '349 Patent. Defendants filed the Paragraph IV certification to the Amneal 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: Amneal denies the allegations in this paragraph.

115. 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: Amneal denies the allegations in this paragraph.

COUNT X
DECLARATORY JUDGMENT OF [ALLEGED] INFRINGEMENT
OF THE '349 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-115 as if fully set forth herein.

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

RESPONSE: Amneal denies the allegations in this paragraph.

118. On information and belief, if the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

119. 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 Amneal 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: Amneal denies the allegations in this paragraph.

120. 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 Amneal 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: Amneal denies the allegations in this paragraph.

121. 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, Amneal admits that a justiciable controversy exists between Plaintiffs and Amneal regarding infringement of the '349 patent.

122. 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: Amneal denies the allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

COUNT XI
[ALLEGED] INFRINGEMENT OF THE '549 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-123 as if fully set forth herein.

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

RESPONSE: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

127. On information and belief, if the Amneal 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: Amneal denies the allegations in this paragraph.

128. On information and belief, upon FDA approval of the Amneal ANDA, Defendants will market and distribute the Amneal ANDA Products to resellers, pharmacies, health care professionals, and end users of the Amneal ANDA Products. Accompanying the Amneal ANDA Products, Defendants will also knowingly and intentionally include a product label and insert containing instructions for administering the Amneal ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal 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: Amneal denies the allegations in this paragraph.

129. 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. 214810, 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: Amneal denies the allegations in this paragraph.

130. Defendants had actual knowledge of the '549 Patent prior to filing the Paragraph IV certification to the Amneal ANDA, and were aware that submitting a Paragraph IV certification requesting FDA approval prior to the expiration of the '549 Patent would constitute an act of infringement of the '549 Patent. Defendants filed the Paragraph IV certification to the Amneal 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: Amneal denies the allegations in this paragraph.

131. 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: Amneal denies the allegations in this paragraph.

COUNT XII
DECLARATORY JUDGMENT OF [ALLEGED] INFRINGEMENT
OF THE '549 PATENT

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

RESPONSE: Amneal repeats and incorporates by reference its responses to paragraphs 1-131 as if fully set forth herein.

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

RESPONSE: Amneal denies the allegations in this paragraph.

134. On information and belief, if the Amneal 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: Amneal admits that Amneal EU, Limited seeks approval to offer to sell and/or sell Amneal's ANDA product that is the subject of ANDA No. 214810 throughout the United States. Amneal denies any remaining allegations in this paragraph.

135. 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 Amneal 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: Amneal denies the allegations in this paragraph.

136. 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 Amneal 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: Amneal denies the allegations in this paragraph.

137. 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, Amneal admits that a justiciable controversy exists between Plaintiffs and Amneal regarding infringement of the '549 patent.

138. 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: Amneal denies the allegations in this paragraph.

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

RESPONSE: Amneal denies the allegations in this paragraph.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

Amneal 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 Amneal.

AMNEAL'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Amneal 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. Amneal reserves the right to amend this Answer with additional defenses as further information is obtained in discovery.

Amneal 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 '673 patent, '117 patent, '337 patent, '073 patent, '549 patent, and '349 patent 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)

Amneal does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '673 patent, '117 patent, '337 patent, '073 patent, '549 patent, and '349 patent. If the product that is the subject of ANDA No. 214810 were marketed, Amneal would not infringe any valid and enforceable claim of the '673 patent, '117 patent, '337 patent, '073 patent, '549 patent, and '349 patent.

THIRD AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Amneal has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '673 patent, '117 patent, '337 patent, '073 patent, '549 patent, and '349 patent. If the product that is the subject of ANDA No. 214810 were marketed, Amneal would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '673 patent, '117 patent, '337 patent, '073 patent, '549 patent, and '349 patent.

FOURTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

FIFTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

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

SIXTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

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

AMNEAL EU, LIMITED AND AMNEAL PHARMACEUTICALS OF NEW YORK, LLC'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its Counterclaims against Intercept Pharmaceuticals, Inc. and Intercept Pharma Europe Ltd. (collectively, "Intercept"), Amneal EU, Limited and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal" or "Counterclaim Plaintiffs") state as follows:

THE PARTIES

1. Amneal EU, Limited is a limited corporation organized and existing under the laws of Ireland, having its principal place of business at 70 Sir John Rogerson's Quay, D02 R296 Dublin, Ireland.

2. Amneal Pharmaceuticals of New York, LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719.

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. 9,238,673 ("the '673 patent"), entitled "Preparations and Uses of Obeticholic Acid," was issued by the United States Patent & Trademark Office ("USPTO") on January 19, 2016.

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

13. 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.

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

15. 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.

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

17. 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.

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

19. 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.

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

21. 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.

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

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

24. Amneal EU, Limited submitted Abbreviated New Drug Application ("ANDA") No. 214810 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 ("Amneal's ANDA Product") prior to the expiration of the '673 patent, '117 patent, '337 patent, '073 patent, '349 patent, and '549 patent.

25. Amneal's ANDA No. 214810 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '673 patent, '117 patent, '337 patent, '073 patent, '349 patent, and '549 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Amneal's ANDA Product.

26. By a letter dated July 17, 2020 (the "Notice Letter I"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Amneal notified Intercept that ANDA No. 214810 includes a Paragraph IV certification with respect to the '673 patent, '117 patent, '337 patent, and '073 patent. Amneal's Notice Letter I, which is hereby incorporated by reference as if fully set forth herein, contained a detailed statement of the factual and legal bases for Amneal's Paragraph IV certification that the claims of the '673 patent, '117 patent, '337 patent, and '073 patent are invalid, unenforceable, and/or will not be infringed by Amneal's ANDA Product.

27. On August 28, 2020, Intercept filed this instant lawsuit alleging infringement of the '673 patent, '117 patent, '337 patent, and '073 patent.

28. By a letter dated October 9, 2020 (the "Notice Letter II"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Amneal notified Intercept that ANDA No. 214810 includes a Paragraph IV certification with respect to the '349 patent and '549 patent. Amneal's Notice Letter II, which is hereby incorporated by reference as if fully set forth herein, contained a detailed statement of the factual and legal bases for Amneal's Paragraph IV certification that the claims of the '349 patent and '549 patent are invalid, unenforceable, and/or will not be infringed by Amneal's ANDA Product.

29. Intercept amended its complaint on November 16, 2020 to allege infringement of the '349 patent and '549 patent.

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

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

31. Amneal 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 '673 patent, and Intercept has brought claims against Amneal alleging infringement of the '673 patent.

33. The manufacture, use, or sale of Amneal'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.

34. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '673 patent.

35. Amneal 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.

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

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

37. Amneal 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 '673 patent, and Intercept has brought claims against Amneal alleging infringement of the '673 patent.

39. 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.

40. 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 Amneal's Notice Letter I that Intercept received.

41. 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.

42. 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.

43. Amneal 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 Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '673 patent.

45. Amneal 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 III
(Declaratory Judgment of Non-Infringement of the '117 Patent)

46. Amneal 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 '117 patent, and Intercept has brought claims against Amneal alleging infringement of the '117 patent.

48. The manufacture, use, or sale of Amneal'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.

49. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '117 patent.

50. Amneal 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.

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

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

52. Amneal 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 '117 patent, and Intercept has brought claims against Amneal alleging infringement of the '117 patent.

54. 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.

55. 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 Amneal's Notice Letter I that Intercept received.

56. 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.

57. 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.

58. Amneal 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 Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '117 patent.

60. Amneal 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 V
(Declaratory Judgment of Non-Infringement of the '337 Patent)

61. Amneal 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 '337 patent, and Intercept has brought claims against Amneal alleging infringement of the '337 patent.

63. The manufacture, use, or sale of Amneal'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.

64. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Amneal's ANDA No. 214810 and/or the manufacture, use,

offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '337 patent.

65. Amneal 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.

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

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

67. Amneal 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 '337 patent, and Intercept has brought claims against Amneal alleging infringement of the '337 patent.

69. 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.

70. 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 Amneal's Notice Letter I that Intercept received.

71. 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.

72. 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.

73. Amneal 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 Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '337 patent.

75. Amneal 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 VII
(Declaratory Judgment of Non-Infringement of the '073 Patent)

76. Amneal repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-75 of its Counterclaims.

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

78. The manufacture, use, or sale of Amneal'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.

79. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '073 patent.

80. Amneal 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.

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

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

82. Amneal 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 '073 patent, and Intercept has brought claims against Amneal alleging infringement of the '073 patent.

84. 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.

85. 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 Amneal's Notice Letter I that Intercept received.

86. 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.

87. 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.

88. Amneal 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 Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '073 patent.

90. Amneal 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 IX
(Declaratory Judgment of Non-Infringement of the '349 Patent)

91. Amneal repeats, re-alleges, and incorporates by reference the allegations in paragraphs 1-90 of its Counterclaims as if fully set forth herein.

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

93. The manufacture, use, or sale of Amneal'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.

94. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '349 patent.

95. Amneal 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.

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

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

97. Amneal 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 '349 patent, and Intercept has brought claims against Amneal alleging infringement of the '349 patent.

99. 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.

100. 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 Amneal's Notice Letter II that Intercept received.

101. 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.

102. 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.

103. Amneal 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 Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '349 patent.

105. Amneal 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 XI
(Declaratory Judgment of Non-Infringement of the '549 Patent)

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

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

108. The manufacture, use, or sale of Amneal'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.

109. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '549 patent.

110. Amneal 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.

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

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

112. Amneal 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 '549 patent, and Intercept has brought claims against Amneal alleging infringement of the '549 patent.

114. 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.

115. 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 Amneal's Notice Letter II that Intercept received.

116. The alleged invention of the '549 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 '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.

117. 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.

118. Amneal 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 Amneal's ANDA No. 214810 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '549 patent.

120. Amneal 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.

PRAYER FOR RELIEF

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

a. declaring that Amneal has not infringed and will not infringe any valid and enforceable claim of the '673 patent;

b. declaring that the claims of the '673 patent are invalid;

c. declaring that Amneal has not infringed and will not infringe any valid and enforceable claim of the '117 patent;

d. declaring that the claims of the '117 patent are invalid;

e. declaring that Amneal has not infringed and will not infringe any valid and enforceable claim of the '337 patent;

f. declaring that the claims of the '337 patent are invalid;

g. declaring that Amneal has not infringed and will not infringe any valid and enforceable claim of the '073 patent;

h. declaring that the claims of the '073 patent are invalid;

i. declaring that Amneal has not infringed and will not infringe any valid and enforceable claim of the '349 patent;

j. declaring that the claims of the '349 patent are invalid;

k. declaring that Amneal has not infringed and will not infringe any valid and enforceable claim of the '549 patent;

l. declaring that the claims of the '549 patent are invalid;

m. declaring this case exceptional and awarding Amneal its attorneys' fees, costs, and expenses in this action under 35 U.S.C § 285 and all other applicable statues and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

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

Dated: November 30, 2020

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CERTIFICATE OF SERVICE

I, Anne Shea Gaza, Esquire, hereby certify that on November 30, 2020, 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 November 30, 2020**,** I caused the foregoing document to be served by e-mail on the following counsel of record:

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