

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL  
PRODUCTS R&D, INC., NORTON  
(WATERFORD) LTD., and TEVA  
PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW  
YORK, LLC, AMNEAL IRELAND LIMITED,  
AMNEAL PHARMACEUTICALS LLC, and  
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964-SRC-MAH

**STIPULATED DISCOVERY CONFIDENTIALITY ORDER**

WHEREAS, Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Plaintiffs") and Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, "Defendants") recognize that discovery in the above-entitled litigation (the "Action") may involve the disclosure of certain documents, things, and information in the possession, custody, or control of a party or non-party that constitute trade secrets or other confidential information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure;

WHEREAS, the parties, through counsel, stipulate to the entry of this Discovery Confidentiality Order ("Confidentiality Order") to prevent unnecessary dissemination or disclosure of such confidential information; and

WHEREAS, the parties, through counsel, stipulate that good cause as set forth in *Pansy v. Borough of Stroudsburg*, 23 F.3d 772 (3d Cir. 1994) and *Glenmede Trust Co. v. Thompson*, 56 F.3d 476 (3d Cir. 1995) exists for the entry of this Discovery Confidentiality Order pursuant to Fed. R. Civ. P. 26(c) to protect against improper disclosure or use of confidential information produced in this case.

**IT IS HEREBY ORDERED AS FOLLOWS:**

**I. DEFINITIONS**

1. As used herein, the following terms shall be used to refer to the Parties in this Action.
  - a. The term “Plaintiffs” shall refer collectively to Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.
  - b. The term “Defendants” shall refer collectively to Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc.
  - c. The term “Party” shall refer individually to Plaintiffs or Defendants, and the term “Parties” shall refer collectively to Plaintiffs and Defendants.
2. The term “Designated In-House Representative” shall mean U.S. or foreign attorneys or patent agents and other non-attorney employees whose duties and responsibilities include managing and overseeing this litigation for a Party.
3. The term “Discovery Material” includes any information, document or portion thereof, thing or portion thereof, correspondence between counsel, depositions, pleadings, exhibits, and any other material subject to discovery or disclosure in this Action, including responses to requests for production of documents, answers to interrogatories, responses to requests for admission, deposition testimony, expert testimony and reports, and all other discovery taken pursuant to the Federal Rules of Civil Procedure, international treaty, party agreement, matters in

evidence, and any other information furnished, directly or indirectly, by or on behalf of any Party, nonparty or witness in connection with this Action.

4. The term “Document(s)” means documents or electronically stored information as defined in Fed. R. Civ. P. 34(a).

5. The term “Outside Counsel” refers to those attorneys who are not employed by a Party or related entity, but are instead, partners, associates, or counsel to the firms of record for the Parties in this Action who have responsibility for this Action even if the individuals have not entered an appearance in this Action, along with the supporting personnel employed by such counsel, including their respective secretarial, clerical, paralegal, and technical advisor staff, provided Outside Counsel undertakes to ensure compliance with this Order by anyone in its employ, whether temporary or permanent.

6. The term “Protected Material” means any Discovery Material designated as “Confidential” or “Highly Confidential” material according to this Order.

7. The term “Producing Party” shall refer to any Party in this Action and to any nonparty that produces Discovery Material according to this Order.

8. The term “Receiving Party” shall refer to any Party, nonparty or individual who receives, is shown, is in possession of, or is exposed to Discovery Material in accordance with this Order.

9. The term “days” shall be construed as calendar days, unless otherwise specifically indicated.

10. Any other term not defined herein shall be given its ordinary meaning.

**II. DESIGNATION AND USE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL MATERIAL**

11. This Order shall be applicable to and govern all Discovery Material which the Party or any non-party designates pursuant to this Order furnished, directly or indirectly, in this Action.

12. **Designation of Confidential Material.** Any Producing Party in this Action shall have the right to designate as “Confidential” and subject to this Order any information, document, or thing, or portion of any document or thing: (a) that contains trade secrets, competitively sensitive technical information, or other confidential research, development, or commercial information, or (b) that contains private or confidential personal information, or (c) that contains information received in confidence from third parties, or (d) which the Producing Party otherwise believes in good faith to be entitled to protection under Federal Rule of Civil Procedure Rule 26(c)(1)(G) and Local Civil Rule 5.3. Any Producing Party covered by this Order, who produces or discloses any Confidential material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “CONFIDENTIAL” or “CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER” (hereinafter “Confidential”).

- a. For the avoidance of doubt, the following non-exhaustive list constitutes Confidential material and shall be so marked: (i) Defendants’ Abbreviated New Drug Application (“ANDA”) No. 211600 and Plaintiffs’ New Drug Application (“NDA”) No. 021457; (ii) any internal correspondence or correspondence with FDA related to the above-referenced ANDA or NDA; and (iii) other technical information (including information regarding the research and development of the patents-in-suit and the research and development of the generic version of ProAir® HFA that is the subject of ANDA No. 211600).

13. **Designation of Highly Confidential Material.** Any Producing Party shall have the right to designate as “Highly Confidential” and subject to this Order any information, document, or thing, or portion of any document or thing that contains highly sensitive business or personal

information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the Producing Party including, but not limited to, confidential and/or proprietary information pertaining to marketing, sales, revenues, profits, forecasts, and business plans or strategies. Any Producing Party covered by this Order, who produces or discloses any Highly Confidential material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “HIGHLY CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER” (hereinafter “Highly Confidential”).

14. Also for the avoidance of doubt, information and things derived from Confidential and/or Highly Confidential material, including summaries, digests, analyses, and other records of such information and things, and any testing or test results of product samples shall be subject to the same Confidential and/or Highly Confidential designation (and thus the same restrictions) as the information or thing from which it was derived. All Confidential and/or Highly Confidential material shall be securely maintained by recipients so as to preclude access by persons who are not entitled to receive such Confidential and/or Highly Confidential materials.

15. All Confidential and Highly Confidential material shall be used by the Receiving Party solely for purposes of the prosecution or defense of this Action, and shall not be used by the Receiving Party for any business, commercial, competitive, personal, or other purpose, and shall not be disclosed by the Receiving Party to anyone other than those set forth in Paragraphs 17 and 19, unless and until the restrictions herein are removed either by written agreement of counsel for the Parties, or by Order of the Court. It is, however, understood that counsel for a Party may give advice and opinions to his or her client solely relating to the Action based on his or her evaluation

of Confidential or Highly Confidential material, provided that such advice and opinions shall not reveal the specific content of such Confidential or Highly Confidential material except by prior written agreement of counsel for the Parties, or by Order of the Court.

16. **Use Bar.** Absent consent of the Producing Party and/or further Order of this Court, all persons receiving information designated Confidential or Highly Confidential under this Discovery Confidentiality Order from an opposing Party in this Action are expressly prohibited from using or disclosing such information in connection with communications with the United States Patent and Trademark Office (“PTO”) or the Patent Trial and Appeal Board (“PTAB”) (including in connection with drafting or amending claims of patent applications), the United States Food and Drug Administration (“FDA”) (including in connection with Citizens Petitions), the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction, and are expressly prohibited from using or disclosing such information in connection with any other civil action. Notwithstanding the above, the Designated In-House Representatives of the Receiving Party shall not be prohibited from advising and representing the Receiving Party in communications with FDA or the Federal Trade Commission related to the above-referenced ANDA or NDA.

17. **Disclosure of Confidential Material.** Confidential material and the contents of Confidential material may be disclosed only to the following individuals under the following conditions:

- a. The Receiving Party’s Outside Counsel (as defined above);
- b. Up to five (5) Designated In-House Representatives of the Receiving Party (as defined above), as well as their support staff, provided that such Designated In-House Representatives (i) are responsible for overseeing this litigation; (ii) need access to Confidential Information to fulfill their duties and responsibilities in connection with this Action; (iii) have signed the Agreement to Be Bound in the form attached hereto as **Exhibit A**; and (iv) as to whom the procedures set forth in Paragraphs 23 and 24 below have been followed before such Designated In-House Representatives receive any Confidential material;

- c. Outside experts or consultants, and any support staff thereof to whom disclosure is reasonably necessary for this Action, retained by Outside Counsel for purposes of this Action who have been approved in accordance with Paragraph 25 below, provided they have signed the Agreement to Be Bound in the form attached hereto as **Exhibit A**;
- d. Secretarial, paralegal, clerical, duplicating and data processing personnel of the foregoing;
- e. The Court and court personnel;
- f. Any deponent may be shown or examined on any information, document or thing designated Confidential if it appears that the witness authored or received a copy of it, was involved in the subject matter described therein, is employed by the Party who produced the information, document or thing, is designated by the Producing Party under Fed. R. Civ. P. 30(b)(6) to provide testimony on a topic relevant to the Confidential material, or if the Producing Party consents to such disclosure;
- g. Vendors retained by or for the Parties to assist in preparing for pretrial discovery, trial and/or hearings including, but not limited to, court reporters, litigation support personnel, jury consultants, individuals to prepare demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials;
- h. Any mediators engaged by the Parties, and their support staff;
- i. Current employees of the Producing Party;
- j. The author or recipient of the Confidential material (not including a person who received the document in the course of the litigation); or other individual who had authorized access to the Confidential material; and
- k. Any other person (i) agreed to in writing by the Parties, as long as such person signs the Agreement to Be Bound in the form attached hereto as **Exhibit A**, or (ii) permitted by the Court.

18. Confidential material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any individual other than those enumerated in Paragraph 17, until and unless (a) Outside Counsel for the Party asserting confidentiality waives the claim of confidentiality, or (b) the Court orders such disclosure.

19. **Disclosure of Highly Confidential Material.** Highly Confidential material and the contents of Highly Confidential material may be disclosed only to the following individuals under the following conditions:

- a. The Receiving Party's Outside Counsel (as defined above);
- b. Outside experts or consultants, and any support staff thereof to whom disclosure is reasonably necessary for this Action, retained by Outside Counsel for purposes of this Action who have been approved in accordance with Paragraph 25 below, provided they have signed the Agreement to Be Bound in the form attached hereto as **Exhibit A**;
- c. Secretarial, paralegal, clerical, duplicating and data processing personnel of the foregoing;
- d. The Court and court personnel;
- e. Any deponent may be shown or examined on any information, document or thing designated Highly Confidential if it appears that the witness authored or received a copy of it, was involved in the subject matter described therein, is employed by the Party who produced the information, document or thing, is designated by the Producing Party under Fed. R. Civ. P. 30(b)(6) to provide testimony on a topic relevant to the Highly Confidential material, or if the Producing Party consents to such disclosure;
- f. Vendors retained by or for the Parties to assist in preparing for pretrial discovery, trial and/or hearings including, but not limited to, court reporters, litigation support personnel, jury consultants, individuals to prepare demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials;
- g. Any mediators engaged by the Parties, and their support staff;
- h. Current employees of the Producing Party;
- i. The author or recipient of the Highly Confidential material (not including a person who received the document in the course of the litigation); or other individual who had authorized access to the Highly Confidential material; and
- j. Any other person (i) agreed to in writing by the Parties, as long as such person signs the Agreement to Be Bound in the form attached hereto as **Exhibit A**, or (ii) permitted by the Court.



20. Highly Confidential material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any individual other than those enumerated in Paragraph 19, until and unless (a) Outside Counsel for the Party asserting confidentiality waives the claim of confidentiality, or (b) the Court orders such disclosure.

21. Nothing in this Order shall preclude a Party from disclosing to anyone or using in any way its own Confidential or Highly Confidential information and things.

22. To the extent that the Parties have produced any documents prior to the submission of this Order, including those bearing the designation “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY” produced pursuant to Local Patent Rule 2.2, those documents will be treated as having been produced and marked as Confidential by default unless otherwise re-designated as Highly Confidential in accordance with the respective definitions.

23. **Identification of Designated In-House Representatives.** Prior to a Party giving, showing, disclosing, making available, or otherwise communicating Confidential material to a Designated In-House Representative under Paragraph 17.b, the Party must follow the following procedures:

- a. The Receiving Party shall serve a written disclosure to the Producing Party that (i) sets forth the name and position of the Designated In-House Representative and for any non-attorney employee, also sets forth a detailed description of their position, role(s), and responsibilities at the company; and (ii) provides a copy of the Agreement to Be Bound in the form attached hereto as **Exhibit A**, signed by the Designated In-House Representative, confirming the person’s agreement to be bound by the terms of this Order.
- b. The Producing Party shall be entitled to object to such disclosure to the proposed Designated In-House Representative within three (3) business days after receipt of the materials in the paragraph above by stating specifically in writing the reasons why it objects to disclosure of the Confidential material to Designated In-House Representative.
- c. The Parties agree to promptly confer and use good faith to resolve any such objection within three (3) business days of the objection. If the Parties are unable

to resolve any objection, the objecting Party may present the dispute to the Court in accordance with Local Civil Rule 37.1(a)(1) within five (5) business days of the conclusion of the meet and confer, or within such other time as the Parties may agree, seeking a protective order with respect to the proposed disclosure. The objecting Party shall have the burden of proving good cause for a protective order. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn.

- d. No disclosure of Confidential material shall be made to the Designated In-House Representative until the time for serving objections to that Designated In-House Representative has passed, or, in the event that a written objection is timely served and a motion to prevent disclosure is filed, until all such objections are resolved by agreement or Court order.
- e. The filing and pendency of objections shall not limit, delay, or defer any disclosures of Confidential material to persons as to whom no such objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct such discovery.
- f. To the extent Confidential material is provided to Designated In-House Representative at their offices, that information shall be maintained in a secure fashion and shall not be shared or disseminated.

24. Each Party shall be permitted to designate no more than five (5) qualifying individuals as Designated In-House Representatives for purposes of this Action. A Party may replace a Designated In-House Representative by providing the other Party written notice of the proposed substitution and following the procedures set forth above in Paragraph 23.

25. **Identification of Experts and Consultants.** Prior to a Party giving, showing, disclosing, making available, or otherwise communicating Confidential or Highly Confidential material to any expert or consultant under Paragraphs 17.c and 19.b, the Party must follow the following procedures:

- a. The Receiving Party shall first give written notice to the Producing Party. Such notice shall include (i) a copy of the individual's current curriculum vitae, (ii) identification of any consulting or other relationship to the Parties in this Action within the last five (5) years (excluding disclosure of the details of any non-testifying litigation consulting, but including disclosure of the identification of the entities for which consulting was provided), (iii) any deposition or trial testimony

given within the last four (4) years, and (iv) a signed Agreement to Be Bound in the form attached hereto as **Exhibit A**.

- b. No Protected Material shall be disclosed to any outside expert or consultant until written approval is obtained from counsel for the Producing Party or until after the expiration of five (5) business days after such notice provided, whichever is earlier.
- c. If, during the five (5) business days, the Party giving notice receives a written objection from the Producing Party or designating party, there shall be no disclosure of Protected Material to the individual identified in the notice except as agreed by the Producing Party or by further Order of the Court.
- d. Prior to seeking resolution by the Court of any such objection, the Party making the objection shall state in writing the bases for the objection and the Parties shall meet and confer in good faith within three (3) business days of receipt of the written objection in an effort to resolve such disagreement.
- e. Failing resolution, the Party seeking to prevent disclosure shall within three (3) days of the conclusion of the meet and confer present the dispute to the Court, <sup>via letter</sup> for an order that disclosure is improper. The Party seeking to prevent disclosure of the Protected Material to an individual shall have the burden to prove to the Court that such disclosure is inappropriate. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn.

26. **Expert Materials Excluded from Discovery.** Discovery of communications between counsel and any independent expert or consultant retained or specially employed by that counsel for purposes of this litigation shall be limited to the factual information, analyses, documents, and/or data considered or relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

27. **Filing Protected Material with the Court.** Any Party filing any document, material, or information designated by another Party as Confidential or Highly Confidential material

shall file such document, material, or information under seal to prevent public disclosure. All requests to seal documents filed with the Court shall comply with Local Civil Rule 5.3.

**28. Redacted Copies of Highly Confidential Documents for Disclosure to Designated In-House Representatives.**

- a. Court Filings and Served Documents: With respect to any document filed or served by any Party that is designated as Highly Confidential or contains information designated as Highly Confidential, the filing or serving Party shall state to the other Party, as of the filing or serving date, if the document contains only the other Party's Highly Confidential material (i.e., does not contain the filing or serving Party's Highly Confidential material) such that the document may be disclosed to the other Party's Designated In-House Representatives.
- b. Redacted Copy of Court Filings. With respect to any document filed by any Party that is designated as Highly Confidential or that contains information designated as Highly Confidential, unless otherwise agreed by the Parties, the Producing Party shall, within two (2) business days of filing, provide the Receiving Party with a redacted, non-public version in which the Producing Party's own Highly Confidential material is redacted so that the filing may be shared with the Designated In-House Representatives of the Receiving Party under Paragraph 17.b.
- c. Redacted Copy of Served Documents. With respect to any document served, but not filed, by any Party that is designated as Highly Confidential or that contains information designated as Highly Confidential, unless otherwise agreed by the Parties, the Producing Party shall, within four (4) business days of filing, provide the Receiving Party with a redacted, non-public version in which the Producing Party's own Highly Confidential material is redacted so that the filing may be shared with the Designated In-House Representatives of the Receiving Party under Paragraph 17.b.
- d. For Paragraphs 28.b and 28.c, the Parties shall not be required to provide redacted versions of Highly Confidential exhibits to briefs, letters, declarations or expert reports; however, each Party reserves the right to request redacted copies of said exhibits on a case-by-case basis.
- e. For the avoidance of doubt, the redacted copies provided in Paragraphs 28.b and 28.c are non-public copies.

**29. Depositions.** With respect to any depositions that involve a disclosure of Confidential or Highly Confidential material of a Party to this Action, such Party shall have until fifteen (15) days after receipt of the final deposition transcript within which to inform all other

Parties that portions of the transcript are to be designated Confidential and/or Highly Confidential. Until the lapse of said fifteen (15) days, or until being informed that certain portions of the deposition are to be designated as Confidential or Highly Confidential, the deposition transcript and the contents of the deposition shall be treated as Highly Confidential. Upon being informed that certain portions of a deposition are to be designated as Confidential and/or Highly Confidential, all Parties shall immediately cause each copy of the transcript in its custody or control to be appropriately marked and limit disclosure of that transcript in accordance with this Order.

30. **Use of Protected Material at Trial/Hearings:** Nothing in this Order shall preclude a Party from introducing into evidence at trial or evidentiary hearing any Protected Material that is admissible under applicable law. The Parties shall meet and confer regarding the procedures for use of Protected Material at trial or any evidentiary hearing and shall move the Court for entry of an appropriate sealing order. At trial or evidentiary hearings, the Court may take such other measures or enter separate orders, as the Court deems appropriate or upon request by any Party, to protect the claimed Protected Material sought to be introduced or admitted.

31. **Challenging Designations.** Nothing in this Order shall prejudice the right of any Party to bring before this Court, pursuant to L. Civ. R. 5.3(b)(5), any dispute concerning the designation of information as Confidential or Highly Confidential. A Party shall not be obligated to challenge the propriety of any designation of Confidential or Highly Confidential information or thing at the time the designation is made and failure to do so shall not preclude a subsequent challenge to the designation. If counsel for a Party receiving documents or information designated as Confidential or Highly Confidential hereunder objects to such designation of any or all of such items, the following procedure shall apply:

- a. The Receiving Party shall serve on the Producing Party a written objection to such designation, which shall describe with particularity the documents or information

in question and shall state the grounds for objection. The Producing Party shall respond in writing to such objection within seven (7) days, and shall state with particularity the grounds for asserting that the document or information is Confidential or Highly Confidential. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the Producing Party makes a timely response to such objection asserting the propriety of the designation, counsel shall then meet and confer in good faith within seven (7) days of receipt of the Producing Party's response in an effort to resolve the dispute.

- b. If a dispute as to a Confidential or Highly Confidential designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall, within five (5) business days after the meet and confer, present the dispute to the Court in accordance with Local Civil Rule 37.1(a)(1). The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute.

32. No information that is in the public domain or which is already known by the Receiving Party through proper means or which is or becomes available to a Party from a source other than the Party asserting confidentiality, rightfully in possession of such information on a non-confidential basis, shall be deemed or considered to be Confidential or Highly Confidential material under this Confidentiality Order.

33. This Confidentiality Order shall not deprive any Party of its right to object to discovery by any other Party or on any otherwise permitted ground. This Confidentiality Order is being entered without prejudice to the right of any party <sup>via letter</sup> to ~~move~~ <sup>request</sup> the Court for modification or for relief from any of its terms, or from applying to the Court for further or additional orders.

34. If a non-party serves a Party in this Action with a request, subpoena, or order ("demand") for disclosure of Confidential or Highly Confidential material, the Party receiving the demand, if not prohibited under applicable law, shall promptly deliver a copy of the demand to the designating Party's counsel, and shall notify the non-party who served the request that some or all of the materials sought by the request are subject to this Confidentiality Order. The Party receiving the demand shall not disclose any Confidential or Highly Confidential material prior to the date

specified for disclosure, or prior to resolution of any dispute regarding production of such material in response to the request, whichever is later. In its sole discretion and at its own cost, the designating Party may oppose or seek to limit the demand in any legal manner. The Party who received the demand shall not oppose or otherwise interfere with the designating Party's actions.

35. **Redactions.** The Producing Party may redact from produced documents, materials, and other things, the following items, or any other item(s) protected from disclosure by statute or decisional authority or agreed upon by the Parties or ordered by the Court:

- a. Nonresponsive information, including, but not limited to, proprietary financial material and products unrelated to this Action, as well as any other material that is neither relevant to the subject matter of this Action nor within the scope of discovery set forth in the Federal Rules of Civil Procedure;
- b. The names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Protected Material, regardless of whether the document containing such names is designated as Protected Material pursuant to 21 C.F.R. §§ 314.430(e) and (f) and 20.63(f); and
- c. Privileged information (e.g., attorney-client privilege, work product, or any other lawful privilege), which is to be clearly marked as "Privileged."
- d. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a Party's ability to challenge such redactions pursuant to the procedures set forth in this Order. The burden as to the propriety of any redaction remains on the Producing Party at all times.

36. **Inadvertent Disclosure of Protected Material.** The inadvertent or unintentional disclosure of Confidential or Highly Confidential material that should have been designated as such, regardless of whether the information, document or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a Party's or non-party's claim that it is Confidential or Highly Confidential material, either as to the specific information, document or thing disclosed or as to any other material or information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by notifying in writing counsel

for all Parties to whom the material was disclosed that the material should have been designated Confidential or Highly Confidential within a reasonable time from discovery of the error. Such notice shall constitute a designation of the information, document or thing as Confidential or Highly Confidential under this Confidentiality Order. For purposes of this section, it shall be irrelevant which Party initially discovers the inadvertently or mistakenly produced information, documents, or tangible items that are otherwise properly qualified to be designated as Confidential or Highly Confidential under this Order.

37. **Inadvertent Failure to Designate or Redact.** Notwithstanding the obligation to timely designate Confidential or Highly Confidential material under the foregoing paragraphs and redact any material subject to redaction pursuant to Paragraph 35, the inadvertent or unintentional failure to designate specific information as Confidential or Highly Confidential, or to redact any material subject to redaction pursuant to Paragraph 35, shall not be deemed a waiver in whole or in part of the claim of confidentiality or the claim that redaction is appropriate. A Producing Party that inadvertently fails to designate or redact an item pursuant to this Discovery Confidentiality Order at the time of production may thereafter make a designation or redaction pursuant to this Discovery Confidentiality Order by serving notice thereof in writing, accompanied by substitute copies of each item, appropriately designated or redacted. No Party shall be held in breach of this Discovery Confidentiality Order if, prior to notification of such later designation, such Confidential or Highly Confidential material had been disclosed or used in a manner inconsistent with such later designation.

38. **Data Breach.** If a Party learns that material that Party received in discovery pursuant to this Confidentiality Order has been the subject of a data breach, that Party must promptly notify the Producing Party of the breach, and cooperate with that Party to address the breach.



39. **Privileged Information.** Nothing in this Order shall require production of any information, document, or thing that a Party contends is protected from disclosure by the attorney-client privilege, the work-product doctrine, or other lawful privilege, doctrine, right, or immunity. The production of any information, document, or thing in this litigation shall not constitute a waiver of any attorney-client privilege or work-product protection that may be asserted by the Producing Party either in this case or in any other federal or state proceeding. This Order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d). When the production or disclosure of any information, document, or thing protected by attorney-client privilege or work-product protection is discovered by or brought to the attention of the Producing Party, the treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B) and subsections 39.a-b below. That treatment shall be deemed to comply with any obligations the Producing Party would otherwise have had pursuant to Fed. R. Evid. 502(b) or under the common law. However, nothing herein restricts the right of the Receiving Party to challenge the Producing Party's claim of attorney-client privilege or work-product protection after receiving notice of the production or disclosure of any information, document, or thing that is subject to a claim of attorney-client privilege or work-product protection.

- a. If any information, document, or thing subject to a claim of attorney-client privilege, work-product doctrine, or other privilege, doctrine, right, or immunity is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver or estoppel as to any such privilege, doctrine, right, or immunity, provided that the Producing Party makes a good-faith representation that such production was inadvertent or mistaken and takes prompt remedial action to withdraw the disclosure. Specifically, the Producing Party shall send the Receiving Party a written request for return of the inadvertently produced or disclosed document or thing within five (5) business days after recognizing that privileged information has been produced or disclosed. Such written request shall specifically identify the documents or electronically stored information ("ESI") in question, by Bates number or otherwise, and the basis on which the privileged information should have been withheld from production. For purposes of this section, it shall be irrelevant which Party initially discovers the inadvertently or

- mistakenly produced information, documents, or tangible items that are otherwise properly subject to a claim of attorney-client privilege, work product immunity, or any other protection from discovery.
- b. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall collect and return to the Producing Party or destroy all reasonably accessible and known copies of any documents or tangible items that the Producing Party represents are covered by a claim of privilege, work-product, or other immunity (“Privileged Material”). The Receiving Party shall also sequester all copies or summaries of, or notes relating to, any such information to which a claim of inadvertent or mistaken production has been made (“Sequestered Material”). Information that resides on a firm’s or production database contractor’s disaster recovery backup tapes need not be identified and deleted if such information will eventually be deleted through the ordinary operation of such disaster recovery backup system (e.g., because backup tapes are recycled) within 30 days.
- c. The Receiving Party may elect to challenge the claim of privilege, work product, or other immunity by (i) notifying the Producing Party of its challenge within five (5) <sup>business days</sup> of receiving the notice of inadvertent production and by (ii) <sup>moving</sup> ~~moving~~ the Court for a ruling on the propriety of the claim of privilege, work product, or other immunity within ten (10) business days of receiving notice of the inadvertent production. If the Receiving Party elects to challenge the claim of privilege, work product, or other immunity, the Receiving Party may retain one copy of the Privileged Material, including the Sequestered Material, for presentation to the Court under seal. During the pendency of such challenge, the Receiving Party shall make no other use or disclosure of the Privileged Material or Sequestered Material or the information contained therein. If the Receiving Party loses the challenge or has not challenged the claim of privilege, work product, or other immunity by notifying the Producing Party and <sup>seeking relief from</sup> ~~moving~~ the Court within the above specified time periods, it must destroy all remaining copies of the Privileged Material and Sequestered Material.

40. **Duration.** All Parties shall be bound by the terms of the Order once submitted to the Court. This Confidentiality Order shall survive the termination of this Action (including any appellate proceedings) and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the Parties filed with the Court.

41. **Return or Destruction of Protected Material.** Within ninety (90) days of the final conclusion of this litigation (including any appellate proceedings), or such other time as the Producing Party may agree in writing, each Party or other individual subject to the terms hereof

shall be under an obligation to either return or destroy all documents, objects, and other materials produced as or designated as Protected Material, including all reproductions thereof, including but not limited to Protected Material given to experts, vendors, and Designated In-House Representatives. Each Receiving Party shall certify to each Producing Party that return or destruction of all such Protected Material has been completed using commercially reasonable efforts. To the extent a Party requests the return of Confidential or Highly Confidential material from the Court after the final conclusion of the litigation, including the exhaustion of all appeals therefrom and all related proceedings, the Party shall file a motion seeking such relief.

42. **Information Permitted to Be Retained.** Notwithstanding the foregoing paragraph, Outside Counsel may retain complete copies of all pleadings, motion papers, discovery responses, correspondence, transcripts and court filings, including any exhibits attached thereto, legal memoranda, and attorney work product, for archival purposes, subject to the provisions of this Confidentiality Order. Nothing in this Order requires the return or destruction of attorney work product or attorney-client communications of any Party that are maintained and stored by Outside Counsel in the regular course of business. All of the above retained materials shall remain subject to the terms of this Order.

43. **Modification.** This Order may be modified only by written agreement of all Parties or further Order of the Court and is without prejudice to the rights of any Party or third party to seek additional or different relief from the Court not specified in this Order

44. **Notice.** Unless otherwise agreed to by Outside Counsel, all notices required by this Confidentiality Order may be served by e-mail, but the date by which a Party receiving notice shall respond, or otherwise take action, shall be computed from the date that the notice was received.

Any of the notice requirements herein may be waived in whole or in part, but only in writing, including email, from an attorney for the Producing Party or Receiving Party.

IT IS SO STIPULATED AND AGREED this 6th day of March 2024 by:

/s/ Liza M. Walsh

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*Attorneys for Plaintiffs Teva Branded  
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(Waterford) Ltd., and Teva Pharmaceuticals  
USA, Inc.*

IT IS SO ORDERED:

Dated: 3/7/24

/s/ Rebekah Conroy

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Amneal Ireland Limited; Amneal  
Pharmaceuticals LLC and Amneal  
Pharmaceuticals, Inc.*

**SO ORDERED**

***s/Michael A. Hammer***  
**Michael A. Hammer, U.S.M.J.**

Date: 3/7/24  
Hon. Michael A. Hammer, U.S.M.J.

**EXHIBIT A TO DISCOVERY CONFIDENTIALITY ORDER**

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

TEVA BRANDED PHARMACEUTICAL  
PRODUCTS R&D, INC., NORTON  
(WATERFORD) LTD., and TEVA  
PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW  
YORK, LLC, AMNEAL IRELAND LIMITED,  
AMNEAL PHARMACEUTICALS LLC, and  
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964-SRC-MAH

**AGREEMENT TO BE BOUND BY CONFIDENTIALITY ORDER**

I, \_\_\_\_\_, being duly sworn, state that:

1. My address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_ and the address of my present employment is \_\_\_\_\_.
3. My present occupation or job description is \_\_\_\_\_.
4. I have carefully read and understood the provisions of the Confidentiality Order in this case signed by the Court, and I will comply with all provisions of the Confidentiality Order and be bound by its terms.
5. I will hold in confidence and not disclose to anyone not qualified under the Confidentiality Order any Protected Material or any words, summaries, abstracts, or indices of Protected Material disclosed to me.
6. I will limit use of Protected Material disclosed to me solely for purpose of this Action.
7. No later than the final conclusion of the case, I will destroy or return all Protected Material

and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to counsel for the Party for whom I was employed or retained in accordance with the provisions of the Confidentiality Order. I further agree and attest to my understanding that my obligation to honor the confidentiality of such Protected Material will continue even after this Action concludes.

8. I hereby submit to the jurisdiction of the United States District Court for the District of New Jersey for the purpose of enforcement of the Confidentiality Order. I understand that if I violate the provisions of the Confidentiality Order, I will be in violation of a Court Order and subject to sanctions or other remedies that may be imposed by the Court and may be liable in a civil action by one or more of the Parties in the above-referenced action.

I declare under penalty of perjury that the foregoing is true and correct.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name