



**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**  
717 MADISON PLACE, N.W.  
WASHINGTON, D.C. 20439

JARRETT B. PERLOW  
CLERK OF COURT

CLERK'S OFFICE  
202-275-8000

June 12, 2024

**NOTICE OF DOCKETING**

**Federal Circuit Docket No.:** 2024-1936

**Federal Circuit Short Caption:** Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

**Date of Docketing:** June 12, 2024

**Originating Tribunal:** United States District Court for the District of New Jersey

**Originating Case No.:** 2:23-cv-20964-SRC-MAH

**Appellants:** Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., Teva Pharmaceuticals USA, Inc.

A notice of appeal has been filed and assigned the above Federal Circuit case number. The court's official caption is included as an attachment to this notice. Unless otherwise noted in the court's rules, the assigned docket number and official caption or short caption must be included on all documents filed with this Court. It is the responsibility of all parties to review the Rules for critical due dates. The assigned deputy clerk is noted below and all case questions should be directed to the Case Management section at (202) 275-8055.

The following filings are due within 14 days of this notice:

- [Entry of Appearance](#) or [Notice of Unrepresented Person](#). (Fed. Cir. R. 47.3.)
- [Certificate of Interest](#). (Fed. Cir. R. 47.4; not required for unrepresented and federal government parties unless disclosing information under Fed. Cir. R. 47.4(a)(6))
- [Docketing Statement](#). Note: The Docketing Statement is due in 30 days if the United States or its officer or agency is a party in the appeal. (Fed. Cir. R. 47.6 and the [Mediation Guidelines](#); no docketing statement is required in cases with an unrepresented party)
- [Statement Concerning Discrimination](#) in MSPB or arbitrator cases. (Fed. Cir. R. 15(c); completed by petitioner only)

- Fee payment or appropriate fee waiver request, if the docketing fee was not prepaid (see Fee Payment below).

**FILING DOCUMENTS:** Each counsel representing a party must be a member of the court's bar and registered for the court's electronic filing system. Parties represented by counsel must make all filings through the court's electronic filing system.

Unrepresented parties may choose to submit case filings to the court either in paper or through the court's electronic filing system; electronic filing will only be permitted for unrepresented parties after successful registration for the court's electronic filing system and submission of a completed Notice of Unrepresented Person Appearance. Fed. Cir. R. 25(a). The court's Electronic Filing Procedures may be accessed at [www.cafc.uscourts.gov/contact/clerks-office/filing-resources](http://www.cafc.uscourts.gov/contact/clerks-office/filing-resources).

**CONTACT INFORMATION:** Electronic filers, or unrepresented parties registered to receive electronic service, must update their contact information in their PACER service center profile whenever their contact information changes. Counsel must file an amended Entry of Appearance and unrepresented parties must file an amended Notice of Unrepresented Person Appearance whenever contact information changes. Fed. Cir. R. 25(a)(5).

**FEE PAYMENT:** Unless the filing fee was prepaid, fee payment must be submitted within fourteen days after this notice. Fed. Cir. R. 52(d). For outstanding docketing fees due to this court, electronic filers must pay the fee using the event Pay Docketing Fee through the court's electronic filing system. Fed. Cir. R. 52(e). Docketing fees due to other courts, such as U.S. District Courts, the U.S. Court of Appeals for Veterans Claims, and non-vaccine cases at the U.S. Court of Federal Claims, must be submitted to those courts in accordance with their procedures. A filer wishing to proceed without fee payment must submit a motion for leave to proceed in forma pauperis, or other fee waiver request, within fourteen days.

**OFFICIAL CAPTION:** The court's official caption is attached and reflects the lower tribunal's caption pursuant to Fed. R. App. P. 12(a), 15(a), and 21(a). Please review the caption carefully and promptly advise this court in writing of any improper or inaccurate designations.



Jarrett B. Perlow  
Clerk of Court

By: J. Phillips, Deputy Clerk

**Attachments:**

- Official caption
- Paper Copies of General Information and Forms (to unrepresented parties only):
  - [General Information and Overview of a Case in the Federal Circuit](#)
  - [Notice of Unrepresented Person Appearance](#)
  - [Informal Brief](#)
  - [Informal Reply Brief](#) (to be completed only after receiving the opposing party's response brief)
  - [Motion and Affidavit for Leave to Proceed in Forma Pauperis](#) (only to filers owing the docketing fee)
  - [Supplemental in Forma Pauperis Form for Prisoners](#) (only to filers in a correctional institution)
  - [Statement Concerning Discrimination](#) (only to petitioners in MSPB or arbitrator case)

**cc:** United States District Court for the District of New Jersey

**Official Caption**

**TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON  
(WATERFORD) LTD., TEVA PHARMACEUTICALS USA, INC.,**  
*Plaintiffs-Appellants*

v.

**AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND  
LTD., AMNEAL PHARMACEUTICALS LLC, AMNEAL  
PHARMACEUTICALS, INC.,**  
*Defendants-Appellees*

**Short Caption**

Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New  
York, LLC

**IN THE UNITED STATES DISTRICT COURT  
FOR THE 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

**NOTICE OF APPEAL**

*Filed Electronically*

NOTICE IS HEREBY GIVEN that Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, “Teva” or “Plaintiffs”) hereby appeal to the United States Court of Appeals for the Federal Circuit pursuant to Federal Rule of Appellate Procedure 3 and 28 U.S.C. § 1295 from the Court’s Order and Opinion entered on June 10, 2024 granting an injunction (D.E. 88), as well as any and all other judgments, orders, opinions, rulings, and findings that merge therein or are pertinent or ancillary to the foregoing that are adverse to Plaintiffs.

Payment of the required \$605 fee is provided with this Notice of Appeal. This fee includes the \$600 fee for docketing a case on appeal required by 28 U.S.C. § 1913 and Federal Circuit Rule 52(a)(2), and the \$5 fee for filing a notice of appeal required by 28 U.S.C. § 1917.

Dated: June 11, 2024

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*Attorneys for Plaintiffs Teva Branded  
Pharmaceutical Products R&D, Inc.,  
Norton  
(Waterford) Ltd., and Teva  
Pharmaceuticals  
USA, Inc.*

**U.S. District Court  
District of New Jersey [LIVE] (Newark)  
CIVIL DOCKET FOR CASE #: 2:23-cv-20964-SRC-MAH  
Internal Use Only**

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D,  
INC. et al v. AMNEAL PHARMACEUTICALS OF NEW  
YORK, LLC et al

Assigned to: Judge Stanley R. Chesler  
Referred to: Magistrate Judge Michael A. Hammer

Related Cases: [2:24-cv-00909-SRC-MAH](#)  
[2:24-cv-04404-SRC-MAH](#)

Cause: 35:271 Patent Infringement

**Plaintiff**

**TEVA BRANDED  
PHARMACEUTICAL PRODUCTS  
R&D, INC.**

represented by **CHRISTINE CLARK**  
WALSH PIZZI O'REILLY FALANGA  
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*ATTORNEY TO BE NOTICED*



**Plaintiff**

**NORTON (WATERFORD) LTD.**

represented by

**CHRISTINE CLARK**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**HECTOR DANIEL RUIZ**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**SELINA MIRIAM ELLIS**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**LIZA M. WALSH**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Plaintiff**

**TEVA PHARMACEUTICALS USA,  
INC.**

represented by **CHRISTINE CLARK**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**HECTOR DANIEL RUIZ**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**SELINA MIRIAM ELLIS**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**LIZA M. WALSH**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**AMNEAL PHARMACEUTICALS OF  
NEW YORK, LLC**

represented by **SHALOM D STONE**  
STONE CONROY LLC  
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*ATTORNEY TO BE NOTICED*

**REBEKAH R. CONROY**  
STONE CONROY LLC  
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*ATTORNEY TO BE NOTICED*

**Defendant**

**AMNEAL IRELAND LIMITED**

represented by **SHALOM D STONE**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**REBEKAH R. CONROY**



(See above for address)  
*ATTORNEY TO BE NOTICED*

**Defendant**

**AMNEAL PHARMACEUTICALS  
LLC**

represented by **SHALOM D STONE**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**REBEKAH R. CONROY**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Defendant**

**AMNEAL PHARMACEUTICALS  
INC.**

represented by **SHALOM D STONE**  
(See above for address)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**REBEKAH R. CONROY**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Defendant**

**PHV ROBIN P. SUMNER**

represented by **ROBIN P. SUMNER**  
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PRO SE

**Amicus**

**FEDERAL TRADE COMMISSION**  
U.S. Federal Trade Commission  
600 Pennsylvania Ave., N.W.  
Washington, DC 20580  
2023862652

represented by **BRADLEY VETTRAINO**  
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*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**AMNEAL PHARMACEUTICALS  
LLC**

represented by **REBEKAH R. CONROY**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**AMNEAL PHARMACEUTICALS OF  
NEW YORK, LLC**

represented by **REBEKAH R. CONROY**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**AMNEAL PHARMACEUTICALS  
INC.**

represented by **REBEKAH R. CONROY**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

**Counter Claimant**

**AMNEAL IRELAND LIMITED**

represented by **REBEKAH R. CONROY**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

V.

**Counter Defendant****NORTON (WATERFORD) LTD.**represented by **SELINA MIRIAM ELLIS**  
(See above for address)  
*ATTORNEY TO BE NOTICED***LIZA M. WALSH**  
(See above for address)  
*ATTORNEY TO BE NOTICED***Counter Defendant****TEVA BRANDED  
PHARMACEUTICAL PRODUCTS  
R&D, INC.**represented by **SELINA MIRIAM ELLIS**  
(See above for address)  
*ATTORNEY TO BE NOTICED***LIZA M. WALSH**  
(See above for address)  
*ATTORNEY TO BE NOTICED***Counter Defendant****TEVA PHARMACEUTICALS USA,  
INC.**represented by **SELINA MIRIAM ELLIS**  
(See above for address)  
*ATTORNEY TO BE NOTICED***LIZA M. WALSH**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

Date Filed	#	Docket Text
10/06/2023	<u>1</u>	COMPLAINT against AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC ( Filing and Admin fee \$ 402 receipt number ANJDC-14771159) , <i>Related Case Selected</i> , filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC., NORTON (WATERFORD) LTD.. (Attachments: # <u>1</u> Exhibit A-C, # <u>2</u> Exhibit D-F, # <u>3</u> Civil Cover Sheet, # <u>4</u> AO120 Form I, # <u>5</u> Ao 120 Form II)(WALSH, LIZA) (Entered: 10/06/2023)
10/06/2023	<u>2</u>	Corporate Disclosure Statement by NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC.. (WALSH, LIZA) (Entered: 10/06/2023)
10/10/2023		Case assigned to Judge Claire C. Cecchi and Magistrate Judge James B. Clark. (jr) (Entered: 10/10/2023)
10/11/2023	<u>3</u>	AO120 Patent/Trademark Form filed. (Attachments: # <u>1</u> Complaint and Exhibits) (jd, ) (Entered: 10/11/2023)
10/11/2023	<u>4</u>	SUMMONS ISSUED as to AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC. Attached is the official court Summons, please fill out Defendant and Plaintiffs attorney information and serve. (jd, ) (Entered: 10/11/2023)
10/13/2023	5	TEXT ORDER REASSIGNING CASE. Case reassigned to Judge Julien Xavier Neals and Magistrate Judge Michael A. Hammer for all further proceedings. Judge Claire C. Cecchi, Magistrate Judge James B. Clark no longer assigned to case. So Ordered by Chief Judge Renee Marie Bumb on 10/13/23. (ak, ) (Entered: 10/13/2023)
10/16/2023	<u>6</u>	NOTICE of Appearance by SELINA MIRIAM ELLIS on behalf of NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC. (ELLIS, SELINA) (Entered: 10/16/2023)

10/16/2023		Notice of Judicial Preferences. <a href="#">Click here</a> for the Judge's Individual Procedure Requirements. (kd) (Entered: 10/16/2023)
10/27/2023	<u>7</u>	AMENDED COMPLAINT against AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC., NORTON (WATERFORD) LTD.. (Attachments: # <u>1</u> Exhibit A-E)(WALSH, LIZA) (Entered: 10/27/2023)
10/30/2023	<u>8</u>	TEXT ORDER: Plaintiff shall mail a tabbed courtesy copy of the Amended Complaint <u>7</u> to Chambers by 11/6/2023. So Ordered by Magistrate Judge Michael A. Hammer on 10/30/2023. (jqb, ) (Entered: 10/30/2023)
11/09/2023	<u>9</u>	ACKNOWLEDGMENT OF SERVICE Executed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC., NORTON (WATERFORD) LTD.. (WALSH, LIZA) (Entered: 11/09/2023)
11/09/2023	<u>10</u>	STIPULATION AND [PROPOSED] ORDER FOR EXTENSION OF TIME by NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC.. (WALSH, LIZA) (Entered: 11/09/2023)
11/13/2023	<u>11</u>	STIPULATION AND ORDER granting Defendants AMNEAL request for an extension of time to answer, move, or otherwise respond to Plaintiff's First Amended Complaint in this action, until 12/1/2023. Signed by Magistrate Judge Michael A. Hammer on 11/13/2023. (jd, ) (Entered: 11/13/2023)
12/01/2023	<u>12</u>	DEFENDANTS' ANSWER to Amended Complaint , <i>Affirmative Defenses and</i> , COUNTERCLAIM against NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC. by AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL PHARMACEUTICALS INC., AMNEAL IRELAND LIMITED. (Attachments: # <u>1</u> Exhibit Exh. A, # <u>2</u> Exhibit Exh. B, # <u>3</u> Exhibit Exh. C, # <u>4</u> Exhibit Exh. D, # <u>5</u> Exhibit Exh. E, # <u>6</u> Exhibit Exh. F, # <u>7</u> Exhibit Exh. G, # <u>8</u> Exhibit Exh. H, # <u>9</u> Exhibit Exh. I, # <u>10</u> Exhibit Exh. J, # <u>11</u> Exhibit Exh. K, # <u>12</u> Exhibit Exh. L, # <u>13</u> Exhibit Exh. M, # <u>14</u> Exhibit Exh. N, # <u>15</u> Exhibit Exh. O, # <u>16</u> Exhibit Exh. P, # <u>17</u> Exhibit Exh. Q, # <u>18</u> Exhibit Exh. R, # <u>19</u> Exhibit Exh. S, # <u>20</u> Exhibit Exh. T, # <u>21</u> Exhibit Exh. U, # <u>22</u> Exhibit Exh. V, # <u>23</u> Exhibit Exh. W, # <u>24</u> Exhibit Exh. X)(CONROY, REBEKAH) (Entered: 12/01/2023)
12/01/2023	<u>13</u>	Corporate Disclosure Statement by AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC. (CONROY, REBEKAH) (Entered: 12/01/2023)
12/19/2023	<u>14</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. re <u>12</u> Answer to Amended Complaint,,, Counterclaim,,, (WALSH, LIZA) (Entered: 12/19/2023)
12/20/2023	<u>15</u>	LETTER ORDER granting <u>14</u> Plaintiffs' Request for an extension from 12/22/2023 until 1/26/2024 to answer or otherwise respond to Defendants' Counterclaims (D.E. <u>12</u> ). Signed by Magistrate Judge Michael A. Hammer on 12/20/2023. (dam) (Main Document 15 replaced on 12/20/2023) (dam, ). (Entered: 12/20/2023)
12/20/2023		<b>CLERK'S QUALITY CONTROL MESSAGE</b> – Please be advised that the document attached to <u>15</u> Letter Order filed by the Clerk's Office on 12/20/2023 was attached in error. The Clerk's Office has replaced the document with the correct version. This message is for informational purposes. This submission will remain on the docket unless otherwise ordered by the court. (dam) (Entered: 12/20/2023)
12/28/2023	<u>16</u>	TEXT ORDER REASSIGNING CASE. Case reassigned to Judge Jamel K. Semper for all further proceedings. Judge Julien Xavier Neals no longer assigned to case. So Ordered by Chief Judge Renee Marie Bumb on 12/28/2023. (adc, ) (Entered: 12/28/2023)
01/07/2024	<u>17</u>	TEXT ORDER: Telephone Scheduling Conference set for 2/7/2024 at 4:30 p.m. The parties will dial 1-888-684-8852 and access code 1456817# to join the conference.

		The parties file a joint discovery plan by 2/5/2024. So Ordered by Magistrate Judge Michael A. Hammer on 1/7/2024. (jqb, ) (Entered: 01/07/2024)
01/12/2024	<u>18</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. encl. Pro Hac Vice Application on Consent. (Attachments: # <u>1</u> Certification of Liza M. Walsh, # <u>2</u> Certification of Christopher T. Holding, # <u>3</u> Certification of Daryl L. Wiesen, # <u>4</u> Certification of Natasha E. Daughtrey, # <u>5</u> Certification of Louis L. Lobel, # <u>6</u> Certification of Thomas V. McTigue IV, # <u>7</u> Text of Proposed Order)(WALSH, LIZA) (Entered: 01/12/2024)
01/12/2024	19	TEXT ORDER REASSIGNING CASE. Case reassigned to Judge Stanley R. Chesler for all further proceedings. Judge Jamel K. Semper no longer assigned to case. So Ordered by Chief Judge Renee Marie Bumb on 1/12/2024. (smf) (Entered: 01/12/2024)
01/12/2024		Set/Reset Hearings: Status Conference set for 1/17/2024 at 01:00 PM before Judge Stanley R. Chesler. ORDERED TRIAL COUNSEL WITH FULL SETTLEMENT AUTHORITY ALONG WITH LOCAL COUNSEL MUST APPEAR IN PERSON. (tt, ) (Entered: 01/12/2024)
01/16/2024	<u>20</u>	CONSENT ORDER granting <u>18</u> the application for the pro hac vice admission of attorneys CHRISTOPHER T. HOLDING, DARYL L. WIESEN, NATASHA E. DAUGHTREY, LOUIS L. LOBEL, and THOMAS V. MCTIGUE IV. Signed by Magistrate Judge Michael A. Hammer on 1/16/2024. (jd, ) (Entered: 01/16/2024)
01/16/2024		Set/Reset Hearings: Status Conference set for 3/5/2024 at 10:00 AM before Judge Stanley R. Chesler. ORDERED TRIAL COUNSEL WITH FULL SETTLEMENT AUTHORITY ALONG WITH LOCAL COUNSEL MUST APPEAR IN PERSON. (tt, ) (Entered: 01/16/2024)
01/17/2024	<u>21</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. re 17 Order,, Set/Clear Flags,. (WALSH, LIZA) (Entered: 01/17/2024)
01/18/2024	22	TEXT ORDER: At the request of Plaintiffs' Counsel, the Rule 16 scheduling conference is adjourned to February 21, 2024 at 3:30 p.m. The conference will be held in person in Courtroom 2C in the Martin Luther King Building and U.S. Courthouse. The parties shall file their joint discovery plan not later than February 16, 2024. So Ordered by Magistrate Judge Michael A. Hammer on 1/18/24. (tad) (Entered: 01/18/2024)
01/24/2024	<u>23</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J.. (WALSH, LIZA) (Entered: 01/24/2024)
01/25/2024	<u>24</u>	Letter from Defendant Amneal Pharmaceuticals LLC to the Hon. Michael A. Hammer, U.S.M.J. re <u>23</u> Letter. (Attachments: # <u>1</u> Exhibit Exhibit 1, # <u>2</u> Exhibit Exhibit 2, # <u>3</u> Exhibit Exhibit 3, # <u>4</u> Exhibit Exhibit 4, # <u>5</u> Exhibit Exhibit 5)(CONROY, REBEKAH) (Entered: 01/25/2024)
01/26/2024	25	TEXT ORDER: The Court has considered Teva's January 24, 2024 letter request to file its answer to the counterclaims until after the District Court rules on Teva's motion to dismiss certain of those counterclaims, pursuant to Local Civil Rule 12.2. The Court also has considered Amneal's January 25, 2024 letter setting forth its objections to Teva's proposal, and requesting that Amneal be permitted to proceed now on its anticipated Rule 12(c) motion. In the interest of judicial efficiency, and it appearing that the subject matter of Teva's Rule 12(b)(6) motion and the subject matter of Amneal's anticipated Rule 12(c) motion will likely overlap, and that both Teva's Rule 12(b)(6) motion and Amneal's Rule 12(c) motion will apply the same legal standard: (1) Teva's request is granted. Teva shall file the answer to all remaining counterclaims upon resolution of the Rule 12(b)(6) motion; and (2) Amneal may proceed at this time with its Rule 12(c) motion. To the extent Teva posits that Amneal's Rule 12(c) motion must await closure of the operative pleadings, that assertion is not well taken. It is well settled that the Court has the discretion to structure Rule 12 motion practice so as to promote timely and efficient resolution of the pleadings, and secure the just and speedy resolution of litigation particularly where, as here, there is likely significant overlap in the subject matter of the anticipated motions and the legal standard is virtually identical. See Fed. R. Civ. P. 1, 16 The Court also is not persuaded that Amneal's Rule 12(c) motion necessarily requires an answer to the de-listing

		counterclaims. Finally, the February 21, 2024 in-person Rule 16 conference shall proceed as scheduled. So Ordered by Magistrate Judge Michael A. Hammer on 1/26/2024. (Hammer, Michael) (Entered: 01/26/2024)
01/26/2024		Pro Hac Vice fee received for Christopher T. Holding, Daryl L. Wiesen, Natasha E. Daughtrey, Louis L. Lobel and Thomas V. McTigue IV: \$ 750, receipt number 136721 (jjc, ) (Entered: 01/26/2024)
01/26/2024	<u>26</u>	MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1-10</i> by NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC.. (Attachments: # <u>1</u> Declaration of Liza M. Walsh, # <u>2</u> Exhibit 2, # <u>3</u> Exhibit 3, # <u>4</u> Text of Proposed Order)(WALSH, LIZA) (Entered: 01/26/2024)
01/26/2024	<u>27</u>	BRIEF in Support filed by NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC. re <u>26</u> MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1-10 (Under Seal)</i> (Attachments: # <u>1</u> Exhibit 1 (Under Seal))(WALSH, LIZA)  <b>NOTICE TO COUNSEL:</b> Counsel is advised that pursuant to Local Civil Rule 5.3(c)(2), a single, consolidated motion to seal shall be filed within 14 days following the completed briefing of the materials sought to be sealed, or within 14 days following the date on which the last of such materials was filed under temporary seal if the motion is resolved, unless otherwise directed by the Court. (Entered: 01/26/2024)
01/29/2024	<u>28</u>	REDACTION to <u>27</u> Brief in Support of Motion,, by NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC.. (WALSH, LIZA) (Entered: 01/29/2024)
01/29/2024	<u>29</u>	Notice of Request by Pro Hac Vice Christopher T. Holding to receive Notices of Electronic Filings. (WALSH, LIZA) (Entered: 01/29/2024)
01/29/2024	<u>30</u>	Notice of Request by Pro Hac Vice Daryl L. Wiesen to receive Notices of Electronic Filings. (WALSH, LIZA) (Entered: 01/29/2024)
01/29/2024	<u>31</u>	Notice of Request by Pro Hac Vice Natasha E. Daughtrey to receive Notices of Electronic Filings. (WALSH, LIZA) (Entered: 01/29/2024)
01/29/2024	<u>32</u>	Notice of Request by Pro Hac Vice Louis L. Lobel to receive Notices of Electronic Filings. (WALSH, LIZA) (Entered: 01/29/2024)
01/29/2024	<u>33</u>	Notice of Request by Pro Hac Vice Thomas V. McTigue IV to receive Notices of Electronic Filings. (WALSH, LIZA) (Entered: 01/29/2024)
01/29/2024		Set Deadlines as to <u>26</u> MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1-10</i> . Motion set for 2/20/2024 before Judge Stanley R. Chesler. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk's Office and does not supersede any previous or subsequent orders from the Court. (jd, ) (Entered: 01/29/2024)
01/31/2024		Pro Hac Vice counsel, CHRISTOPHER T. HOLDING, DARYL L. WIESEN, NATASHA E. DAUGHTREY, LOUIS L. LOBEL and THOMAS MCTIGUE, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (jd, ) (Entered: 01/31/2024)
02/06/2024	<u>34</u>	Letter from Defendants on Behalf of All Parties to the Hon. Michael A. Hammer, U.S.M.J.. (CONROY, REBEKAH) (Entered: 02/06/2024)
02/07/2024	<u>35</u>	LETTER ORDER granting <u>34</u> Joint consolidated briefing schedule and page limits for Plaintiffs'. Signed by Magistrate Judge Michael A. Hammer on 2/7/2024. (jd, ) (Entered: 02/08/2024)
02/09/2024	<u>36</u>	NOTICE of Appearance by HECTOR DANIEL RUIZ on behalf of NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC. (RUIZ, HECTOR) (Entered: 02/09/2024)



02/09/2024	<u>37</u>	NOTICE of Appearance by CHRISTINE CLARK on behalf of NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC. (CLARK, CHRISTINE) (Entered: 02/09/2024)
02/14/2024	<u>38</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. encl. Joint Discovery Plan. (Attachments: # <u>1</u> Joint Discovery Plan)(WALSH, LIZA) (Entered: 02/14/2024)
02/16/2024	<u>39</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J.. (CLARK, CHRISTINE) (Entered: 02/16/2024)
02/20/2024	40	TEXT ORDER: The Court has reviewed the parties' February 16, 2024 letter [D.E. 39], which requests that the February 21st Rule 16 conference proceed via telephonically. In an effort to accommodate counsel, and in view of there being no disputes at this time, the conference shall proceed via Microsoft Teams at the same time. The Court will provide the Teams link to counsel. So Ordered by Magistrate Judge Michael A. Hammer on 2/20/2024. (Hammer, Michael) (Entered: 02/20/2024)
02/20/2024	<u>41</u>	MOTION for Judgment on the Pleadings <i>as to Counterclaims 1–5</i> by AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC. (Attachments: # <u>1</u> Declaration of Rebekah Conroy, # <u>2</u> Exhibit 1 to Conroy Decl., # <u>3</u> Exhibit 2 to Conroy Decl., # <u>4</u> Exhibit 3 to Conroy Decl., # <u>5</u> Exhibit 4 to Conroy Decl., # <u>6</u> Exhibit 5 to Conroy Decl., # <u>7</u> Exhibit 6 to Conroy Decl., # <u>8</u> Exhibit 7 to Conroy Decl., # <u>9</u> Exhibit 8 to Conroy Decl., # <u>10</u> Exhibit 9 to Conroy Decl., # <u>11</u> Exhibit 10 to Conroy Decl., # <u>12</u> Exhibit 11 to Conroy Decl., # <u>13</u> Exhibit 12 to Conroy Decl., # <u>14</u> Text of Proposed Order Granting Motion for Judgment on the Pleadings <i>as to Counterclaims 1–5</i> )(CONROY, REBEKAH) (Entered: 02/20/2024)
02/20/2024	<u>42</u>	BRIEF in Support filed by AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC re <u>26</u> MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1–10</i> , <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1–5 and in Opposition to Plaintiffs' Motion to Dismiss</i> (CONROY, REBEKAH) <hr/> <u>NOTICE TO COUNSEL:</u> Counsel is advised that pursuant to Local Civil Rule 5.3(c)(2), a single, consolidated motion to seal shall be filed within 14 days following the completed briefing of the materials sought to be sealed, or within 14 days following the date on which the last of such materials was filed under temporary seal if the motion is resolved, unless otherwise directed by the Court. (Entered: 02/20/2024)
02/21/2024		Set Deadlines as to <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1–5</i> . Motion set for 3/18/2024 before Judge Stanley R. Chesler. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk's Office and does not supersede any previous or subsequent orders from the Court. (jd, ) (Entered: 02/21/2024)
02/21/2024	<u>43</u>	PRETRIAL SCHEDULING ORDER. Signed by Magistrate Judge Michael A. Hammer on 2/21/2024. (jd, ) (Entered: 02/22/2024)
02/21/2024		Minute Entry for proceedings held before Magistrate Judge Michael A. Hammer: Scheduling Conference held on 2/21/2024. (ECR) (jqb, ) (Entered: 02/22/2024)
02/22/2024	<u>44</u>	Letter from Defendants with Consent of All Parties re <u>35</u> Order. (CONROY, REBEKAH) (Entered: 02/22/2024)
02/23/2024	<u>45</u>	LETTER ORDER granting <u>44</u> Defendant's request for a one–week extension to the briefing schedule for the pending motions. Signed by Magistrate Judge Michael A. Hammer on 2/22/2024. (jd, ) Modified on 2/23/2024 (jd, ). (Entered: 02/23/2024)
02/26/2024	<u>46</u>	Letter from Liza M. Walsh, Esq. to the Hon. Michael A. Hammer, U.S.M.J... (WALSH, LIZA) (Entered: 02/26/2024)
02/27/2024	47	TEXT ORDER: There will be a telephone conference today at 4:00 p.m. to discuss the parties' February 26, 2024 proposal to extend the deadline to serve written discovery until thirty days before the close of fact discovery. Counsel will dial 1–888–684–8852

		and enter 1456817# to join the conference. So Ordered by Magistrate Judge Michael A. Hammer on 2/27/2024. (Hammer, Michael) (Entered: 02/27/2024)
02/27/2024	<u>48</u>	REDACTION to <u>42</u> Brief in Support of Motion,,, <i>Redacted Memorandum of Law</i> by AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC. (CONROY, REBEKAH) (Entered: 02/27/2024)
02/27/2024	49	TEXT ORDER: As discussed during today's telephone conference, the parties shall meet and confer and file a proposed amended scheduling order not later than March 8, 2024. So Ordered by Magistrate Judge Michael A. Hammer on 2/27/24. (tad) (Entered: 02/27/2024)
02/27/2024		Minute Entry for proceedings held before Magistrate Judge Michael A. Hammer: Status Conference held on 2/27/2024. (ECR) (jqb, ) (Entered: 02/27/2024)
03/05/2024	<u>50</u>	Minute Entry for proceedings held before Judge Stanley R. Chesler: Status Conference held on 3/5/2024. Local and Trial Counsel present. Pro hac vice for defendants shall be filed. (tt, ) (Entered: 03/05/2024)
03/05/2024	<u>51</u>	MOTION for Leave to File <i>Motion for Leave to File as Amicus by March 22, 2024</i> by FEDERAL TRADE COMMISSION. (Attachments: # <u>1</u> Text of Proposed Order Proposed Order)(VETTRAINO, BRADLEY) (Entered: 03/05/2024)
03/06/2024	<u>52</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. encl. Proposed Stipulated Discovery Confidentiality Order. (Attachments: # <u>1</u> Text of Proposed Order, # <u>2</u> Declaration of Liza M. Walsh, # <u>3</u> Declaration of Rebekah Conroy)(WALSH, LIZA) (Entered: 03/06/2024)
03/07/2024		Set Deadlines as to <u>51</u> MOTION for Leave to File Motion for Leave to File as Amicus by March 22, 2024. Motion set for 4/1/2024 before Magistrate Judge Michael A. Hammer. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk's Office and does not supersede any previous or subsequent orders from the Court. (jd, ) (Entered: 03/07/2024)
03/07/2024	<u>53</u>	Discovery Confidentiality Order. Signed by Magistrate Judge Michael A. Hammer on 3/7/2024. (jd, ) (Entered: 03/07/2024)
03/08/2024	<u>54</u>	ORDER granting the Federal Trade Commission's <u>51</u> Motion for Leave to File a Motion Seeking Leave to File an Amicus Brief. Signed by Judge Stanley R. Chesler on 3/8/2024. (mxw, ) (Entered: 03/08/2024)
03/08/2024	<u>55</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. re 49 Order. (Attachments: # <u>1</u> Text of Proposed Order)(WALSH, LIZA) (Entered: 03/08/2024)
03/11/2024	<u>56</u>	AMENDED PRETRIAL SCHEDULING ORDER. Signed by Magistrate Judge Michael A. Hammer on 3/11/2024. (jd, ) (Entered: 03/11/2024)
03/11/2024	<u>57</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. re briefing schedule. (CLARK, CHRISTINE) (Entered: 03/11/2024)
03/12/2024	<u>58</u>	LETTER ORDER granting <u>57</u> the parties request to modify the briefing schedule. TEVA's consolidated opposition papers to AMNEAL'S motion and reply brief due on 4/15/2024. Signed by Magistrate Judge Michael A. Hammer on 3/12/2024. (jd, ) (Entered: 03/12/2024)
03/13/2024	<u>59</u>	Letter from Defendants Seeking Pro Hac Vice Admission of Counsel with Consent. (Attachments: # <u>1</u> Certification of Rebekah Conroy, # <u>2</u> Certification of Jeremy J. Edwards, # <u>3</u> Certification of Steven A. Maddox, # <u>4</u> Certification of Melissa Hatch O'Donnell, # <u>5</u> Certification of Robin P. Sumner, # <u>6</u> Certification of Andrew P. Zappia, # <u>7</u> Text of Proposed Order Admitting Counsel Pro Hac Vice by Consent)(CONROY, REBEKAH) (Entered: 03/13/2024)
03/13/2024	<u>60</u>	ORDER granting <u>59</u> Application for the admission of pro hac vice Attorneys JEREMY J. EDWARDS, STEVEN A. MADDOX, MELISSA HATCH O'DONNELL, ROBIN P. SUMNER, and ANDREW P. ZAPPIA. Signed by Magistrate Judge Michael A. Hammer on 3/13/2024.(jd, ) Modified on 3/13/2024 (jd, ). (Entered: 03/13/2024)

03/21/2024	<u>62</u>	Transcript of Hearing held on February 21, 2024, before Magistrate Judge Michael A. Hammer. Transcriber: King Transcription Services (973-237-6080). <b>NOTICE REGARDING (1) REDACTION OF PERSONAL IDENTIFIERS IN TRANSCRIPTS AND (2) MOTION TO REDACT AND SEAL:</b> The parties have seven (7) calendar days to file with the Court a Notice of Intent to Request Redaction of this Transcript to comply with Fed.R.Civ.P.5.2(a) (personal identifiers). Parties seeking to redact and seal this Transcript, or portions thereof, pursuant to L.Civ.R. 5.3(g) must e-file a Motion to Redact and Seal utilizing the event `Redact and Seal Transcript/Digital Recording`. Redaction Request to Transcription Agency due, but not filed, by 4/11/2024. Redacted Transcript Deadline set for 4/22/2024. Release of Transcript Restriction set for 6/20/2024. (jml) (Entered: 03/22/2024)
03/22/2024	<u>61</u>	Consent MOTION for Leave to File <i>Brief as Amicus Curiae</i> by FEDERAL TRADE COMMISSION. (Attachments: # <u>1</u> Proposed Amicus Brief, # <u>2</u> Text of Proposed Order)(VETTRAINO, BRADLEY) (Entered: 03/22/2024)
03/25/2024		Set Deadlines as to <u>61</u> Consent MOTION for Leave to File Brief as Amicus Curiae. Motion set for 4/15/2024 before Magistrate Judge Michael A. Hammer. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk's Office and does not supersede any previous or subsequent orders from the Court. (jd, ) (Entered: 03/25/2024)
03/28/2024	<u>63</u>	ORDER granting <u>61</u> The Federal Trade Commission's Motion for Leave to File as Amicus Curiae. Signed by Magistrate Judge Michael A. Hammer on 3/28/2024. (jd, ) (Entered: 03/28/2024)
04/15/2024	<u>64</u>	BRIEF in Opposition filed by All Plaintiffs re <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1-5 AND REPLY IN SUPPORT OF PLAINTIFFS MOTION TO DISMISS</i> (Attachments: # <u>1</u> Declaration of Liza M. Walsh, # <u>2</u> Exhibit 11)(CLARK, CHRISTINE) <hr/> <a href="#">NOTICE TO COUNSEL:</a> Counsel is advised that pursuant to Local Civil Rule 5.3(c)(2), a single, consolidated motion to seal shall be filed within 14 days following the completed briefing of the materials sought to be sealed, or within 14 days following the date on which the last of such materials was filed under temporary seal if the motion is resolved, unless otherwise directed by the Court. (Entered: 04/15/2024)
04/15/2024	<u>65</u>	Exhibit to <u>64</u> Brief in Opposition to Motion,, <i>Exhibits 4, 5, 6, 7, 8, 9, and 10</i> by All Plaintiffs. (CLARK, CHRISTINE) (Entered: 04/15/2024)
04/15/2024	<u>66</u>	Certification of Service of Liza M. Walsh on behalf of All Plaintiffs Re <u>64</u> Brief in Opposition to Motion,, <u>65</u> Exhibit (to Document). (CLARK, CHRISTINE) (Entered: 04/15/2024)
04/26/2024	<u>67</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J.. (WALSH, LIZA) (Entered: 04/26/2024)
04/29/2024	<u>68</u>	LETTER ORDER granting <u>67</u> Plaintiff's request to modify the Amended Pretrial Scheduling Order. Signed by Magistrate Judge Michael A. Hammer on 4/29/2024. (jd, ) (Entered: 04/29/2024)
05/02/2024	<u>69</u>	REDACTION to <u>64</u> Brief in Opposition to Motion,, by All Plaintiffs. (Attachments: # <u>1</u> (Redacted) Declaration of L. Walsh)(WALSH, LIZA) (Entered: 05/02/2024)
05/07/2024	<u>70</u>	REPLY BRIEF to Opposition to Motion filed by AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC re <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1-5</i> (CONROY, REBEKAH) (Entered: 05/07/2024)
05/07/2024		Set/Reset Deadlines as to <u>26</u> MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1-10</i> , <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1-5</i> . Motion set for 5/14/2024 at 10:00 AM in Newark - Courtroom 2 before Judge Stanley R. Chesler. ORDERED ALL PARTIES TO APPEAR IN PERSON READY TO PROCEED (tt, ) (Entered: 05/07/2024)



05/09/2024		Set/Reset Deadlines as to <u>26</u> MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1-10</i> , <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1-5</i> . Motion set for 5/22/2024 at 10:00 AM in Newark – Courtroom 2 before Judge Stanley R. Chesler. ORDERED ALL PARTIES TO APPEAR READY TO PROCEED (tt, ) (Entered: 05/09/2024)
05/13/2024	<u>71</u>	MOTION for Leave to Appear Pro Hac Vice <i>Kathryn S. Kayali</i> by All Plaintiffs. (Attachments: # <u>1</u> Certification of Kathryn S. Kayali, # <u>2</u> Certification of Liza M. Walsh, # <u>3</u> Text of Proposed Order)(WALSH, LIZA) (Entered: 05/13/2024)
05/14/2024	<u>72</u>	TEXT ORDER: In light of the recent amendments to the Amended Pretrial Scheduling Order, D.E. 68, the telephone conference set for May 20, 2024 is adjourned to August 15, 2024 at 3:00 p.m. Counsel shall dial 1-888-684-8852 and enter access code 1456817# to join the call. So Ordered by Magistrate Judge Michael A. Hammer on 5/14/24. (tad) (Entered: 05/14/2024)
05/14/2024	<u>73</u>	CONSENT ORDER granting <u>71</u> Motion for Leave to Appear Pro Hac Vice as to KATHRYN S. KAYALI. Signed by Magistrate Judge Michael A. Hammer on 5/14/2024. (jd, ) (Entered: 05/14/2024)
05/14/2024	<u>74</u>	Notice of Request by Pro Hac Vice Andrew P. Zappia, Esq. to receive Notices of Electronic Filings. ( Pro Hac Vice fee \$ 250 receipt number ANJDC-15366306.) (CONROY, REBEKAH) (Entered: 05/14/2024)
05/14/2024	<u>75</u>	Notice of Request by Pro Hac Vice Brett Garrison to receive Notices of Electronic Filings. ( Pro Hac Vice fee \$ 250 receipt number ANJDC-15366333.) (CONROY, REBEKAH) (Entered: 05/14/2024)
05/14/2024	<u>76</u>	Notice of Request by Pro Hac Vice Jeremy Edwards, Esq. to receive Notices of Electronic Filings. ( Pro Hac Vice fee \$ 250 receipt number ANJDC-15366343.) (CONROY, REBEKAH) (Entered: 05/14/2024)
05/14/2024	<u>77</u>	Notice of Request by Pro Hac Vice Melissa Hatch O'Donnell, Esq. to receive Notices of Electronic Filings. ( Pro Hac Vice fee \$ 250 receipt number ANJDC-15366352.) (CONROY, REBEKAH) (Entered: 05/14/2024)
05/14/2024	<u>78</u>	Notice of Request by Pro Hac Vice Robin P. Summer, Esq. to receive Notices of Electronic Filings. ( Pro Hac Vice fee \$ 250 receipt number ANJDC-15366358.) (CONROY, REBEKAH) (Entered: 05/14/2024)
05/14/2024	<u>79</u>	Notice of Request by Pro Hac Vice Steven Maddox, Esq. to receive Notices of Electronic Filings. ( Pro Hac Vice fee \$ 250 receipt number ANJDC-15366362.) (CONROY, REBEKAH) (Entered: 05/14/2024)
05/14/2024		Pro Hac Vice counsel, ANDREW P. ZAPPIA, BRETT GARRISON, JEREMY J. EDWARDS, MELISSA HATCH O'DONNELL, ROBIN P. SUMNER and STEVEN A. MADDOX, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (jd, ) (Entered: 05/14/2024)
05/16/2024	<u>80</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J. re <u>68</u> Order. (WALSH, LIZA) (Entered: 05/16/2024)
05/17/2024	<u>81</u>	LETTER ORDER granting <u>80</u> Plaintiff's request to Amend pretrial schedule. Signed by Magistrate Judge Michael A. Hammer on 5/16/2024. (jd, ) (Entered: 05/17/2024)
05/22/2024	<u>82</u>	Minute Entry for proceedings held before Judge Stanley R. Chesler: Motion Hearing held on 5/22/2024 re <u>41</u> MOTION for Judgment on the Pleadings <i>as to Counterclaims 1-5</i> filed by AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS INC., AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, <u>26</u> MOTION to Dismiss <i>DEFENDANTS' COUNTERCLAIM COUNTS 1-10</i> filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., TEVA PHARMACEUTICALS USA, INC., Motions Taken Under Advisement: DECISION RESERVED (Court Reporter, Mary Jo Monteleone (973-645-3833)) (tt, ) (Entered: 05/22/2024)

05/23/2024	<u>83</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J.. (WALSH, LIZA) (Entered: 05/23/2024)
05/23/2024	<u>85</u>	LETTER ORDER granting <u>83</u> Plaintiff's request for a one-week extension of the deadline for the parties to negotiate their ESI protocol, until 5/31/2024. Signed by Magistrate Judge Michael A. Hammer on 5/23/2024. (jd, ) (Entered: 05/24/2024)
05/24/2024	<u>84</u>	Transcript of Motion Hearing held on May 22, 2024, before Judge Stanley R. Chesler. Court Reporter: Mary Jo Monteleone (973-645-3833). <b>NOTICE REGARDING (1) REDACTION OF PERSONAL IDENTIFIERS IN TRANSCRIPTS AND (2) MOTION TO REDACT AND SEAL:</b> The parties have seven (7) calendar days to file with the Court a Notice of Intent to Request Redaction of this Transcript to comply with Fed.R.Civ.P.5.2(a) (personal identifiers). Parties seeking to redact and seal this Transcript, or portions thereof, pursuant to L.Civ.R. 5.3(g) must e-file a Motion to Redact and Seal utilizing the event `Redact and Seal Transcript/Digital Recording`. Redaction Request to Court Reporter due, but not filed, by 6/14/2024. Redacted Transcript Deadline set for 6/24/2024. Release of Transcript Restriction set for 8/22/2024. (adc) (Entered: 05/24/2024)
05/31/2024	<u>86</u>	Letter from Liza M. Walsh to the Hon. Michael A. Hammer, U.S.M.J.. (Attachments: # <u>1</u> Text of Proposed Order)(WALSH, LIZA) (Entered: 05/31/2024)
06/03/2024	<u>87</u>	STIPULATION AND ORDER Establishing the protocol for the production of documents and electronically stored information. Signed by Magistrate Judge Michael A. Hammer on 6/3/2024. (jd, ) (Entered: 06/03/2024)
06/10/2024	<u>88</u>	OPINION & ORDER denying <u>26</u> Plaintiff's Motion to Dismiss Counterclaim Counts 1-10; granting <u>41</u> Defendant's Motion for Partial Judgment on the Pleadings. Judgment is entered in favor of Counts 1-5 of Defendants' Counterclaims. Signed by Judge Stanley R. Chesler on 6/10/2024. (jd, ) (Entered: 06/10/2024)
06/11/2024	<u>89</u>	TEXT ORDER: The Court having been informed that Teva intends to file a motion to stay, it is ORDERED that: 1) Teva shall file its moving papers by close of business today, June 11, 2024; 2) Amneal shall file its opposition papers by close of business tomorrow, June 12, 2024; and 3) oral argument on the motion shall be heard on Thursday, June 13, 2024 at 11:00 a.m. (re: O/O (d.e. 88)). So Ordered by Judge Stanley R. Chesler on 6/11/2024. (tt, ) (Entered: 06/11/2024)
06/11/2024		Set/Reset Hearings: Hearing set for 6/13/2024 at 11:00 AM in Newark – Courtroom 2 before Judge Stanley R. Chesler. regarding ENTRY ((d.e. 89)). ORDERED ALL PARTIES TO APPEAR IN PERSON. (tt, ) (Entered: 06/11/2024)
06/11/2024	<u>90</u>	MOTION to Stay by All Plaintiffs. (Attachments: # <u>1</u> Text of Proposed Order, # <u>2</u> Certificate of Service)(WALSH, LIZA) (Entered: 06/11/2024)
06/11/2024	<u>91</u>	DECLARATION of Liza M. Walsh re <u>90</u> MOTION to Stay by All Plaintiffs. (Attachments: # <u>1</u> Brief Memorandum of Law in Support of Motion to Stay, # <u>2</u> Exhibit A, # <u>3</u> Exhibit B, # <u>4</u> Exhibit C)(WALSH, LIZA) <hr/> <b>NOTICE TO COUNSEL:</b> Counsel is advised that pursuant to Local Civil Rule 5.3(c)(2), a single, consolidated motion to seal shall be filed within 14 days following the completed briefing of the materials sought to be sealed, or within 14 days following the date on which the last of such materials was filed under temporary seal if the motion is resolved, unless otherwise directed by the Court. (Entered: 06/11/2024)
06/11/2024	<u>92</u>	NOTICE OF APPEAL to Federal Circuit as to <u>88</u> Order on Motion to Dismiss,, Order on Motion for Judgment on the Pleadings, by NORTON (WATERFORD) LTD., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA PHARMACEUTICALS USA, INC.. Filing fee \$ 605, receipt number ANJDC-15439392. The Clerk's Office hereby certifies the record and the docket sheet available through ECF to be the certified list in lieu of the record and/or the certified copy of the docket entries. (WALSH, LIZA) (Entered: 06/11/2024)
06/12/2024	<u>93</u>	NOTICE of Appearance by SHALOM D STONE on behalf of AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC (STONE, SHALOM) (Entered: 06/12/2024)

**FOR PUBLICATION**

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

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

**Civil Action No. 23-20964 (SRC)**

Plaintiffs,

**OPINION & ORDER**

v.

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

Defendants.

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**CHESLER, U.S.D.J.**

This matter comes before the Court on two motions: 1) the motion to dismiss by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”); and 2) the motion for partial judgment on the pleadings, pursuant to Federal Rule of Civil Procedure 12(c), by Defendants Amneal Pharmaceuticals Of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, “Amneal.”) For the reasons that follow, the motion to dismiss will be denied, and the motion for partial judgment on the pleadings will be granted.

This case arises out of a patent infringement dispute under the Hatch-Waxman Act between Teva and Amneal. Teva holds approved NDA No. 021457 for ProAir® HFA (albuterol sulfate) Inhalation Aerosol (“ProAir® HFA”), and owns certain patents listed in the Orange Book as covering this product: U.S. Patent Nos. 8,132,712 (the “712 patent”), 9,463,289 (the “289 patent”), 9,808,587 (the “587 patent”), 10,561,808 (the “808 patent”), and 11,395,889 (the “889 patent”) (collectively, the “Patents at issue” or the “Inhaler Patents”). Amneal has filed ANDA No. 211600, seeking to make and sell a generic version of ProAir® HFA. The following facts are undisputed. The Amneal ANDA contains a paragraph IV certification that the proposed product will not infringe any valid claim of the Patents at issue. After Amneal sent Teva the required notice letter, Teva filed the instant suit. The Amended Complaint asserts claims for patent infringement of the Patents at issue. Amneal filed an Amended Answer to the Amended Complaint asserting, *inter alia*, twelve counterclaim counts. Counterclaim Counts 1-5 seek declarations ordering Teva to delist the Patents at issue from the Orange Book. Counterclaim Counts 6-9 allege violations of the Sherman Act, and Count 10 alleges a violation of the New Jersey Antitrust Act, N.J.S.A. § 56:9. Counterclaims 11 and 12 are not at issue on these motions.

The Federal Trade Commission (“FTC”) requested and was granted leave to file a brief as *amicus curiae*.

#### **I. Teva’s motion to dismiss Counterclaim Counts 6-10**

Teva moves to dismiss Counterclaim Counts 1-10. The Court first considers the motion to dismiss the antitrust counterclaims, Counterclaim Counts 6-10. Teva contends that the

antitrust counterclaims are premised on two forms of alleged anticompetitive conduct: 1) improper Orange Book listing; and 2) sham litigation.

Teva contends that antitrust law provides no cause of action for improper Orange Book listing. First, Teva argues that because “Teva’s patents are properly listed as a matter of law . . . any claim based on purported improper listing necessarily fails.” (Pls.’ MTD Br. at 25.) Later in this Opinion, this Court will consider and address Amneal’s motion for judgment on the pleadings; as will be explained, the Court concludes that Teva’s patents are *not* properly listed in the Orange Book as a matter of law. This conclusion does not support a Rule 12(b)(6) dismissal of an antitrust claim for improper Orange Book listing.

Second, Teva argues that, even if the Court were to find that the listings are improper, given the Trinko doctrine, “antitrust law does not create a cognizable claim for Amneal based on purported improper listing in any event.” (Pls.’ MTD Br. at 25.) In short, Teva argues that the instant case is analogous to Trinko, but this Court is not persuaded. The Supreme Court’s syllabus for Trinko states the relevant key points of that case:

The Telecommunications Act of 1996 imposes upon an incumbent local exchange carrier (LEC) the obligation to share its telephone network with competitors.

...

*Held:* Respondent's complaint alleging breach of an incumbent LEC's 1996 Act duty to share its network with competitors does not state a claim under § 2 of the Sherman Act.

...

(c) Traditional antitrust principles do not justify adding the present case to the few existing exceptions from the proposition that there is no duty to aid competitors.

Verizon Communs., Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 398-99

(2004). Teva argues that the Listing Statute, 21 U.S.C. § 355, imposes upon an NDA holder an analogous obligation:

[T]he Hatch-Waxman Act created a statutory obligation on a brand drug company to list patents in the Orange Book in order to help generic drug companies compete with the brand company by getting FDA approval for and launching their competing generic products more quickly. This duty is, for all relevant purposes, indistinguishable from the statutory duty imposed on incumbent service providers at issue in *Trinko*.

(Pls.’ MTD Opening Br. at 28.)

Teva has failed to persuade this Court that the statutes at issue in the two cases are analogous. As the statement from the Supreme Court’s Syllabus makes clear, the key attribute of the statutory provision at issue was that it “imposes . . . the obligation to share its telephone network with competitors.” *Trinko*, 540 U.S. at 398. The Listing Statute does not impose any analogous obligation on the holder of an NDA. In fact, the Listing Statute says nothing about competitors or other drug companies; it speaks only about certain information that must be submitted “to the Secretary as part of the application.” 21 U.S.C. § 355(b)(1)(A). That subsection, 21 U.S.C. § 355(b)(1)(A), lists eight subparagraphs which set forth what must be submitted to the Secretary as part of the application.

Teva offers nothing more than *ipse dixit* in support of its argument that the duty imposed by the Listing Statute is “indistinguishable” from the statutory duty at issue in *Trinko*. Teva’s opening brief quotes the Supreme Court’s discussion of the Hatch-Waxman Act in *Caraco*: “To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents.” *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). This says nothing about anyone helping competitors or cooperating with competitors. Teva has given this Court no basis to find that the Listing Statute imposes on NDA applicants a duty to aid competitors.



Furthermore, the FTC aptly summarizes the bases for distinguishing Trinko from the instant case as follows:

*Trinko* is inapplicable because Amneal’s counterclaims are not an expansion of antitrust law, the FDA does not directly police the Orange Book, and the statutory amendment to add a delisting counterclaim does not transform a patent enforcement framework into an antitrust regulatory scheme.

(FTC *Amicus* Br. at 33.) The FTC contends that the FDA’s ministerial role<sup>1</sup> in Orange Book listings differs greatly from the extensive scheme for FCC regulation of telecommunications competition described in Trinko. The Telecommunications Act of 1996 established the regulatory scheme of interest in Trinko:

The Telecommunications Act of 1996, Pub. L. 104-104, 110 Stat. 56, imposes certain duties upon incumbent local telephone companies in order to facilitate market entry by competitors, and establishes a complex regime for monitoring and enforcement. . .

The 1996 Act sought to uproot the incumbent LECs’ monopoly and to introduce competition in its place. Central to the scheme of the Act is the incumbent LEC’s obligation under 47 U.S.C. § 251(c) to share its network with competitors.

Trinko, 540 U.S. at 401-2 (citations omitted). Teva does not contend that, in enacting the Orange Book listing provisions of the Hatch-Waxman Act, Congress sought to uproot any monopolies, nor that, as to the Orange Book, the FDA has any enforcement function. The only enforcement mechanism Teva points to is the delisting counterclaim – but this is plainly a judicial remedy<sup>2</sup> (as Teva admits), not an enforcement power entrusted to a regulator.

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<sup>1</sup> See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 60 F.4th 1373, 1378 (Fed. Cir. 2023) (“Notably, the FDA does not verify that submitted patents actually meet statutory listing criteria, nor does the FDA proactively remove improperly listed patents. See Apotex, Inc. v. Thompson, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (“[T]he FDA’s . . . duties with respect to Orange Book listings are purely ministerial.”)”).

<sup>2</sup> In Trinko, the Supreme Court expressed skepticism that, where continuing supervision is needed, a court could serve as an effective enforcer. Id. at 415 (“An antitrust court is unlikely to

Compare this judicial remedy to the “regulatory structure” the Supreme Court described in

Trinko:

One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny. Where, by contrast, there is nothing built into the regulatory scheme which performs the antitrust function, the benefits of antitrust are worth its sometimes considerable disadvantages. . . .

The regulatory framework that exists in this case demonstrates how, in certain circumstances, regulation significantly diminishes the likelihood of major antitrust harm.

Id. at 412 (citations omitted). Teva has not demonstrated that the Orange Book listing provisions at issue comprise a regulatory structure designed to deter and remedy anticompetitive harm. In the absence of such a regulatory structure, the Supreme Court stated, it is more plausible that antitrust law provides additional scrutiny.

Having reviewed the enforcement mechanisms established by the Telecommunications Act of 1996, the Supreme Court concluded that “the [regulatory] regime was an effective steward of the antitrust function.” Id. at 413. In the instant case, Teva does not even claim that there is any regulator with enforcement powers. This Court is not persuaded that availability of the judicial remedy of delisting significantly diminishes the likelihood of major antitrust harm, nor that this remedy alone is an effective steward of the antitrust function. As the FTC points out, the judicial delisting remedy does not provide for damages; that remedy alone cannot be an effective steward of the antitrust function.

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be an effective day-to-day enforcer of these detailed sharing obligations.”)



In sum, *amicus* FTC has persuasively distinguished Trinko. Teva has failed to persuade that Trinko is analogous and forecloses Amneal's antitrust counterclaims.

Teva argues as well that the plain language of the Listing Statute precludes an antitrust claim predicated on improper listing, citing 21 U.S.C. § 355(j)(5)(c)(ii)(II), which states:

(ii) Counterclaim to infringement action.

(I) In general. If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

Again, Teva presents only an *ipse dixit* conclusion about the meaning of 21 U.S.C. § 355(j)(5)(c)(ii)(II), without analysis or argument. On its face, subclause (II) delimits the authority of subclause (I), which authorizes the assertion of a counterclaim to correct Orange Book information in particular cases. The clear purpose of subclause (II) is to bar an independent suit seeking the relief stated in subsection (I) in the absence of a Hatch-Waxman infringement suit; it is designed to prevent the filing of claims for correction of the Orange Book as independent actions.

Amneal has asserted Counterclaim Counts 1-5, seeking orders of correction, and these appear to be permitted by 21 U.S.C. § 355(j)(5)(c)(ii); Teva does not argue that Counts 1-5 are not permitted by 21 U.S.C. § 355(j)(5)(c)(ii). Teva does not explain how 21 U.S.C. §

355(j)(5)(c)(ii) impacts the assertion of the Counterclaim Counts 6-10 under antitrust law. Counts 6-10 do not seek any order requiring the holder to correct or delete Orange Book information. Counts 6, 9, and 10 reference improper listing in the Orange Book as an example of an anticompetitive act. (Am. Answer at ¶¶ 281, 318, 322.) Count 7 does not mention the Orange Book. Count 8 references improper listing of patents in the Orange Book as an example of “a predatory scheme to monopolize the Relevant Market.” (Am. Answer at ¶ 310.) Counterclaim Counts 6-10 do not seek correction or deletion of information in the Orange Book and do not fall within the ambit of 21 U.S.C. § 355(j)(5)(c)(ii)(I).

The Court finds that subsections (I) and (II) neither authorize nor prohibit Counterclaim Counts 6-10. Teva has offered nothing to support its contention that the plain language of these subsections prohibits the assertion of the antitrust counterclaims.

Teva next argues that Counterclaim Count 7, for sham litigation in violation of the Sherman Act, fails to state a valid claim. Teva’s arguments for dismissal are all variants of the contention that Count 7 is unlikely to succeed at trial or summary judgment. As the Supreme Court stated in Twombly, “of course, a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and ‘that a recovery is very remote and unlikely.’” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974).) Teva does no more here than argue that recovery on Count 7 is remote and unlikely; Plaintiff does not argue that Count 7 fails to plead a legally cognizable claim for relief.

Next, Teva argues that Count 6, alleging an anticompetitive scheme, fails to state a claim because the counterclaim components of that scheme all fail to state valid claims. Because this

Court has concluded that Amneal has pled viable claims for anticompetitive conduct, it is not persuaded that Count 6 is invalid because all the other counterclaims are also invalid.

The Court concludes that Teva has failed to persuade that any of the antitrust counterclaims fail to state a legally cognizable claim for relief, and the Rule 12(b)(6) motion to dismiss the antitrust counterclaims will be denied.

## II. Counterclaim Counts 1-5 and the Listing Statute

As to the delisting counterclaims, Counts 1-5, Teva moves to dismiss them too. Amneal cross-moves for judgment on the pleadings on Counterclaim Counts 1-5. The Third Circuit has stated:

We analyze a motion for judgment on the pleadings under Federal Rule of Civil Procedure Rule 12(c) under the same standards that apply to a Rule 12(b)(6) motion. Under Rule 12(c), a court must accept all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw all reasonable inferences in favor of the non-moving party. A court may grant a Rule 12(c) motion if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law. A plaintiff can survive a Rule 12(c) motion if her complaint contains sufficient factual matter to show that the claim is facially plausible, thus enabling the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged.

Bibbs v. Trans Union LLC, 43 F.4th 331, 339 (3d Cir. 2022) (citations omitted.)

In short, Teva contends that the delisting claims are premised on erroneous interpretations of the Listing Statute. As to Amneal's motion for judgment on the pleadings, Amneal and *amicus* the FTC argue that the listing of the Inhaler Patents in the Orange Book is improper and not authorized by the Listing Statute. Both of these motions turn on issues of interpretation of the Listing Statute.

The Listing Statute states, in relevant part:

(b) Filing application; contents.

- (1)
  - (A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—
    - ...
    - (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—
      - (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
      - (II) claims a method of using such drug for which approval is sought or has been granted in the application.

21 U.S.C. § 355. Although the Orange Book is not mentioned by name in the statute, the parties agree that 21 U.S.C. § 355(b)(1)(A)(viii) states the fundamental requirements to effect the listing of a patent in the Orange Book. Subsection § 355(b)(1)(A)(viii) authorizes the listing of certain patents of three kinds: drug substance patents, drug product patents, and method of use patents. Teva contends that the Inhaler Patents are drug product patents, and that they are properly listed pursuant to § 355(b)(1)(A)(viii)(I).

Subsection § 355(b)(1)(A)(viii)(I) states two requirements: 1) the patent must “claim[] the drug for which the applicant submitted the application;” and 2) the patent must be directed to a drug substance or a drug product. This Court finds that the listing issue in this case turns on the interpretation of the first element and concludes, in short, that the Inhaler Patents do not claim the drug for which the applicant submitted the application.

There is no dispute that the Inhaler Patents contain no claim for the active ingredient at issue, albuterol sulfate. Amneal contends that the Inhaler Patents do not meet the requirement that they claim the relevant drug. The FTC agrees.

Teva points out that the word “drug” in § 355 is expressly defined in 21 U.S.C. §

321(g)(1):

The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

The Court acknowledges that this definition includes articles intended for use in the treatment of disease, and that the ProAir® HFA inhaler falls within its scope. The problem for Teva is that this broad statutory definition of drug does not suffice to establish that the Inhaler Patents claim the drug for which Teva submitted its application, NDA No. 021457.<sup>3</sup> Teva offers the FDA approval letter for this NDA, dated October 29, 2004; the first line of this letter states: “Please refer to your new drug application (NDA) dated January 30, 2003, received January 31, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for albuterol sulfate HFA Inhalation Aerosol.” (Answer Ex. A at 1.) According to the FDA, the drug for which the applicant submitted the NDA is “albuterol sulfate HFA Inhalation Aerosol.”

Furthermore, the Amended Complaint states:

45. Teva Branded is the holder of New Drug Application (“NDA”) No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. ProAir® HFA (albuterol sulfate) Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive

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<sup>3</sup> It is not sufficient that a patent claim a drug that falls within the scope of the definition of “drug” in 21 U.S.C. § 321(g)(1); the statute requires that the patent claim *the* drug for which the applicant submitted *the* application. Teva overlooks the significance of the statutory language that modifies the phrase, “the drug.”

airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

46. On October 1, 2022, the manufacturing of branded ProAir® HFA (albuterol sulfate) Inhalation Aerosol was discontinued. Teva USA currently distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States.

Teva has thus premised this case on the factual allegation that the subject of NDA No. 021457 was the product, “ProAir® HFA (albuterol sulfate) Inhalation Aerosol.” It is undisputed that no claim in any of the Inhaler Patents discloses albuterol sulfate.

The First Circuit construed the phrase, a patent which “claims the drug for which the applicant submitted the application,” as used in § 355, in Cesar Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.), 950 F.3d 1, 3 (1st Cir. 2020). Teva objects that, despite Lantus being a 2020 case, Congress has since changed the language of § 355 with the passage of the Orange Book Transparency Act (“OBTA”). Indeed, the OTBA did make changes to the language of § 355, but the key phrase, “claims the drug for which the applicant submitted the application,” has not changed. At the time the First Circuit decided Lantus, the listing provision in § 355 required that the NDA applicant list a patent which “claims the drug for which the applicant submitted the application,” and the current Listing Statute contains the same requirement today. Congress may have amended parts of the Listing Statute, but the OTBA did not change this particular requirement for listing a patent in the Orange Book: a listed patent must still claim the drug for which the applicant submitted the application.

In Lantus, Sanofi a filed a supplemental NDA “to sell insulin glargine in a disposable injector pen device called the Lantus SoloSTAR.” Lantus, 950 F.3d at 5. The patent at issue, the ‘864 patent, was directed to drive mechanisms used in drug delivery devices. Id. In short,

the First Circuit found that the ‘864 patent did not claim the drug for which the applicant submitted the application. Id. at 8. Moreover, the First Circuit rejected the idea that § 355 authorizes the listing of “patents that claim only components of a proposed drug.” Id. at 9.

The Court concluded:

More importantly, even assuming that the drive mechanism claimed by the ‘864 patent is itself a drug, we still find Sanofi falling short of its goal because the drive mechanism is not the “drug for which [Sanofi] submitted” the NDA. 21 U.S.C. § 355(b)(1). For that reason alone the patent for the drive mechanism does not qualify for listing in the Orange Book as claiming the Lantus SoloSTAR.

...

The statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book. The ‘864 patent, which neither claims nor even mentions insulin glargine or the Lantus SoloSTAR, does not fit the bill.

Id. at 9-10.

The facts of Lantus are parallel to those of the instant case. The Inhaler Patents are directed to components of a metered inhaler device, but do not claim or even mention albuterol sulfate or the ProAir® HFA. The applicant filed an NDA for an albuterol sulfate HFA Inhalation Aerosol. The statutory requirement that each patent “claim[] the drug for which the applicant submitted the application” is not met.

The FTC points out that the Second Circuit followed the relevant reasoning of Lantus in United Food & Commer. Workers Local 1776 v. Takeda Pharm. Co., 11 F.4th 118, 134 (2d Cir. 2021). United is a meaty opinion and much could be said about it, but two points are most relevant: 1) the Second Circuit decided United after passage of the OBTA and agreed with the pre-OBTA Lantus decision about the interpretation of “claims the drug for which the applicant submitted the application” in the Listing Statute; and 2) “claims” in the Listing Statute has the meaning established in patent law: “patent claims ‘are the numbered paragraphs which

particularly point out and distinctly claim the subject matter which the applicant regards as his invention” (United, 11 F.4<sup>th</sup> at 132 (quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1258 (Fed. Cir. 1989)). Applying the Second Circuit’s analysis to the instant case, because the Inhaler Patents plainly do not regard an “albuterol sulfate HFA Inhalation Aerosol” as that which was invented, they do not claim the drug for which the applicant submitted the NDA application.

Teva offers two strategies that attempt to expand the scope of the key phrase in § 355, “claims the drug.” First, Teva proffers a confusing set of arguments about the meaning of the word, “claims.” Teva begins with the uncontroversial proposition that the word “claims” in the Listing Statute “should be given its meaning under patent law.” (Pls.’ MJP Opp. Br. at 13.) Somehow, Teva ends up at the position that “a patent ‘claims’ a product if the patent would be infringed by the product.” (Id. at 15.) In support, Teva relies on the Second Circuit’s decision in United Food. (Id.) The problem for Teva is that, as just stated, the Second Circuit in United Food based its entire analysis on this fundamental principle: “patent claims ‘are the numbered paragraphs which particularly point out and distinctly claim the subject matter which the applicant regards as his invention.” (United, 11 F.4<sup>th</sup> at 132 (quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1258 (Fed. Cir. 1989)). Thus, a patent claims *only* that subject matter that it has particularly pointed out as the invention, and no more. This is inconsistent with Teva’s contention that a patent claims all products that are infringing. Furthermore, the Second Circuit carefully explained the difference between the meaning of “claims” in patent law and “infringement.” Id. at 134. In short, Teva has failed to persuade that, applying the common meaning of “claims” in patent law, any claim in any of the Inhaler



Patents particularly identifies the subject of the NDA application, an albuterol sulfate HFA Inhalation Aerosol, as the invention.

Second, Teva points to the broad statutory definition of “drug.” The Court agrees with Teva that the statute, 21 U.S.C. § 321(g)(1), expressly gives the term, “drug,” a broad scope, and specifically includes “articles intended for use as a component of any article” intended for use for the treatment of disease. Given the broad statutory definition of “drug,” the Inhaler Patents do claim articles intended for use as a component of the ProAir® HFA (albuterol sulfate) Inhalation Aerosol, and it is undisputed that the albuterol sulfate HFA Inhalation Aerosol is intended for the treatment of disease. The problem for Teva is that this determination does not suffice to establish that the Inhaler Patents “claim[] the drug for which the applicant submitted the application,” as required by the Listing Statute. Teva’s arguments overlook the statutory phrase which modifies “drug:” “for which the applicant submitted the application.” The drug for which the applicant submitted the application is “albuterol sulfate HFA Inhalation Aerosol.” The Inhaler Patents do not contain any claims which claim “albuterol sulfate HFA Inhalation Aerosol.” In short, the fact that the statutory definition of “drug” expressly includes devices for treating disease, and their components, does not nullify the restrictive action of the modifying phrase, “for which the applicant submitted the application.” Teva tries hard to get around the effect of this modifying phrase, but fails to do so.

Lastly, as already noted, Teva maintains that the Inhaler Patents have been listed as “drug product” patents, within the meaning of § 355. The relevant Regulation defines “drug product” as follows: “Drug product is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other

ingredients.” 21 C.F.R. § 314.3(b). As the FTC observes, the Regulations also state: “For patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, *that is described in the pending or approved NDA.*” 21 C.F.R. § 314.53(b)(1)(italics added). The Inhaler Patents do not claim the “finished dosage form” that is the subject of NDA No. 021457.

Furthermore, the FTC cites a response to public comments made by the FDA during the 2003 rulemaking process for the Regulation, 21 C.F.R. § 314.53:

(Comment 3) Most comments agreed that patents claiming packaging should not be submitted for listing. However, some comments stated that patents claiming devices or containers that are “integral” to the drug product or require prior FDA approval should be submitted and listed. These comments distinguished between packaging and devices such as metered dose inhalers and transdermal patches, which are drug delivery systems used and approved in combination with a drug.

(Response) We agree that patents claiming a package or container must not be submitted. Such packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission. However, we have clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing.

Section 314.3 defines a “drug product” as “\* \* \* a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.” The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. *The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product.* Patents must not be submitted for bottles or containers and other packaging, as these are not “dosage forms.”

68 Fed. Reg. 36676, 36680 (italics added). The Inhaler Patents do not claim the finished dosage form of the approved drug product.

The Court concludes that the Inhaler Patents do not meet a key requirement of the Listing Statute: they do not claim “the drug for which the applicant submitted the application,” NDA No.

021457, ProAir® HFA (albuterol sulfate) Inhalation Aerosol. Nor do the Inhaler Patents claim the “finished dosage form” that is the subject of that NDA application. Because the Inhaler Patents fail to meet these requirements, that have been improperly listed in the Orange Book. As to Counterclaim Counts 1-5, Teva’s motion to dismiss will be denied. Amneal has demonstrated that, on the basis of the pleadings, it is entitled to judgment as a matter of law on Counterclaim Counts 1-5. Amneal’s motion for judgment on the pleadings will be granted.

For these reasons,

**IT IS** on this 10th day of June, 2024

**ORDERED** that Plaintiff’s motion to dismiss Counterclaim Counts 1-10 (Docket Entry No. 26) is **DENIED**; and it is further

**ORDERED** that Defendant’s motion for partial judgment on the pleadings (Docket Entry No. 41) is **GRANTED**; and it is further

**ORDERED** that Judgment is entered in Defendants’ favor as to Counts 1-5 of Defendants’ Counterclaims; and it is further

**ORDERED** that it is the Judgment of this Court that U.S. Patent Nos. 8,132,712, 9,463,289, 9,808,587, 10,561,808, and 11,395,889 have been improperly listed in the Orange Book in regard to the drug product that is the subject of NDA No. 021457; and it is further

**ORDERED** that, pursuant to 21 U.S.C. § 355(j)(5)(c)(ii)(I), Teva must correct or delete the relevant Orange Book patent information listings to reflect the Judgment of this Court.

/s Stanley R. Chesler  
STANLEY R. CHESLER, U.S.D.J.