PATENT

# U.S. District Court
# District of Delaware (Wilmington)
# CIVIL DOCKET FOR CASE #: 1:24-cv-00846-GBW

Nivagen Pharmaceuticals, Inc. v. Amneal Pharmaceuticals Inc. et al
Assigned to: Judge Gregory B. Williams
Cause: 35:1 Patent Infringement

Date Filed: 07/19/2024
Jury Demand: Plaintiff
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

**Plaintiff**

**Nivagen Pharmaceuticals, Inc.**

represented by **Bindu Ann George Palapura**
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Amneal Exhibit 1016, Page 6 of 42
Amneal Pharmaceuticals, Inc. v. Nivagen Pharmaceuticals, Inc.
IPR2025-00731

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| Date Filed | # | Docket Text |
|---|---|---|
| 07/19/2024 | 1 | COMPLAINT for PATENT INFRINGEMENT filed with Jury Demand against Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC ( Filing fee $ 405, receipt number |

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|---|---|---|
| | | ADEDC-4456039.) - filed by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A-C, # 2 Civil Cover Sheet)(mws). (Entered: 07/22/2024) |
| 07/19/2024 | 2 | Notice, Consent and Referral forms re: U.S. Magistrate Judge jurisdiction. (mws) (Entered: 07/22/2024) |
| 07/19/2024 | 3 | Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number(s) US 11,813,291 B2; US 11,925,661 B2. (mws) (Entered: 07/22/2024) |
| 07/19/2024 | 4 | Disclosure Statement pursuant to Rule 7.1: No Parents or Affiliates Listed filed by Nivagen Pharmaceuticals, Inc. (mws) (Entered: 07/22/2024) |
| 07/19/2024 | 5 | Summons Issued as to Amneal Pharmaceuticals, Inc. on 7/19/2022; Amneal Pharmaceuticals LLC on 7/19/2022. (Attachments: # 1 Summons) (mws). (Entered: 07/22/2024) |
| 07/22/2024 | 6 | SUMMONS Returned Executed by Nivagen Pharmaceuticals, Inc..Amneal Pharmaceuticals LLC served on 7/22/2024, answer due 8/12/2024. (Palapura, Bindu) (Entered: 07/22/2024) |
| 07/22/2024 | 7 | SUMMONS Returned Executed by Nivagen Pharmaceuticals, Inc. Amneal Pharmaceuticals, Inc. served on 7/22/2024, answer due 8/12/2024. (Palapura, Bindu) (Entered: 07/22/2024) |
| 07/24/2024 | | Case Assigned to Judge Gregory B. Williams. Please include the initials of the Judge (GBW) after the case number on all documents filed. (rjb) (Entered: 07/24/2024) |
| 07/25/2024 | 8 | MOTION for Pro Hac Vice Appearance of Attorney Shashank Upadhye, Yixin H. Tang and Brent Batzer of Upadhye Tang LLP - filed by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 07/25/2024) |
| 07/25/2024 | 9 | Pro Hac Vice Fee - Credit Card Payment received for Shashank Upadhye, Yixin H. Tang, and Brent Batzer. ( re 8 MOTION for Pro Hac Vice Appearance of Attorney Shashank Upadhye, Yixin H. Tang and Brent Batzer of Upadhye Tang LLP )( Payment of $ 150, receipt number ADEDC-4460804).(Palapura, Bindu) (Entered: 07/25/2024) |
| 07/26/2024 | | SO ORDERED, re 8 MOTION for Pro Hac Vice Appearance of Attorney Shashank Upadhye, Yixin H. Tang and Brent Batzer of Upadhye Tang LLP filed by Nivagen Pharmaceuticals, Inc. Signed by Judge Gregory B. Williams on 7/26/2024. (lnb) (Entered: 07/26/2024) |
| 07/29/2024 | | Pro Hac Vice Attorney Brent A. Batzer for Nivagen Pharmaceuticals, Inc. added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (mws) (Entered: 07/29/2024) |
| 07/29/2024 | | Pro Hac Vice Attorney Yixin H. Tang for Nivagen Pharmaceuticals, Inc. added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (mws) (Entered: 07/29/2024) |
| 08/01/2024 | | Pro Hac Vice Attorney Shashank D. Upadhye for Nivagen Pharmaceuticals, Inc. added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (cdd) (Entered: 08/01/2024) |
| 08/09/2024 | 10 | [SEALED] First AMENDED COMPLAINT *for Declaratory Judgment of Patent Infringement of U.S. Patents 11,813,291 and 11,925,661* against Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals of New York, LLC, |

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| | | Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd.- filed by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A-F)(Palapura, Bindu) (Entered: 08/09/2024) |
| 08/12/2024 | 11 | SUMMONS Returned Executed by Nivagen Pharmaceuticals, Inc..Amneal Pharmaceuticals of New York, LLC served on 8/12/2024, answer due 9/3/2024. (Palapura, Bindu) (Entered: 08/12/2024) |
| 08/13/2024 | 12 | MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) - filed by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Text of Proposed Order) (Palapura, Bindu) (Entered: 08/13/2024) |
| 08/13/2024 | 13 | [SEALED] OPENING BRIEF in Support re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) filed by Nivagen Pharmaceuticals, Inc..Answering Brief/Response due date per Local Rules is 8/27/2024. (Palapura, Bindu) (Entered: 08/13/2024) |
| 08/13/2024 | 14 | DECLARATION re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) , 13 Opening Brief in Support, *[Declaration of Barrett Rabinow, Ph.D.]* by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1-5) (Palapura, Bindu) (Entered: 08/13/2024) |
| 08/13/2024 | 15 | [SEALED] DECLARATION re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) , 13 Opening Brief in Support, *[Declaration of Jay Shukla]* by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1-3)(Palapura, Bindu) (Entered: 08/13/2024) |
| 08/14/2024 | 16 | MOTION for Pro Hac Vice Appearance of Attorney Jonathan R. Wise and Giancarlo L. Scaccia - filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 08/14/2024) |
| 08/14/2024 | 17 | Pro Hac Vice Fee - Credit Card Payment received for Jonathan R. Wise and Giancarlo L. Scaccia. ( re 16 MOTION for Pro Hac Vice Appearance of Attorney Jonathan R. Wise and Giancarlo L. Scaccia )( Payment of $ 100, receipt number ADEDC-4475626).(Gaza, Anne) (Entered: 08/14/2024) |
| 08/14/2024 | 18 | Disclosure Statement pursuant to Rule 7.1: identifying Corporate Parent Amneal Singapore Pvt. Ltd. for Amneal Pharmaceuticals Pvt. Ltd.; Corporate Parent Amneal Pharmaceuticals LLC for Amneal Pharmaceuticals of New York, LLC; Corporate Parent Amneal Pharmaceuticals, Inc. for Amneal Pharmaceuticals LLC; Corporate Parent Amneal Pharmaceuticals Holding GmbH for Amneal EU Ltd. filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Wilson, Samantha) (Entered: 08/14/2024) |
| 08/15/2024 | | SO ORDERED, re 16 MOTION for Pro Hac Vice Appearance of Attorney Jonathan R. Wise and Giancarlo L. Scaccia filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 8/15/2024. (lnb) (Entered: 08/15/2024) |
| 08/15/2024 | | Pro Hac Vice Attorney Giancarlo L. Scaccia, Jonathan R. Wise for Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc. added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (cdd) (Entered: 08/15/2024) |

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|---|---|---|
| 08/15/2024 | 19 | MOTION for Pro Hac Vice Appearance of Attorney Richard C. Pettus - filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 08/15/2024) |
| 08/15/2024 | 20 | Pro Hac Vice Fee - Credit Card Payment received for Richard C. Pettus. ( re 19 MOTION for Pro Hac Vice Appearance of Attorney Richard C. Pettus )( Payment of $ 50, receipt number ADEDC-4476703).(Gaza, Anne) (Entered: 08/15/2024) |
| 08/16/2024 | | SO ORDERED, re 19 MOTION for Pro Hac Vice Appearance of Attorney Richard C. Pettus filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 8/16/2024. (lnb) (Entered: 08/16/2024) |
| 08/16/2024 | 21 | REDACTED VERSION of 10 Amended Complaint, by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A-F)(Palapura, Bindu) (Entered: 08/16/2024) |
| 08/16/2024 | | Pro Hac Vice Attorney Richard C. Pettus for Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc. added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (cdd) (Entered: 08/16/2024) |
| 08/20/2024 | 22 | REDACTED VERSION of 13 Opening Brief in Support, by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 08/20/2024) |
| 08/20/2024 | 23 | REDACTED VERSION of 15 Declaration, by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1-3)(Palapura, Bindu) (Entered: 08/20/2024) |
| 08/21/2024 | 24 | ORAL ORDER: Having reviewed Plaintiff's Motion for a Temporary Restraining Order ("TRO") (D.I. 12), IT IS HEREBY ORDERED that Defendants shall file a response to Plaintiff's request for a TRO by Tuesday, August 27, 2024, at 5:00 pm, and Plaintiff shall file a reply by no later than Friday August 30, 2024, at 5:00 pm. A Hearing on Plaintiff's Motion will be held on Thursday, September 5, 2024, at 4:00 pm, in Courtroom 6B, and each side will be allocated thirty (30) minutes for argument. ORDERED by Judge Gregory B. Williams on 8/21/2024. (lnb) (Entered: 08/21/2024) |
| 08/22/2024 | 25 | WAIVER OF SERVICE returned executed by Nivagen Pharmaceuticals, Inc.: For Amneal Pharmaceuticals Pvt. Ltd. waiver sent on 8/12/2024, answer due 10/11/2024. (Palapura, Bindu) (Entered: 08/22/2024) |
| 08/22/2024 | 26 | WAIVER OF SERVICE returned executed by Nivagen Pharmaceuticals, Inc.: For Amneal EU Ltd. waiver sent on 8/12/2024, answer due 10/11/2024. (Palapura, Bindu) (Entered: 08/22/2024) |
| 08/22/2024 | 27 | STIPULATION TO EXTEND TIME for the U.S. Defendants to answer, move against, or otherwise respond to the First Amended Complaint to November 11, 2024 - filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Wilson, Samantha) (Entered: 08/22/2024) |
| 08/26/2024 | | STIUPLATION AND ORDER re 27 TO EXTEND TIME for the U.S. Defendants to answer, move against, or otherwise respond to the First Amended Complaint to November 11, 2024 filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 8/26/24. (jaa) (Entered: 08/26/2024) |

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| 08/27/2024 | 28 | [SEALED] ANSWERING BRIEF in Opposition re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc..Reply Brief due date per Local Rules is 9/3/2024. (Gaza, Anne) (Entered: 08/27/2024) |
| 08/27/2024 | 29 | DECLARATION re 28 Answering Brief in Opposition, *of Mansoor M. Amiji, Ph.D.* by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A - F, # 2 Exhibit G - K)(Gaza, Anne) (Entered: 08/27/2024) |
| 08/27/2024 | 30 | [SEALED] DECLARATION re 28 Answering Brief in Opposition, *of Ivan T. Hoffman* by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 08/27/2024) |
| 08/27/2024 | 31 | DECLARATION re 28 Answering Brief in Opposition, *of Jonathan R. Wise* by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A - D)(Gaza, Anne) (Entered: 08/27/2024) |
| 08/30/2024 | 32 | [SEALED] REPLY BRIEF re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) filed by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 08/30/2024) |
| 08/30/2024 | 33 | [SEALED] DECLARATION re 32 Reply Brief *[Reply Declaration of Peter A. Malaspina, Ph.D.]* by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1-5) (Palapura, Bindu) (Entered: 08/30/2024) |
| 08/30/2024 | 34 | DECLARATION re 32 Reply Brief *[Declaration of Dennis Jenke, Ph.D. in Response to the Declaration of Mansoor M. Amiji, Ph.D.]* by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1-5)(Palapura, Bindu) (Entered: 08/30/2024) |
| 08/30/2024 | 35 | DECLARATION re 32 Reply Brief *[Declaration of Brent A. Batzer]* by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A)(Palapura, Bindu) (Entered: 08/30/2024) |
| 09/03/2024 | 36 | REDACTED VERSION of 28 Answering Brief in Opposition, by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/03/2024) |
| 09/03/2024 | 37 | REDACTED VERSION of 30 Declaration, by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/03/2024) |
| 09/03/2024 | | Set/Reset Hearings: A Motion Hearing is set for 9/5/2024 at 04:00 PM in Courtroom 6B before Judge Gregory B. Williams (jaa) (Entered: 09/04/2024) |
| 09/04/2024 | 38 | MOTION For Exemption of Persons From the District of Delawares May 17, 2024 Standing Order on Personal Devices - filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Attachments: # 1 Text of Proposed Order)(Mackrides, Daniel) (Entered: 09/04/2024) |
| 09/04/2024 | 39 | MOTION to Strike - filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal |

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| | | Pharmaceuticals, Inc.. (Attachments: # 1 Certification Pursuant to D.Del.LR 7.1.1, # 2 Text of Proposed Order)(Gaza, Anne) (Entered: 09/04/2024) |
| 09/04/2024 | 40 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Motion to Strike - re 39 MOTION to Strike . (Attachments: # 1 Exhibit A - B) (Gaza, Anne) (Entered: 09/04/2024) |
| 09/05/2024 | 41 | SO ORDERED, re 38 MOTION For Exemption of Persons From the District of Delawares May 17, 2024 Standing Order on Personal Devices filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 9/5/2024. (lnb) (Entered: 09/05/2024) |
| 09/05/2024 | | Minute Entry for proceedings held before Judge Gregory B. Williams - Motion Hearing held on 9/5/2024 re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) filed by Nivagen Pharmaceuticals, Inc. (Court Reporter M. Rolfe) (lnb) (Entered: 09/05/2024) |
| 09/06/2024 | 42 | REDACTED VERSION of 32 Reply Brief by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 09/06/2024) |
| 09/06/2024 | 43 | REDACTED VERSION of 33 Declaration by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1-5)(Palapura, Bindu) (Entered: 09/06/2024) |
| 09/09/2024 | 44 | Letter to The Honorable Gregory B. Williams from Bindu A. Palapura regarding Response to Motion to Strike - re 39 MOTION to Strike . (Palapura, Bindu) (Entered: 09/09/2024) |
| 09/09/2024 | 45 | Letter to The Honorable Gregory B. Williams from Bindu A. Palapura regarding "Best Cases" - re Motion Hearing,. (Palapura, Bindu) (Entered: 09/09/2024) |
| 09/09/2024 | 46 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Case Support for the Preliminary Injunction Factors. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7) (Gaza, Anne) (Entered: 09/09/2024) |
| 09/10/2024 | 47 | MOTION for Pro Hac Vice Appearance of Attorney Elana B. Araj - filed by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Mackrides, Daniel) (Entered: 09/10/2024) |
| 09/10/2024 | 48 | Pro Hac Vice Fee - Credit Card Payment received for Elana B. Araj. ( re 47 MOTION for Pro Hac Vice Appearance of Attorney Elana B. Araj )( Payment of $ 50, receipt number ADEDC-4494894).(Mackrides, Daniel) (Entered: 09/10/2024) |
| 09/11/2024 | | SO ORDERED, re 47 MOTION for Pro Hac Vice Appearance of Attorney Elana B. Araj filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 9/11/2024. (lnb) (Entered: 09/11/2024) |
| 09/11/2024 | | Pro Hac Vice Attorney Elana B. Araj for Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc. added for electronic noticing. Pursuant to Local Rule 83.5 (d)., Delaware counsel shall be the registered users of CM/ECF and shall be required to file all papers. (mws) (Entered: 09/11/2024) |
| 09/11/2024 | 49 | REDACTED VERSION of 40 Letter *to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Motion to Strike* by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, |

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| | | Amneal Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A and B)(Gaza, Anne) (Entered: 09/11/2024) |
| 09/11/2024 | 50 | Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Reply to Amneal's Motion to Strike - re 39 MOTION to Strike , 40 Letter, 44 Letter. (Gaza, Anne) (Entered: 09/11/2024) |
| 09/12/2024 | 51 | Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Request for Teleconference - re 39 MOTION to Strike , 40 Letter, 44 Letter, 50 Letter. (Gaza, Anne) (Entered: 09/12/2024) |
| 09/16/2024 | 52 | REDACTED VERSION of 46 Letter, by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2 - 7)(Gaza, Anne) (Entered: 09/16/2024) |
| 09/18/2024 | 53 | ORAL ORDER: In reviewing the parties' respective briefing on the motion for temporary restraining order and preliminary injunction, the Court noticed that neither side briefed the issue of the required amount of bond in the event the Court grants the requested relief. Thus, IT IS HEREBY ORDERED THAT each side shall file a supplemental letter brief, not to exceed five (5) pages, setting forth their respective position, and support for their respective position, on the amount of the required bond the Court should require to be posted in the event the Court grants preliminary injunctive relief. Each side shall simultaneously file their opening letter brief, not to exceed five (5) pages, on or before Monday September 23, 2024, at 5:00 pm ET. Each side may file a reply letter brief, not to exceed two (2) pages, on or before Wednesday September 25, 2024, at 5:00 pm ET. Nothing in this Order is meant to and should not be construed to mean that the Court has reached its decision on the motion for preliminary injunctive relief. On the contrary, the Court is still evaluating the motion and has not reached a final decision. ORDERED by Judge Gregory B. Williams on 9/18/2024. (lnb) (Entered: 09/18/2024) |
| 09/18/2024 | 54 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza - re 12 MOTION for a Temporary Restraining Order (TRO) and for a Preliminary Injunction (PI) . (Gaza, Anne) (Entered: 09/18/2024) |
| 09/19/2024 | 55 | [SEALED] Letter to The Honorable Gregory B. Williams from Bindu A. Palapura regarding Nivagen's request to accelerate briefing schedule (D.I. 53) - re 53 Order,,,, 54 Letter. (Palapura, Bindu) (Entered: 09/19/2024) |
| 09/19/2024 | 56 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza - re 53 Order,,,, 54 Letter, 55 Letter. (Gaza, Anne) (Entered: 09/19/2024) |
| 09/23/2024 | 57 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Amneal's Response Regarding Bond Amount - re 53 Order,,,,. (Attachments: # 1 Exhibit 1)(Gaza, Anne) (Entered: 09/23/2024) |
| 09/23/2024 | 58 | [SEALED] DECLARATION re 57 Letter *of Ivan T. Hoffmann* by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/23/2024) |
| 09/23/2024 | 59 | [SEALED] Letter to The Honorable Gregory B. Williams from Andrew M. Moshos regarding Opening Letter Brief Regarding Bond Amount - re 53 Order,,,,. (Attachments: # 1 Exhibit 1)(Moshos, Andrew) (Entered: 09/23/2024) |
| 09/23/2024 | 60 | ORAL ORDER: Having reviewed Defendants Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals PVT Ltd., and Amneal EU, Ltd.'s (collectively, "Amneal") Motion to |

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| | | Strike the Reply Declaration of Peter A. Malaspina, Ph.D., Exhibits 1-5 attached thereto, and the corresponding portions of the Reply which rely thereon (collectively, "Reply Declaration") (D.I. 39), and all related briefing (D.I. 40, D.I. 44, D.I. 50), IT IS HEREBY ORDERED THAT Amneal's Motion to Strike is DENIED. Amneal contends that the Reply Declaration introduced several "new" arguments, including arguments "based on Nivagen and Amneal allegedly being the only two competitors in the relevant market, making harm a certainty.'" D.I. 40 at 2 (citing D.I. 32 at 8). However, as Nivagen notes, the declaration of Nivagen's CEO, Jay Shukla, established that the parties would compete directly in a two-player market. D.I. 44 at 1. For instance, Shukla explained that Nivagen holds the first and only patents for "novel" and "groundbreaking" RTU products. Shukla Decl., 4. Shukla explicitly noted that "[t]he Nivagen Product and the Amneal RTU products will directly compete in [the relevant] market." Id., 5. While Amneal contends that "direct competition does not equate to a two-player market," D.I. 50 at 1, Shukla also explained that some of the alleged harm would result "if Amneal launches first" and "would be caused by Amneal's first mover advantage." Id., 16-17. According to Shukla, this includes the risk that Amneal would lock-up key customers in the market by establishing strong relationships and signing long-term agreements in the few months before Nivagen's entrance. Id., 13. And even if Amneal's products are removed from the market after a finding of infringement, Shukla explained that "customers may continue to use Amneal's... product codes" and may blame Nivagen for removing Amneal's RTU Product from the market. Id. 17, 21. Thus, according to Shukla, Nivagen is at risk of experiencing irreparable harm because "the market will not be [the] same...." Id., 19. Consistent with Shukla's declaration, Dr. Malaspina opined that a "launch by Amneal prior to trial will immediately start to alter the marketplace in a manner that will ultimately negatively affect Nivagen when it launches its RTU Product" and would cause harm that would continue even after a finding of infringement. Reply Declaration, 16-19. Having reviewed both declarations, the Court finds that Dr. Malaspina's opinions regarding the two-player market, first-mover advantage, and the immediate and irreparable impact of the parties' direct competition on price and market share do not constitute "new" or "undisclosed" theories. Thus, the Reply Declaration does not violate Local Rule 7.1.3(c)(2). ORDERED by Judge Gregory B. Williams on 9/23/2024. (lnb) (Entered: 09/23/2024) |
| 09/23/2024 | 61 | MEMORANDUM OPINION. Signed by Judge Gregory B. Williams on 9/23/2024. (lnb) (Main Document 61 replaced on 10/15/2024) (jaa). (Entered: 09/23/2024) |
| 09/23/2024 | 62 | ORDER re 61 Memorandum Opinion. Signed by Judge Gregory B. Williams on 9/23/2024. (lnb) (Entered: 09/23/2024) |
| 09/24/2024 | 63 | MEMORANDUM ORDER Setting Required Bond Amount: Plaintiff shall post bond in the amount of $30,000,000.00 (Thirty Million Dollars) on or before October 1, 2024. The bond amount shall remain in effect during the pendency of this action or until further Order of the Court. Signed by Judge Gregory B. Williams on 9/24/2024. (lnb) (Entered: 09/24/2024) |
| 09/25/2024 | 64 | REDACTED VERSION of 54 Letter by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/25/2024) |
| 09/25/2024 | 65 | REDACTED VERSION of 56 Letter by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/25/2024) |
| 09/25/2024 | 66 | [SEALED] Letter to The Honorable Gregory B. Williams from Andrew M. Moshos regarding Nivagen's Request for Reconsideration of the Bond Amount - re 63 Memorandum and Order,. (Moshos, Andrew) (Entered: 09/25/2024) |

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| 09/25/2024 | 67 | ORAL ORDER: In light of Plaintiff Nivagen Pharmaceuticals, Inc.'s Motion for Reconsideration (D.I. 66), IT IS HEREBY ORDERED THAT Defendants shall file any response letter in opposition, which shall not exceed three (3) pages, by Thursday, September 26, 2024, at 5:00 pm ET. ORDERED by Judge Gregory B. Williams on 9/25/2024. (lnb) Modified on 9/25/2024 (lnb). (Entered: 09/25/2024) |
| 09/26/2024 | 68 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Cross-Motion for Reconsideration of Injunction Order and response to Nivagen's Request for Reconsideration of the Bond Amount - re 62 Order, 61 Memorandum Opinion, 66 Letter, 67 Order,. (Attachments: # 1 Exhibit A)(Gaza, Anne) (Entered: 09/26/2024) |
| 09/26/2024 | 69 | REDACTED VERSION of 55 Letter by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 09/26/2024) |
| 09/27/2024 | 70 | MEMORANDUM ORDER. Signed by Judge Gregory B. Williams on 9/27/2024.(lnb) Modified on 10/15/2024 (jaa). (Main Document 70 replaced on 10/15/2024) (jaa). Modified on 10/15/2024 (jaa). 70 document unsealed and replaced on 10/15/24. (Entered: 09/27/2024) |
| 09/27/2024 | 71 | ORAL ORDER: IT IS HEREBY ORDERED that, by no later than fourteen (14) days from the date of this Order, the parties shall file a proposed redacted version of the Court's recent opinions (D.I. 61, D.I. 70), along with motions for each opinion supported by a declaration that contains a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., 924 F.3d 662, 672 (3d Cir. 2019) (internal quotations omitted). If the parties do not file a proposed redacted versions and corresponding motions by the deadline, or if the Court determines that the parties lack a meritorious basis for their proposed redactions, the opinions will be unsealed in whole or in part. ORDERED by Judge Gregory B. Williams on 9/27/2024. (lnb) (Entered: 09/27/2024) |
| 09/30/2024 | 72 | REDACTED VERSION of 59 Letter by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1)(Moshos, Andrew) (Entered: 09/30/2024) |
| 09/30/2024 | 73 | REDACTED VERSION of 66 Letter by Nivagen Pharmaceuticals, Inc.. (Moshos, Andrew) (Entered: 09/30/2024) |
| 09/30/2024 | 74 | REDACTED VERSION of 57 Letter by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/30/2024) |
| 09/30/2024 | 75 | REDACTED VERSION of 58 Declaration *of Ivan T. Hofmann* by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 09/30/2024) |
| 10/01/2024 | 76 | [SEALED] Letter to The Honorable Gregory B. Williams from Bindu A. Palapura regarding Court's Order Regarding Bond Amount - re 63 Memorandum and Order,. (Palapura, Bindu) (Entered: 10/01/2024) |
| 10/01/2024 | 77 | [SEALED] Letter to The Honorable Gregory B. Williams from Samantha G. Wilson regarding Nivagen's letter and required bond - re 76 Letter, 70 Memorandum and Order. (Wilson, Samantha) (Entered: 10/01/2024) |
| 10/02/2024 | 78 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding Update to Amneal's October 1, 2024 letter regarding bond - re 77 Letter, 76 |

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| | | Letter, 70 Memorandum and Order. (Attachments: # 1 Exhibit A)(Gaza, Anne) (Entered: 10/02/2024) |
| 10/03/2024 | 79 | REDACTED VERSION of 68 Letter, by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 10/03/2024) |
| 10/08/2024 | 80 | REDACTED VERSION of 77 Letter by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Wilson, Samantha) (Entered: 10/08/2024) |
| 10/08/2024 | 81 | REDACTED VERSION of 78 Letter, by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 10/08/2024) |
| 10/08/2024 | 82 | REDACTED VERSION of 76 Letter by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 10/08/2024) |
| 10/09/2024 | 83 | [SEALED] Letter to The Honorable Gregory B. Williams from Anne Shea Gaza regarding request for status conference re: dissolution of injunction order. (Gaza, Anne) (Entered: 10/09/2024) |
| 10/11/2024 | 84 | Joint Letter to The Honorable Gregory B. Williams from Samantha G. Wilson regarding redactions to Opinions - re 71 Order,,,. (Wilson, Samantha) (Entered: 10/11/2024) |
| 10/15/2024 | | Document Unsealed. 61 Memorandum Opinion unsealed. (jaa) (Entered: 10/15/2024) |
| 10/15/2024 | | Document Unsealed. 70 Memorandum and Order unsealed. (jaa) (Entered: 10/15/2024) |
| 10/15/2024 | 85 | REDACTED VERSION of 83 Letter by Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.. (Gaza, Anne) (Entered: 10/15/2024) |
| 10/15/2024 | 86 | ORDER that the temporary restraining order and preliminary injunction issued by the Court on September 23, 2024 (D.I.62) are hereby terminated due to Plaintiff's failure to post bond. Signed by Judge Gregory B. Williams on 10/15/24. (jaa) (Entered: 10/15/2024) |
| 11/08/2024 | 87 | [SEALED] STIPULATION and [Proposed] Order Regarding Defendants' Response to Complaint and to Allow Plaintiff to Amend Complaint by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 1 - Amended Complaint with Exhibits A-F, # 2 Exhibit 2 - Redline of Amended Complaint)(Palapura, Bindu) (Entered: 11/08/2024) |
| 11/13/2024 | | SO ORDERED, re 87 Stipulation, filed by Nivagen Pharmaceuticals, Inc.. Signed by Judge Gregory B. Williams on 11/13/2024. (lnb) (Entered: 11/13/2024) |
| 11/13/2024 | 88 | [SEALED] Second AMENDED COMPLAINT *of Patent Infringement of U.S. Patents 11,813,291 and 11,925,661* against Amneal EU Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals, Inc.- filed by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A-F)(Palapura, Bindu) (Entered: 11/13/2024) |
| 11/15/2024 | 89 | REDACTED VERSION of 87 Stipulation, by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2)(Palapura, Bindu) (Entered: 11/15/2024) |
| 12/05/2024 | 90 | STIPULATION TO EXTEND TIME for all Defendants to answer, move against, or otherwise respond to the Second Amended Complaint for Patent Infringement of U.S. Patents 11,813,291 and 11,925,661 (D.I. 88) to December 6, 2024 - filed by Amneal |

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| | | Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC. (Wilson, Samantha) (Entered: 12/05/2024) |
| 12/06/2024 | | SO ORDERED, re 90 STIPULATION TO EXTEND TIME for all Defendants to answer, move against, or otherwise respond to the Second Amended Complaint for Patent Infringement of U.S. Patents 11,813,291 and 11,925,661 (D.I. 88) to December 6, 2024 filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 12/5/2024. (lnb) (Entered: 12/06/2024) |
| 12/06/2024 | 91 | [SEALED] ANSWER to Amended Complaint, re: 88 Amended Complaint, with Jury Demand , COUNTERCLAIM *by Amneal Pharmaceuticals, LLC* against Nivagen Pharmaceuticals, Inc. by Amneal Pharmaceuticals LLC, Amneal EU Ltd., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A - F)(Gaza, Anne) (Entered: 12/06/2024) |
| 12/12/2024 | 92 | STIPULATION TO EXTEND TIME to Answer, Move Against, or Otherwise Respond to Amneal Pharmaceuticals LLC's Counterclaims to January 3, 2025 - filed by Nivagen Pharmaceuticals, Inc.. (Moshos, Andrew) (Entered: 12/12/2024) |
| 12/13/2024 | | SO ORDERED, re 92 STIPULATION TO EXTEND TIME to Answer, Move Against, or Otherwise Respond to Amneal Pharmaceuticals LLC's Counterclaims to January 3, 2025 filed by Nivagen Pharmaceuticals, Inc. Signed by Judge Gregory B. Williams on 12/13/2024. (lnb) (Entered: 12/13/2024) |
| 12/13/2024 | 93 | REDACTED VERSION of 91 Answer to Amended Complaint,, Counterclaim, by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC. (Attachments: # 1 Exhibit A - F)(Gaza, Anne) (Entered: 12/13/2024) |
| 12/31/2024 | 94 | MOTION to Dismiss for Failure to State a Claim *[Counts V and VI of Amneal Pharmaceuticals LLC's Counterclaims and Motion to Strike Defendants' Second, Third, and Seventeenth Affirmative Defenses]* - filed by Nivagen Pharmaceuticals, Inc.. (Attachments: # 1 Text of Proposed Order)(Palapura, Bindu) (Entered: 12/31/2024) |
| 12/31/2024 | 95 | OPENING BRIEF in Support re 94 MOTION to Dismiss for Failure to State a Claim *[Counts V and VI of Amneal Pharmaceuticals LLC's Counterclaims and Motion to Strike Defendants' Second, Third, and Seventeenth Affirmative Defenses]* filed by Nivagen Pharmaceuticals, Inc..Answering Brief/Response due date per Local Rules is 1/14/2025. (Palapura, Bindu) (Entered: 12/31/2024) |
| 01/08/2025 | 96 | STIPULATION TO EXTEND TIME for Defendants to file their answering brief in opposition to Plaintiff Nivagen Pharmaceuticals, Inc.s Motion to Dismiss and Motion to Strike to January 28, 2025, and to extend the deadline for Plaintiff to file its reply brief in support of its Motion to February 11, 2025 - filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC. (Gaza, Anne) (Entered: 01/08/2025) |
| 01/09/2025 | | SO ORDERED, re 96 STIPULATION TO EXTEND TIME for Defendants to file their answering brief in opposition to Plaintiff Nivagen Pharmaceuticals, Inc.s Motion to Dismiss and Motion to Strike to January 28, 2025, and to extend the deadline for Plaintiff to file its reply br filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 1/9/2025. (lnb) (Entered: 01/09/2025) |

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| 01/20/2025 | 97 | STIPULATION TO EXTEND TIME for Defendants to file their answering brief in opposition to Plaintiff Nivagen Pharmaceuticals, Inc.s Motion to Dismiss and Motion to Strike to February 4, 2025, and to extend the deadline for Plaintiff to file its reply brief in support of its Motion to February 21, 2025 - filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC. (Gaza, Anne) (Entered: 01/20/2025) |
| 01/22/2025 | | SO ORDERED, re 97 STIPULATION TO EXTEND TIME for Defendants to file their answering brief in opposition to Plaintiff Nivagen Pharmaceuticals, Inc.s Motion to Dismiss and Motion to Strike to February 4, 2025, and to extend the deadline for Plaintiff to file its reply br filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal EU Ltd., Amneal Pharmaceuticals Pvt. Ltd. Signed by Judge Gregory B. Williams on 1/22/2025. (lnb) (Entered: 01/22/2025) |
| 01/22/2025 | 98 | [SEALED] ANSWER to 91 Answer to Amended Complaint,, Counterclaim, *[Partial Answer to Counterclaims]* by Nivagen Pharmaceuticals, Inc..(Moshos, Andrew) (Entered: 01/22/2025) |
| 01/29/2025 | 99 | REDACTED VERSION of 98 Answer to Counterclaim *[Partial Answer to Counterclaims]* by Nivagen Pharmaceuticals, Inc.. (Moshos, Andrew) (Entered: 01/29/2025) |
| 02/04/2025 | 100 | [SEALED] ANSWERING BRIEF in Opposition re 94 MOTION to Dismiss for Failure to State a Claim *[Counts V and VI of Amneal Pharmaceuticals LLC's Counterclaims and Motion to Strike Defendants' Second, Third, and Seventeenth Affirmative Defenses]* filed by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC.Reply Brief due date per Local Rules is 2/11/2025. (Attachments: # 1 Exhibit A, # 2 Exhibit B) (Gaza, Anne) (Entered: 02/04/2025) |
| 02/11/2025 | 101 | REDACTED VERSION of 100 Answering Brief in Opposition,, by Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt. Ltd., Amneal EU Ltd., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC. (Attachments: # 1 Exhibit A - B)(Gaza, Anne) (Entered: 02/11/2025) |
| 02/21/2025 | 102 | REPLY BRIEF re 94 MOTION to Dismiss for Failure to State a Claim *[Counts V and VI of Amneal Pharmaceuticals LLC's Counterclaims and Motion to Strike Defendants' Second, Third, and Seventeenth Affirmative Defenses]* filed by Nivagen Pharmaceuticals, Inc.. (Palapura, Bindu) (Entered: 02/21/2025) |

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# District Judge Gregory Brian Williams of the U.S. District Court for the District of Delaware D.Del.

Showing **633** federal motion chains with an order issued by District Judge Gregory Brian Williams; filed between 2000-01-01 and 2025-04-11.; sorted by textual relevance.

## Motion Types

| Motion Type | Orders | Outcomes (% is the nat'l avg. grant rate) | Grant | Deny | Partial | Other |
|---|---|---|---|---|---|---|
| Dismiss (Contested) | 191 | 48% | 43% | 20% | 10% | 27% |
| Dismiss (Uncontested) | 214 | 92% | 87% | <1% | 0% | 13% |
| Stay | 133 | 69% | 84% | 5% | 2% | 8% |
| Stay Pending PTAB | 17 | 62% | 71% | 12% | 12% | 6% |
| Stay Pending USPTO | 3 | 58% | 0% | 100% | 0% | 0% |
| Summary Judgment | 62 | 41% | 37% | 39% | 18% | 6% |
| Transfer | 13 | 54% | 54% | 8% | 0% | 38% |

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Gregory B. Williams

Trial Date

January 1, 2008 – April 11, 2025

Dates to Exclude

Exclude cases with Transfers

Exclude cases with Stays

Exclude Outliers

Exclude cases with Consolidations

Case Size

Small | Medium | Large

Trial Type

Bench Trials | Jury Trials

AVERAGE MONTHS

**36**

National Average: 32

MEDIAN MONTHS

**32**

National Median: 29

MAXIMUM MONTHS

**65**

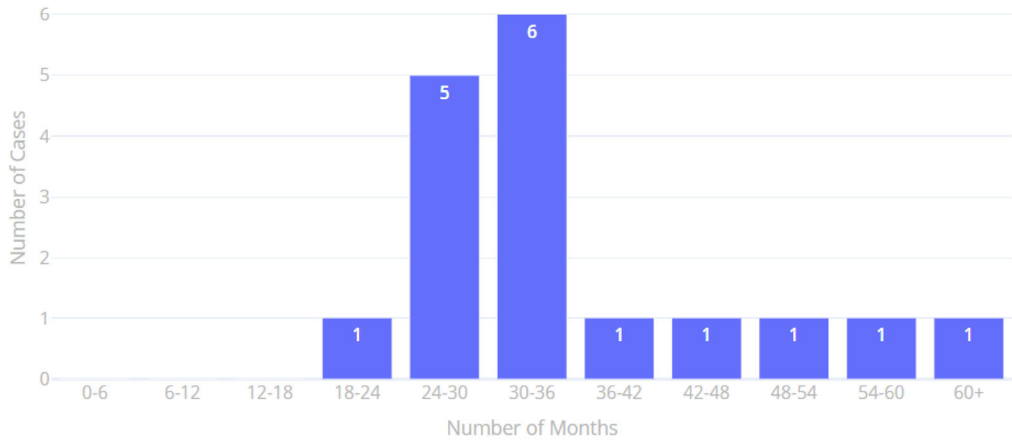
National Maximum: 85

MINIMUM MONTHS

**24**

National Minimum: 10

TIME TO TRIAL FOR GREGORY B. WILLIAMS



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

| | |
|---|---|
| RHEEM MANUFACTURING COMPANY and RHEEM SALES COMPANY, INC.,<br><br>*Plaintiffs*,<br><br>v.<br><br>A. O. SMITH CORPORATION,<br><br>*Defendant*. | C.A. No. 24-910-GBW |

**[PROPOSED] SCHEDULING ORDER [PATENT, NON-ANDA]**

This 9th day of October 2024, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.l(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within five (5) days of the date the Court enters this Order. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at

http://www.ded.uscourts.gov (see Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before December 11, 2024. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 4(g) and 5.

3. Disclosures. Absent agreement among the parties, and approval of the Court:

(a) By October 31, 2024, Defendant shall identify the accused product(s), including accused methods and systems, and its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s). Defendant shall also produce the file history for each asserted patent.

(b) By December 17, 2024, Plaintiffs shall produce core technical documents related to the accused product(s), sufficient to show how the accused product(s) work(s), including but not limited to non-publicly available operation manuals, product literature, schematics, and specifications. Plaintiffs shall also produce sales figures for the accused product(s).

(c) By January 31, 2025, Defendant shall produce an initial claim chart relating each known accused product to the asserted claims each such product



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allegedly infringes.

(d) By March 17, 2025, Plaintiffs shall produce their initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

(e) Within 21 days after the Court's claim construction order, Defendant shall provide final infringement Contentions.

(f) Within 42 days after the Court's claim construction order, Plaintiffs shall provide final invalidity contentions.

4. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules of Civil Procedure shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before March 12, 2026.

(b) Document Production. Document production shall be substantially complete by November 12, 2025.

(c) Requests for Admission. A maximum of 75 requests for admission are permitted for each side. Requests for admission solely for the purpose of authenticating documents, establishing that documents are business records, or are prior art to the patent(s) at issue in the case are excluded from this limit.



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(d) Interrogatories.

i. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (i.e., the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination of the other party, other party witnesses, and third-parties. Such limits exclude expert depositions. Any deposition will count as a minimum of three hours towards the total number of permitted hours, regardless of the actual time of taking testimony.

ii. Location of Depositions. Depositions of a party or a party witness will be held at a location, within the continental United States, of the convenience of such party or party witness to be deposed. Depositions of a third-party will be held at a location of the convenience of such third-party.



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Exceptions to this general rule may be made by agreement of the parties or by order of the Court.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before April 16, 2026. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before May 21, 2026. Reply expert reports from the party with the initial burden of proof are due on or before June 11, 2026. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court. Briefing on such motions is subject to the page limits set out in connection with briefing of case dispositive motions.



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iii. Expert Discovery Cut-Off. All expert discovery in this case shall be initiated so that it will be completed between June 15, 2026 and July 16, 2026.

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts—including verbal communications among Delaware and Lead Counsel for all parties to the dispute—that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

> Dear Judge Williams:
>
> The parties in the above-referenced matter write to request the scheduling of a discovery teleconference.
>
> The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet- and-confer (in person and/or by telephone) on the following date(s):
>
> Delaware Counsel: _____
> Lead Counsel: _____
>
> The disputes requiring judicial attention are listed below:

[provide here a non-argumentative list of disputes requiring judicial attention]

iii. On a date to be set by separate order, generally not less than forty-eight (48) hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than twenty-four (24) hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. Each party shall submit two (2) courtesy copies of its discovery letter and any attachments.

v. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

5. Motions to Amend.

(a) Any motion to amend (including a motion for leave to amend) a pleading shall ***NOT*** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a "blackline" comparison to the prior pleading.



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(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

6. Motions to Strike.

(a) Any motion to strike any pleading or other document shall *NOT* be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

7. Technology Tutorials. Unless otherwise ordered by the Court, the parties jointly shall provide the Court, no later than the date on which the Joint Claim Construction Chart is due, a tutorial on the technology at issue. In that regard,



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the parties shall jointly submit to the Court an electronic tutorial of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and educate the Court about the same and should not be used for argument. As to the format selected, the parties should confirm the Court's technical abilities to access the information contained in the tutorial ("mpeg," "quicktime," etc.). The parties may choose to file their tutorial under seal, subject to any protective order in effect.

8. Claim Construction Issue Identification. On or April 14, 2025, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). On or before April 24, 2025, the parties shall respond to and provide their proposed construction for any term(s)/phrase(s) presented by the other side for which the party did not initially provide a construction. These documents will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than May 8, 2025. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to gbw_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as



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those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

9. Claim Construction Briefing. Defendant shall serve, but not file, its opening brief, not to exceed 5,000 words, on June 5, 2025. Plaintiffs shall serve, but not file, their answering brief not to exceed 7,500 words, on July 3, 2025. Defendant shall serve, but not file, its reply brief, not to exceed 5,000 words, on July 24, 2025. Plaintiffs shall serve, but not file, their sur-reply brief, not to exceed 2,500 words, on August 14, 2025. No later than August 21, 2025, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their untiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

**JOINT CLAIM CONSTRUCTION BRIEF**

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Defendant's Opening Position
2. Plaintiffs' Answering Position
3. Defendant's Reply Position
4. Plaintiffs' Sur-Reply Position



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[TERM 2]

1. Defendant's Opening Position
2. Plaintiffs' Answering Position
3. Defendant's Reply Position
4. Plaintiffs' Sur-Reply Position

If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

10. Hearing on Claim Construction. Beginning at 11:00 a.m. on November 13, 2025 **(the parties request October 23, 2025, subject to the Court's availability)**, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.



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11. Interim Status Report. On January 14, 2026, counsel shall submit a joint letter to the Court with an interim report of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

12. Supplementation. Absent agreement among the parties, and approval of the Court, no later than 21 days after the Court's claim construction order, the patentee must finally supplement the identification of all accused products and serve final infringement contentions; and no later than Within 42 days after the Court's claim construction order, the accused infringers must finally supplement the identification of all invalidity references and serve final invalidity contentions.

13. Case Dispositive Motions.

(a) All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before August 17, 2026. Oppositions thereto shall be filed within 28 days, as calculated consistent with Fed. R. Civ. P. 6(a) and CM/ECF Procedures. Once the opposition papers have been deemed served, the moving party may file a reply within 21 days, as calculated consistent with Fed. R. Civ. P. 6(a) and CM/ECF Procedures. Briefing will otherwise be presented pursuant to the Court's Local Rules. No case dispositive motion under Rule 56 may be filed more than ten (10) days before the above date without leave of the Court.

(b) Concise Statement of Facts Requirement. Any motion for summary judgment shall be accompanied by a separate concise statement, not to exceed six (6) pages, which details each material fact which the moving party contends is essential for the Court's resolution of the summary judgment motion (not the entire case) and as to which the moving party contends there is no genuine issue to be tried. Each fact shall be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

Any party opposing the motion shall include with its opposing papers a response to the moving party's concise statement, not to exceed eight (8) pages, which admits or disputes the facts set forth in the moving party's concise statement on a paragraph-by-paragraph basis. To the extent a fact is disputed, the basis of the dispute shall be supported by specific citation(s) to the record. Failure to respond to a fact presented in the moving party's concise statement of facts shall indicate that fact is not in dispute for purposes of summary judgment. The party opposing the motion may also include with its opposing papers a separate concise statement, not to exceed six (6) pages, which sets forth material facts as to which the opposing party contends there is a genuine issue to be tried. Each fact asserted by the opposing party shall also be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.



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The moving party shall include with its reply papers a response to the opposing party's concise statement of facts, not to exceed four (4) pages, on a paragraph-by-paragraph basis. Failure to respond to a fact presented in the opposing party's concise statement of facts shall indicate that fact remains in dispute for purposes of summary judgment.

(c) Page limits combined with Daubert motion page limits. Each party is permitted to file as many case dispositive motions as desired provided, however, that each ***SIDE*** will be limited to a combined total of 40 pages for all opening briefs, a combined total of 40 pages for all answering briefs, and a combined total of 20 pages for all reply briefs regardless of the number of case dispositive motions that are filed. In the event that a party files, in addition to a case dispositive motion, a Daubert motion to exclude or preclude all or any portion of an expert's testimony, the total amount of pages permitted for all case dispositive and Daubert motions shall be increased to 50 pages for all opening briefs, 50 pages for all answering briefs, and 25 pages for all reply briefs for each ***SIDE***.[1]

(d) Ranking of Summary Judgment Motions. Any party that files more than one summary judgment motion shall number each motion to indicate the

[1] The parties must work together to ensure that the Court receives no more than a total of 250 pages (i.e., 50 + 50 + 25 regarding one side's motions, and 50 + 50 + 25 regarding the other side's motions) of briefing on all case dispositive motions and Daubert motions that are covered by this scheduling order and any other scheduling order entered in any related case that is proceeding on a consolidated or coordinated pretrial schedule.

order in which the party wishes the Court to review its pending motions. The first motion the party wishes the Court to consider shall be designated #1, the second motion shall be designated #2, and so on. The Court will review the party's summary judgment motions in the order designated by the party. If the Court decides to deny a motion filed by the party, barring exceptional reasons determined *sua sponte* by the Court, the Court will not review any lower ranked summary judgment motions filed by the party.

14. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

15. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date the Court enters this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 4(g) above.

Any proposed protective order must include the following paragraph:

> Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in

> another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

16. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

17. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of filings (i.e., briefs, appendices, exhibits, declarations, affidavits etc.). Courtesy copies of appendices and exhibits should include hard tabs. This provision also applies to papers filed under seal.

18. Motions *in Limine*. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to four (4) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1)



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additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

19. Pretrial Conference. On May 4, 2027 **(the parties request January 18, 2027, subject to the Court's availability)**, the Court will hold a pretrial conference in Court with counsel beginning at 3:00pm. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)–(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

20. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1 the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms seven (7) business days before the final pretrial conference. This submission shall be accompanied by a courtesy copy containing electronic files of these documents, in Microsoft Word format, which may be submitted by e-mail to gbw_civil@ded.uscourts.gov.

21. Trial. This matter is scheduled for a five-day jury trial beginning at 9:30 a.m. on May 10, 2027 **(the parties request February 1, 2027, subject to the Court's availability)** with the subsequent trial days beginning at 9:30 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 5:30 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

22. Judgment on Verdict and Post-Trial Status Report. Within seven (7) days after a jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict. At the same time, the parties shall submit a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

23. Post-Trial Motions. Unless otherwise ordered by the Court, all ***SIDES*** are limited to a maximum of 25 pages of opening briefs, 25 pages of answering



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briefs, and 15 pages of reply briefs relating to any post-trial motions filed by that side, no matter how many such motions are filed.

24. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

The Honorable Gregory B. Williams
United States District Judge



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## CHART OF ALL RELEVANT DEADLINES

| EVENT | DEADLINE |
|---|---|
| Rule 26(a)(1) Initial Disclosures | Within 5 days of the scheduling order |
| Defendant to Identify the Accused Product and Produce Asserted Patents and File Histories | October 31, 2024 |
| Protective Order | Within 10 days of the scheduling order |
| Plaintiffs to Produce Core Technical Documents and Sales Figures | December 17, 2024 |
| Initial Infringement Claim Chart | January 31, 2025 |
| Initial Invalidity Contentions and Production of Known Invalidating References | March 17, 2025 |
| Exchange of Proposed Terms and Constructions | April 14, 2025 |
| Response to Constructions | April 24, 2025 |
| Joint Claim Construction Chart and Technology Tutorial | May 8, 2025 |
| Defendant's Opening Claim Construction Brief | June 5, 2025 |
| Plaintiffs' Answering Claim Construction brief | July 3, 2025 |
| Defendant's Reply Claim Construction Brief | July 24, 2025 |
| Plaintiffs' Sur-reply Claim Construction Brief | August 14, 2025 |

| | |
|---|---|
| Joint Claim Construction Brief | August 21, 2025 |
| *Markman* Hearing | November 13, 2025 at 11a.m. |
| Substantial Completion of Document Production | November 12, 2025 |
| **EVENT** | **DEADLINE** |
| Joinder of Other Parties and Amendment of Pleadings | December 11, 2024 |
| Defendant's Final Infringement Contentions | Within 21 days after the *Markman* Order |
| Plaintiffs' Final Invalidity Contentions | Within 42 days after the *Markman* Order |
| Close of Fact Discovery | March 12, 2026 |
| Opening Expert Reports | April 16, 2026 |
| Rebuttal Expert Reports | May 21, 2026 |
| Reply Expert Reports | June 11, 2026 |
| Close of Expert Discovery | July 16, 2026 |
| Filing of any Summary Judgment or Daubert Motions | August 17, 2026 |
| Parties Submit Joint Pretrial Order | 7 days before the Pre-Trial Conference |
| Pre-Trial Conference | May 4, 2027 at 3:00 p.m. |
| Trial | May 10, 2027 – May 14, 2027 |