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

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Nivagen Ex. 2015
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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,

		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)

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)

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

		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

		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)

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

		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)

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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PACER Login:	babatzer	**Client Code:**	Nivagen
Description:	Docket Report	**Search Criteria:**	1:24-cv-00846-GBW Start date: 1/1/1975 End date: 6/27/2025
Billable Pages:	17	**Cost:**	1.70