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October 26, 2026

The Honorable Jennifer L. Hall
United States District Court
for the District of Delaware
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING
AND HAND DELIVERY

Re: *Harmony Biosciences Management Inc. and Novitium Pharma LLC v. AET Pharma US, Inc., et al.*, C.A. No. 26-453 (JLH)

Dear Judge Hall:

Plaintiffs and/or Counter-Defendants Harmony Biosciences Management, Inc., Harmony Biosciences, LLC, Harmony Biosciences Holdings, Inc., and Novitium Pharma LLC and Defendants and/or Counter-Plaintiffs AET Pharma US, Inc., AET Laboratories Private Limited, Alfred E. Tiefenbacher (GmbH & Co. KG), Sandoz Inc., and Sandoz AG jointly write the Court pursuant to the Court's instructions at the conclusion of closing arguments in C.A. 23-1286 (JLH) for the parties to set forth their views on scheduling issues.

Specifically, the parties set forth their views on whether the Court should either schedule a trial in early February 2027 or, alternatively, set a schedule for preliminary injunction proceedings. The parties' respective positions are set forth below.

Plaintiffs' Position: Plaintiffs' primary concern is that Defendants not launch their ANDA Product before this Court has the opportunity to consider preliminary or permanent injunctive relief restraining that launch. Plaintiffs seek an orderly process that ensures this Court has an opportunity to consider the evidence, deliberate, and rule on Plaintiffs' patent infringement claims before any commercial launch by Defendants.

Given this primary concern, and with the 30-month stay expiring on February 14, 2027, Plaintiffs request that this Court schedule either a bench trial on the merits of the patent infringement case or, alternatively, a preliminary injunction hearing in early February 2027.

Plaintiffs believe that a February trial is most efficient for both the Court and the parties. Rather than having to expend judicial resources considering the evidence and rendering a decision on the issues of infringement and invalidity twice—once during the preliminary injunction proceeding and subsequently a second time at trial—a bench trial in February would require

consideration of the merits only a single time. Moreover, with a trial, the Court would have a full evidentiary record on which to render the decision that is of clear importance to all the parties. Finally, a bench trial prior to the expiry of the 30-month stay would also avoid the need to potentially hear evidence and rule on a preliminary record for issues of irreparable harm and the balance of equities.

Below, Plaintiffs provide their proposed schedules for both options. These proposals assume that the Court will not render a decision in the first case in Defendants' favor before the expiration of the 30-month stay. If the Court plans to issue its decision in that case earlier than February 14, 2027, then Harmony and Novitium request that the Court enter a schedule either for trial or preliminary injunction proceedings at a date that would permit the Court to consider and decide whether Harmony and Novitium are entitled to an injunction on the '920 patent before any potential commercial launch by Defendants.[1]

At the October 21, 2026 hearing, Harmony and Novitium represented that they would not seek a preliminary injunction against Defendants with respect to U.S. 11,945,788 that is asserted in the newly filed pending matter, Case No. 26-cv-1191. Given the proposed expedited proceedings, and to narrow and focus the disputes between the parties, Harmony and Novitium also plan to file a notice of voluntary dismissal without prejudice of that matter.

1) Proposed Schedule for a February 2027 Trial

As this Court noted during the October 21st hearing, the subject matter of the '920 patent has significant overlap with the infringement issues presented in C.A. 23-1286 (JLH). The parties therefore have a substantial head-start when it comes to assembling relevant discovery, retaining knowledgeable experts, and developing their positions. While Defendants assume that they may need to resort to motion practice and/or the Hague Convention to depose the third-party named inventors,[2] Defendants have yet to identify any specific discovery they would seek from the named inventors and how that bears on a specific issue in this case. Moreover, to the extent Harmony and Novitium plan to present any of the third-party named inventors at trial, Harmony and Novitium will ensure that Defendants have the opportunity to depose those individuals in advance. Defendants will also have the ability to take other proportional and appropriate discovery related

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[1] Defendants' assertion that a patentee must practice the asserted patent to be awarded injunctive relief is not correct. *See, e.g.*, *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) ("While Presidio conceded during this litigation that its BB capacitors do not practice the ′356 patent, this does not prevent Presidio from receiving injunctive relief, as the district court properly noted. Even without practicing the claimed invention, the patentee can suffer irreparable injury.") Moreover, courts have found that a claim for infringement under 35 U.S.C. § 271(e)(2), and the corresponding injunction under 35 U.S.C. 271(e)(4), is not limited to Orange Book patents. *See, e.g.*, *Celgene Corp. v. Sun Pharma Global FZE*, No. 19-10099, 2020 WL 1921700, at *3 (D.N.J. Apr. 6, 2020).

[2] The named inventors of the '920 patent are current or former employees of a third-party company called Nuray Chemicals Private Limited that is not affiliated with any party. Defendants incorrectly allege that Nuray "is an affiliate of Plaintiff Novitium."

to the inventions of the '920 patent through, e.g., interrogatories, document requests, and Rule 30(b)(6) deposition notices.

Plaintiffs propose the following schedule for a February trial on Plaintiffs' patent infringement claims, including infringement, invalidity and any affirmative defenses that have not been stricken:

EVENT	**DEADLINE**
Deadline to Serve Discovery Requests	October 30, 2026
Deadline to Respond to Document Requests	November 6, 2026
Plaintiffs Serve Infringement Contentions	November 6, 2026
Parties Exchange List of Claim Terms for Construction, Proposed Construction, and Supporting Intrinsic Evidence	November 6, 2026
Substantial Completion of Document Production	November 13, 2026
Parties Exchange Rebuttal Proposed Claim Constructions and Supporting Intrinsic Evidence	November 13, 2026
Deadline to Meet and Confer and File Joint Claim Construction Chart[3]	November 18, 2026
Defendants Serve Invalidity Contentions	November 20, 2026
Deadline to Respond to Interrogatories and Requests for Admission	November 24, 2026
Close of Fact Discovery	November 30, 2026
Opening Expert Reports on Issues for which the Party Bears the Burden of Proof	December 2, 2026
Rebuttal Expert Reports	December 23, 2026
Reply Expert Reports	January 6, 2027
Complete Expert Discovery	January 19, 2027
Pretrial Order	January 22, 2027
Pretrial Conference	Week of January 25, 2027
2-Day Bench Trial on Plaintiffs' Patent Infringement Claims	Week of February 1, 2027

[3] Harmony and Novitium propose that the parties address any claim construction issues in their trial briefs, with the Court deciding any such issues in conjunction with its post-trial ruling.

2) Proposed Schedule for a February 2027 Preliminary Injunction Hearing

If the Court would prefer that the parties pursue preliminary injunction proceedings, Plaintiffs propose that the Court schedule a one-day preliminary injection hearing and that the Court require any declarant, fact or expert, be made available for deposition. Plaintiffs' proposed schedule for preliminary injunction proceedings is below:

EVENT	DEADLINE
Plaintiffs File Preliminary Injunction Motion	November 5, 2026
Defendants File Opposition to Preliminary Injunction Motion	December 17, 2026
Plaintiffs File Reply in Support of Preliminary Injunction Motion	January 14, 2027
1-Day Preliminary Injunction Hearing	Week of February 1, 2027

Defendants' Position:

This Harmony-2 action (C.A. No. 26-453) is not a Hatch-Waxman litigation; it is a traditional patent infringement lawsuit. The litigation does not generate a 30-month stay of approval of AET's ANDA under 21 U.S.C. § 355(c)(3)(C) and does not properly implicate the statutory framework of 35 U.S.C. § 271(e)(2) or relief under 35 U.S.C. § 271(e)(4), because the asserted patent does not cover Harmony's drug, WAKIX®. *See, e.g.*, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355–56 (Fed. Cir. 2003). To Defendants' knowledge, there has never been a case which has permitted relief under § 271(e)(4) for a patent that does not cover the reference listed drug. This is a threshold issue that has far-reaching implications for the timing and scope of relief available to Plaintiffs. Given that Plaintiff Harmony does not practice the asserted patent, and Plaintiff Novitium has agreed not to sell a product until 2030, there is no immediacy to this case that would warrant any preliminary relief or an expedited trial schedule. It is, at best, a reasonable royalty case to be properly resolved after Sandoz has launched its generic pitolisant hydrochloride product. Plaintiffs' attempt to hijack the Hatch-Waxman Act in furtherance of its anticompetitive scheme to prevent generic competition should not be permitted. Defendants intend to seek leave this week to file a Rule 12(b)(1)/(c) motion regarding Plaintiffs' improper § 271(e)(2) claim. Resolution of this threshold issue may obviate all of the extraordinary relief Plaintiffs are requesting.

A. Defendants Would Be Prejudiced by a February Trial

A February trial on the merits would afford Defendants inadequate time to develop a complete record on infringement and invalidity issues (in addition to the antitrust claims), which would therefore be unfairly prejudicial to Defendants. To the extent that the Court entertains Plaintiffs' request for an expedited schedule, Defendants believe that a preliminary injunction proceeding would be more appropriate than an expedited trial, particularly given that this case is in its early stages. Indeed, the pleadings have not even closed as to several of the parties' claims

and defenses. This action raises distinct factual issues that will require discovery beyond the scope of the prior *Harmony* litigation. While Defendants' generic drug is the same as in the prior *Harmony* litigation, the '920 Patent asserted here is different. That patent originated from Nuray Chemicals Private Limited ("Nuray"), which is an affiliate of Plaintiff Novitium. Unlike in the prior *Harmony* litigation, where AET and Novitium were co-defendants, they are now adverse and AET will be seeking discovery from Novitium and Nuray.

To date, Defendants have received essentially no discovery concerning Nuray, its development of the '920 Patent, and its transfer of rights to Novitium. Both Plaintiffs identified the named inventors of the asserted patent as having discoverable information concerning conception, reduction to practice, and development of the claimed subject matter. Harmony also indicated in its initial disclosures that its counsel does not represent the inventors (affiliated with Nuray), and that only "to the extent" the inventors are "subject to discovery in U.S. legal proceedings" will Novitium's counsel represent them; Novitium makes the same qualification regarding inventor availability. Because the inventors are identified through an India-based entity, and Plaintiffs' qualification raises a threshold dispute over whether the foreign inventors are subject to U.S. discovery, obtaining this discovery may require motion practice and potentially resort to Hague Convention procedures. A merits trial may also require additional expert testing and full discovery concerning Defendants' invalidity defenses under §§ 102, 103, and 112, including potential prior use or sale, Nuray's development record, and rebuttal to secondary considerations.

Moreover, claim construction should precede expert discovery or any trial on the merits, whereas a preliminary injunction may proceed based on a preliminary claim construction where necessary. *See Abbott Lab'ys v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1339-1340 n.4 (Fed. Cir. 2006); *Biomedical Device Consultants & Lab'ys of Colorado, LLC v. ViVitro Labs, Inc.*, 2024 WL 1318251, at *2, *6 (Fed. Cir. Mar. 28, 2024). Here Defendants anticipate a material claim-construction dispute that could support a dispositive noninfringement position and/or an indefiniteness question, which may also be addressed during the claim-construction process. Defendants therefore submit that the parties should complete full claim construction briefing and a *Markman* hearing before full expert discovery and any trial on the merits.

Finally, an expedited patent trial would not resolve the parties' disputes and instead risks serial proceedings. Sandoz independently asserts antitrust claims that would remain regardless of the outcome of a patent bench trial and include issues that Defendants contend must ultimately be resolved by a jury. A preliminary-injunction proceeding in this action, by contrast, would permit the Court to address Plaintiffs' request for immediate relief while claim construction and the remaining fact and expert discovery proceed toward trial.[4]

[4] Plaintiffs' position suggests that a trial on the merits would somehow avoid issues of irreparable harm and the balance of equities. But Plaintiffs are not entitled to relief under § 271(e)(4) and must show they are entitled to any injunctive relief using all four of the traditional *eBay* factors.

For these reasons, Defendants respectfully submit that a trial in February 2027 would be unnecessary and prejudicial to Defendants.

B. Defendants' Proposed Preliminary Injunction Schedule (If Applicable)

If the Court permits Plaintiffs to proceed with their preliminary injunction motion, the schedule should provide adequate time for the issues to be briefed and necessary discovery to take place. Accordingly, Defendants propose that the preliminary injunction briefing schedule proceeds as follows:

- Plaintiffs' motion: October 30, 2026
- Defendants' response: November 30, 2026
- Plaintiffs' reply: December 14, 2026.

Given that Plaintiffs filed this suit in April and advised the Court in August that they intended to move for a preliminary injunction (*see* D.I. 66 at 3), Defendants do not understand Plaintiffs' continued delay to file their motion, undermining Plaintiffs' manufactured urgency. To avoid further prejudice to Defendants in what is already a tight briefing schedule, overlapping with winter holidays, Defendants believe it is appropriate for Plaintiffs to file their motion this week. To the extent that the parties submit expert declarations in conjunction with their papers, the parties may conduct depositions following the conclusion of the briefing.

A preliminary injunction requires a substantially narrower record than a trial. Plaintiffs must establish, among other things, a likelihood of success on infringement and validity. To defeat a request for a preliminary injunction, Defendants need raise only a substantial question concerning infringement or validity which Plaintiffs cannot show lacks substantial merit. *Biomedical Device*, 2024 WL 1318251, at *3; *Abbott Lab'ys*, 452 F.3d at 1335. Plaintiffs must separately establish likely irreparable harm and a causal nexus to the claimed invention; bare allegations of price erosion, *e.g.*, from generic competition, do not warrant an injunction. *See Mallinckrodt Pharms. Ir. Ltd. v. Airgas Therapeutics LLC*, 2025 WL 472557, at *7, *9 (D. Del. Feb. 12, 2025). Accordingly, preliminary-injunction discovery may focus on discrete issues such as Harmony's settlement agreements and licenses, its alleged development program for amorphous pitolisant, relevant market information, and Defendants' equitable defenses. Defendants note such discovery also will be critical to understanding the extent of Plaintiffs' anticompetitive conduct and highlight the underlying tension between their purported need for an injunction and arguments they will present in response to Defendants' antitrust counterclaims. Additionally, at present, Plaintiffs seek only equitable relief but note that they may seek a trial on damages if the proposed ANDA Product launches by that time. If a preliminary injunction proceeding is conducted prior to launch, targeted preliminary-injunction discovery can therefore focus on matters pertinent to preliminary relief, rather than including Plaintiffs' potential future damages claim and the full scope of Defendants' antitrust claims, which also include damages.

Respectfully,

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

JAT:ncf
cc: Clerk of the Court (by hand delivery)
Counsel of Record (by CM/ECF and email)