

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, INC.,
Petitioner,

v.

NIVAGEN PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00731
Patent 11,925,661

Mailed: May 20, 2025

Before Andrew Kellogg, *Deputy Chief Clerk, Trials*

NOTICE OF FILING DATE ACCORDED TO PETITION
AND
TIME FOR FILING PATENT OWNER PRELIMINARY RESPONSE

The petition for *inter partes* review filed in the above proceeding has been accorded the filing date of April 11, 2025.

Patent Owner may file a preliminary response to the petition no later than three months from the date of this notice. The preliminary response is limited to setting forth the reasons why the requested review should not be instituted. Patent Owner may also file an election to waive the preliminary response to expedite the proceeding. For more information, please consult

the Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 (Aug. 14, 2012), which is available on the Board Web site at <http://www.uspto.gov/PTAB>.

Patent Owner is advised of the requirement to submit mandatory notice information under 37 C.F.R. § 42.8(a)(2) within 21 days of service of the petition. Mandatory notices include identifying any other judicial or administrative matter that would affect, or be affected by, a decision in the proceeding. 37 C.F.R. § 42.8(b)(2). Such administrative matters include requests for certificates of correction.

The parties are encouraged to use the heading on the first page of this Notice for all future filings in the proceeding.

In general, all represented parties must designate a lead counsel and at least one back-up counsel, and lead counsel must be a registered practitioner. 37 C.F.R. § 42.10(a). The Board, however, may permit a party to proceed without back-up counsel upon a showing of good cause, so long as lead counsel is a registered practitioner. *Id.* Once a party has designated a registered practitioner as lead counsel pursuant to 37 C.F.R. § 42.10(a) and filed a power of attorney for lead counsel if required by 37 C.F.R. § 42.10(b), that party is authorized to file a motion seeking leave to proceed without back-up counsel. Such a motion shall not be filed earlier than 21 days after service of the petition, which is the time for filing patent owner mandatory notices. A party that files such a motion need not designate back-up counsel unless and until its motion to proceed without back-up counsel is denied. The parties are advised that the types of good cause sufficient to permit a party to proceed without back-up counsel are limited. *See Expanding Opportunities To Appeal Before the Patent Trial and Appeal*

Board, 89 C.F.R. 82172, 82174 (Oct. 10, 2024), which is available at <https://www.federalregister.gov/d/2024-23319>. The parties are also advised that permission to proceed without back-up counsel may be revoked at the Board's discretion at any time during a proceeding. *See id.* For example, permission to proceed without back-up counsel may be revoked if the absence of back-up counsel causes scheduling problems or impedes Board proceedings. *See id.*

Once a party has designated a registered practitioner as lead counsel pursuant to 37 C.F.R. § 42.10(a) and filed a power of attorney for lead counsel if required by 37 C.F.R. § 42.10(b), that party is also authorized to file one or more motions for *pro hac vice* recognition of back-up counsel pursuant to 37 C.F.R. § 42.10(c)(1) and/or one or more notices of intent to designate a provisionally recognized PTAB attorney as back-up counsel pursuant to 37 C.F.R. § 42.10(c)(2). A motion or notice seeking *pro hac vice* recognition shall not be filed earlier than 21 days after service of the petition, which is the time for filing patent owner mandatory notices.

A motion for *pro hac vice* recognition filed pursuant to 37 C.F.R. § 42.10(c)(1) shall be accompanied by the fee set forth in 37 C.F.R. § 42.15(e). Such motion must:

- a. Contain a statement of facts showing there is good cause for the Board to recognize counsel *pro hac vice* during the proceeding; and
- b. Be accompanied by an affidavit or declaration in which the individual seeking *pro hac vice* recognition attests to the following:
 - i. Membership in good standing of the Bar of at least one State or the District of Columbia;

- ii. No suspensions or disbarments from practice before any court or administrative body;
- iii. No application for admission to practice before any court or administrative body ever denied;
- iv. No sanctions or contempt citations ever imposed by any court or administrative body;
- v. The individual seeking to appear has read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in 37 CFR part 42;
- vi. The individual will be subject to the USPTO Rules of Professional Conduct set forth in 37 CFR 11.101 *et seq.* and disciplinary jurisdiction under 37 CFR 11.19(a);
- vii. All other proceedings before the Office for which the individual has applied to appear *pro hac vice* in the last three years; and
- viii. Familiarity with the subject matter at issue in the proceeding.¹

If the affiant or declarant is unable to provide any of the information requested above or make the required statements or representations under oath, the individual must provide a full explanation of the circumstances as part of the affidavit or declaration. A party must also file a power of attorney for the person seeking *pro hac vice* recognition pursuant to 37 C.F.R. § 42.10(b).

¹ The type of familiarity referenced in the Board's rules regarding *pro hac vice* admission is legal familiarity; technical familiarity, though expected, is not required. *See* Expanding Opportunities To Appear Before the Patent Trial and Appeal Board, 89 F.R. 82172, 82175 (Oct. 10, 2024); 37 C.F.R. § 42.10(c)(1).

A notice of intent to designate a provisionally recognized PTAB attorney as back-up counsel filed pursuant to 37 C.F.R. § 42.10(c)(2) must:

- (a) Identify the registered practitioner who will serve as lead counsel;
- (b) Identify the most recent prior proceeding in which the person seeking to appear was recognized *pro hac vice* by order of the Patent Trial and Appeal Board pursuant to a motion of the type described in 37 C.F.R. § 42.10(c)(1); and
- (c) Be accompanied by Certification in the form of an affidavit or declaration in which the individual seeking *pro hac vice* recognition attests to the following:
 - i. Membership in good standing of the Bar of at least one State or the District of Columbia;
 - ii. No suspensions or disbarments from practice before any court or administrative body;
 - iii. No application for admission to practice before any court or administrative body ever denied;
 - iv. No sanctions or contempt citations ever imposed by any court or administrative body;
 - v. The individual seeking to appear has read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in 37 CFR part 42;
 - vi. The individual will be subject to the USPTO Rules of Professional Conduct set forth in 37 CFR 11.101 *et seq.* and disciplinary jurisdiction under 37 CFR 11.19(a);
 - vii. All other proceedings before the Office for which the individual has applied to appear *pro hac vice* in the last three years; and
 - viii. Familiarity with the subject matter at issue in the proceeding.

The Certification should be a separate document that is filed as an exhibit.

If the affiant or declarant is unable to provide the information requested above or make the required statements or representations under oath, or if the affiant or declarant does not qualify as a provisionally recognized PTAB attorney pursuant to 37 C.F.R. § 42.10(c)(2), the procedure set forth in 37 C.F.R. § 42.10(c)(2) is not available, and *pro hac vice* recognition may only be obtained via the process set forth in 37 C.F.R. § 42.10(c)(1). *See* 37 C.F.R. § 42.10(c)(2)(iv). A party must also file a power of attorney for the person seeking *pro hac vice* recognition pursuant to 37 C.F.R. § 42.10(b). *Pro hac vice* recognition will not be effective until the party files an updated mandatory notice after the expiration of the applicable time period (5 or 10 days) set forth in 37 C.F.R. § 42.10(c)(2)(iii).

The parties are also reminded that unless otherwise permitted by 37 C.F.R. § 42.6(b)(2), all filings in this proceeding must be made electronically in the Patent Trial Appeal Case Tracking System (P-TACTS), accessible from the Board Web site at <http://www.uspto.gov/PTAB>.

To file documents, users must first obtain a user ID by registering with MyUSPTO. Information regarding how to register with MyUSPTO and use P-TACTS is available at the Board Web site at <https://www.uspto.gov/patents/ptab/patent-trial-and-appeal-case-tracking-system-p-tacts>.

The parties may request a conference call as needed. An email requesting a conference call with the Board shall: (a) copy all parties, (b) indicate generally the relief being requested or the subject matter of the conference call, (c) include multiple times when all parties are available, (d)

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state whether the opposing party opposes any relief requested, and (e) if opposed, either certify that the parties have met and conferred telephonically or in person in an attempt to reach agreement, or explain why such meet and confer did not occur. If a party is unable to include any of the above information, the party shall explain in the email why doing so was not possible. The email may not contain substantive argument and, unless otherwise authorized, may not include attachments. *See* Trial Practice Guide at 9–10. If practicable, in order to ensure emails are consistent with the above, the parties shall send a single, joint email that includes items (a)–(e).

If there are any questions pertaining to this notice, please contact the Patent Trial and Appeal Board at trials@uspto.gov or 571-272-7822.

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**NOTICE CONCERNING ALTERNATIVE DISPUTE RESOLUTION
(ADR)**

The Patent Trial and Appeal Board (PTAB) strongly encourages parties who are considering settlement to consider alternative dispute resolution as a means of settling the issues that may be raised in an AIA trial proceeding. Many AIA trials are settled prior to a Final Written Decision. Those considering settlement may wish to consider alternative dispute resolution techniques early in a proceeding to produce a quicker, mutually agreeable resolution of a dispute or to at least narrow the scope of matters in dispute. Alternative dispute resolution has the potential to save parties time and money.

Many non-profit organizations, both inside and outside the intellectual property field, offer alternative dispute resolution services. Listed below are the names and addresses of several such organizations. The listings are provided for the convenience of parties involved in cases before the PTAB; the PTAB does not sponsor or endorse any particular organization's alternative dispute resolution services. In addition, consideration may be given to utilizing independent alternative dispute resolution firms. Such firms may be located through a standard keyword Internet search.

CPR INSTITUTE FOR DISPUTE RESOLUTION	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION (AIPLA)	AMERICAN ARBITRATION ASSOCIATION (AAA)	WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)	AMERICAN BAR ASSOCIATION (ABA)
Telephone: (212) 949-6490	Telephone: (703) 415-0780	Telephone: (212) 484-3266	Telephone: 41 22 338 9111	Telephone : (202) 662-1000
Fax: (212) 949-8859	Fax: (703) 415-0786	Fax: (212) 307-4387	Fax: 41 22 733 5428	N/A
575 Lexington Ave	241 18th Street, South, Suite 700	140 West 51st Street	34, chemin des Colombettes	1050 Connecticut Ave, NW
New York, NY 10022	Arlington, VA 22202	New York, NY 10020	CH-1211 Geneva 20, Switzerland	Washington D.C. 20036
www.cpradr.org	www.aipla.org	www.adr.org	www.wipo.int	www.americanbar.org

If parties to an AIA trial proceeding consider using alternative dispute resolution, the PTAB would like to know whether the parties ultimately decided to engage in alternative dispute resolution and the reasons why or why not. If the parties actually engage in alternative dispute resolution, the PTAB

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would be interested to learn what mechanism (e.g., arbitration, mediation, etc.) was used and the general result. Such a statement from the parties is not required but would be helpful to the PTAB in assessing the value of alternative dispute resolution to parties involved in AIA trial proceedings. To report an experience with ADR, please forward a summary of the particulars to the following email address: PTAB_ADR_Comments@uspto.gov