

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Nexus Pharmaceuticals, LLC,
Petitioner

v.

Exela Pharma Sciences, LLC,
Patent Owner

Case No.: PGR2024-00016
Patent No. 11,642,370

**PETITIONER'S REPLY TO PATENT OWNER'S
PRELIMINARY RESPONSE**

Mail Stop: Patent Board
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

The arguments presented in the Petition addressed the two-part *Advanced Bionics* framework.

First, the non-enablement ground is not the same or substantially the same as what the Patent Office addressed during prosecution of a parent application (“the ’460 Application”). Paper 6 at 26-30. The non-enablement ground (Ground 1) is presented in tension with Patent Owner’s new non-obviousness arguments in later PTAB and district court proceedings—and the decisions in those proceedings—all after the ’460 Application prosecution closed . *See, e.g.*, Paper 1 at 12-13, 27-37, 40, 44-45. Patentee made contradictory arguments in different fora. The Examiner did not and could not have considered the arguments in the Petition.

Second, the Petition also explains how the Examiner erred in considering the patentability of those ’460 Application claims. Specifically, the Petition explains that the Examiner failed to apply the appropriate standard for enablement later defined in *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023). Paper 1 at 24-26, 40. Again, the Examiner did not have and could not have considered the standard the Supreme Court set only after prosecution of the ’460 Application closed. The Petition therefore raises new grounds for review.

For at least these reasons, Petitioner respectfully suggests that the Board does not have the basis to exercise discretion under § 325(d).

Respectfully submitted,

Dated: May 30, 2024

/s/ Imron T. Aly
Imron T. Aly (Reg. No. 48,706)
ArentFox Schiff, LLC
233 S. Wacker Dr., Suite 7100
Chicago, IL 60606
Tel: 312 258 5500
Fax: 312 258 5600
imron.aly@afslaw.com

Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.105 and 42.6, I certify I caused a true and correct copy of the forgoing PETITIONER’S REPLY TO PATENT OWNER’S PRELIMINARY RESPONSE was served on May 30, 2024, on the Patent Owner’s designated counsel:

Richard Oakes
Corrin Drakulich (*pro hac vice* forthcoming)
Christina Brown-Marshall (*pro-hac vice* forthcoming)
Deanna Reichel (*pro-hac vice* forthcoming)
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN, 55402
PGR48751-0013PS1@fr.com

Dated: May 30, 2024

/s/ Jason G. Harp
Jason G. Harp (Reg. No. 42,634)
ArentFox Schiff, LLC
233 S. Wacker Dr., Suite 7100
Chicago, IL 60606
Tel: 312 258 5500
Fax: 312 258 5600
jason.harp@afslaw.com
Counsel for Petitioner