

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 PGR2024-00016
Patent No. 11,642,370

PATENT OWNER'S SURREPLY BRIEF

Nexus's non-enablement arguments are not new; the Patent Office has already considered and rejected them. Paper 6 at 26-30. Nor are there contradictions between Exela's statements during prosecution and in later PTAB and district court proceedings. As explained in the Preliminary Response, Exela's statements in the later proceedings were about the *prior art*, and why the inventors' solution was not obvious in view of that prior art. Because those statements were addressing non-obviousness, they do not speak to the teachings in Exela's own specification, which of course must be the starting point for any enablement analysis. *See* Paper 6 at 4-5, 35-37. Moreover, the Patent Office considered the unpredictability of the prior art, including in the very same file history as the enablement rejection Exela overcame. Paper 6 at 12-14 (discussing Ex. 1024).

As for the second prong of *Advanced Bionics*, nowhere does the Petition assert that the Examiner committed *any* error—let alone material error—in finding the related '460 application claims enabled. Nor does the Petition assert that the Examiner failed to apply the appropriate legal standard, as Nexus now asserts for the first time in its Reply. To the contrary, the Petition correctly acknowledges that the Supreme Court's *Amgen* decision simply “reiterated the proper standard for enablement.” Paper No. 1 at 40.

The Board should thus deny institution under § 325(d) because Petitioner's arguments were already considered and Petitioner has not shown material error.

Respectfully submitted,

Date: June 6, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4), the undersigned certifies that on June 6, 2024, a complete and entire copy of this Patent Owner's Surreply Brief was provided via email to the Petitioner by serving the correspondence email addresses of record as follows:

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