

On behalf of **Padagis Israel Pharmaceuticals Ltd;**
Padagis US LLC; and Padagis, LLC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PADAGIS ISRAEL PHARMACEUTICALS LIMITED;
PADAGIS US LLC; AND PADAGIS, LLC
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED
Patent Owner.

IPR2023-01114
Patent No. 11,311,482

**PETITIONERS' REPLY TO PATENT OWNER'S CORRECTED
PRELIMINARY RESPONSE**

The Board should not credit Patent Owner’s (“PO”) arguments regarding the expected trial date for the parallel district court litigation involving the ’482 patent because they are unsupported by the factual record and ignore the Director’s Interim Procedure for Discretionary Denials. The Corrected POPR notably omits that the district court has still not set a trial date in the parallel litigation. The current schedule in the now-consolidated district court litigation does not set any deadlines after the close of expert discovery. (*See* Ex. 2013.) Thus, the district court has given no indication that trial will likely take place in mid-summer or September of 2024, as PO suggests. Because no trial date has been set by the court, PO attempts to instead “calculate” a trial date based on a joint discovery plan filed in the parallel litigation in November 2022. (*See* Corrected POPR, 30, 53-54.) However, that joint discovery plan was provided by the parties at the beginning of the case, before it was consolidated with the ’116 patent action that was filed in June 2023, which will necessarily have a major impact on the trial date. Moreover, the March 2024 date estimated in the joint discovery plan has *never* been adopted by the district court in any scheduling order in the parallel litigation. Thus, the November 2022 joint discovery plan, and PO’s “calculations” relying thereon, have little, if any, relevance to the actual trial date.

PO also ignores the Director’s Interim Procedure, which instructs the Board to consider the median time-to-trial for civil actions in the district where the parallel

litigation resides when performing the Section 314(a) analysis. (Interim Procedure at 3, 8-9.) PO does not even attempt to reconcile its positions regarding Section 314(a) and the expected trial date with the 52.9 month median time-to-trial in the District of New Jersey. (See Ex. 1036.) Consideration of those statistics is especially appropriate here, where the district court has not set a trial date. Based on those statistics, trial will likely take place well after the statutory deadline for the Board's Final Written Decision in January 2025. Moreover, because there is no 30-month stay of regulatory approval in effect for the parallel litigation, the district court lacks the impetus for an expeditious trial date to avoid expiration of such a stay before the litigation is concluded. Accordingly, for these reasons and the reasons explained in the Petition, the Board should not exercise its discretion to deny institution under Section 314(a) and should institute *inter partes* review and find the challenged claims of the '482 patent unpatentable as obvious.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 1, 2023

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITIONERS' REPLY TO PATENT OWNER'S CORRECTED PRELIMINARY RESPONSE** is being served are being served via electronic mail pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for Patent Owner as addressed below:

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