

From: [Houston, Michael R.](#)
To: [Director PTABDecision Review](#)
Cc: [Nick Cerrito](#); [Meara, Joe](#); [Catherine Mattes](#); [QE - Hangzhou DAC](#); [Frank Calvosa](#)
Subject: IPR2022-01531 -- PETITIONER'S REQUEST FOR DIRECTOR REVIEW
Date: Thursday, September 21, 2023 5:30:19 PM
Attachments: [Paper 18 - Petitioner's Request for Director Review \(IPR2022-01531\).pdf](#)

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Dear Director,

Petitioner in the above-captioned IPR respectfully requests Director Review of the Board's non-institution decision (the "Decision"), in which the Board misapprehended or overlooked the relevant details of the chemical formulas used to claim a broad swath of pharmaceutical compounds and the import of an amendment and accompanying applicant remarks identified in the Decision sua sponte as constituting a prosecution history disclaimer never argued by Patent Owner, and resulting in a claim interpretation at odds with the determinative intrinsic evidence and the Petition grounds based thereon.

Petitioner hereby provides the following priority-ranked list of the issues for which Petitioner seeks Director Review:

I. Important issue of law or policy:

Whether, in light of the Director's announcement that in the face of declining AIA challenges to pharmaceutical patents the USPTO would begin initiatives to improve the examination and review of pharmaceutical patents, the Decision should be reviewed and vacated based on the misapprehension and fundamental errors contained in its assessment of the claimed chemical formulas, patent examples and prosecution history, in order to strengthen the public's confidence in the ability of the USPTO to technically assess such patents and correctly apply the appropriate legal standards.

II. Abuse of discretion:

Whether the Board abused its discretion when identifying an alleged prosecution history disclaimer that is not only unsupported but expressly contradicted by the record evidence. Specifically, the issue is whether the very amendment and remarks relied upon in the Decision to find a disavowal of claim scope can support the Decision's findings even when they (as well as additional, later prosecution history) show an opposite intent by the Applicant. This is most clearly

demonstrated by the Decision's sua sponte reliance on the aforementioned amendment and remarks to adopt a prosecution-history-disclaimer-based claim construction that the Decision admits results in the exclusion of a whole class of compounds disclosed in the specification—including the specific exemplary compounds in this class that the Applicant expressly identified in its accompanying remarks as supporting the very amendment relied upon by the Decision to find the alleged disclaimer.

Also at issue is legal question of whether the Board correctly applied Federal Circuit precedent requiring claim scope disavowals to be clear and unmistakable, although this issue is arguably subsumed by the profound misapprehension of the prosecution history giving rise to the more fundamental question of whether any disavowal occurred to begin with, let alone whether it was clear and unmistakable.

All counsel of record have been copied on this email, and a copy of the Request for Director Review has been filed in the PTACTS system as Paper 18, a copy of which is attached hereto.

Sincerely,
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