

From: [Torczon, Richard](#)
To: [Precedential Opinion Panel Request](#)
Cc: [Bryan C. Diner](#); [Caitlin O'Connell \(FINNEGAN\)](#); [Joshua Goldberg \(FINNEGAN\)](#); [Justin J. Hasford](#); [Kassandra Officer](#); [Kyu Yun Kim \(FINNEGAN\)](#); [Lauren Robinson](#); [Mills, Jad](#); [Stafford, Nicole](#); [Gregory, Dennis](#)
Subject: POP Recommendation: IPR2022-01102, -01103, -01104 & -01105 - Mylan v. Bausch
Date: Friday, February 3, 2023 4:19:45 PM
Attachments: [image001.png](#)
[2023.02.03 \[17\] REQUEST for rehearing ID \(-01102\).pdf](#)
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Your Honors,

Petitioner Mylan Pharmaceuticals Inc. recommends review for a matter of precedential importance in IPR Nos., 2022-01102, 2022-01103, 2022-01104, and 2022-01105, which rely on substantially the same flawed analysis in each case. Mylan timely filed substantially similar requests for rehearing (attached) today and recommends a Precedential Opinion Panel to consider the decisions under Standard Operating Procedure 2.

Review by the Precedential Opinion Panel is necessary in these cases to clarify that:

- A specific motivation is not required when a general motivation exists for a class of compounds. A prior-art teaching that a class of compounds generally share a particular trait is sufficient to raise a *prima facie* case that a compound within that class would share that trait absent affirmative evidence that the particular compound was believed to be an exception to the general rule;
- Attorney speculation without even an assertion of contrary fact is not

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sufficient to avoid trial. A panel cannot appropriately deny institution based on attorney speculation—unsupported by evidence—that a specific exception to a general rule not even alleged to be likely might nevertheless apply to the claimed compound—at a minimum because a petitioner cannot reasonably be expected to anticipate and rebut contrafactual arguments inconsistent with the prosecution history and patent specification;

- A pre-institution reply should not be denied without understanding the basis of the request. A panel should not deny a petitioner request for a reply without providing the petitioner an opportunity to explain the need, and here good cause for a reply existed when the panel then denied institution on the basis the reply sought to address; and
- The Office should not overturn its own previous finding without any showing. A panel cannot appropriately deny institution based on attorney speculation that is contrary to a previous uncontested Office finding during prosecution of the involved patent, such that the patent owner is unfairly advantaged (and petitioner is unfairly disadvantaged) by the patent owner's change in position between examination and these reviews.

Based on my professional judgment, I believe the Board panel decision is contrary to the following decisions of the Supreme Court of the United States, the United States Court of Appeals for the Federal Circuit, or the precedents of the Board:

- *KSR International v. Teleflex*, 550 U.S. 398, 418 (2007) (“As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”).
- *In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990) (en banc) (rejecting argument that raising a prima facie case requires showing allegedly novel activity of a compound was known in the art because the physical properties of physically-similar compounds are presumptively obviousness).
- *Vicor Corp. v. SynQor, Inc.*, 869 F.3d 1309, 1321-1322 (Fed. Cir. 2017) (inconsistent USPTO decision without any explanation to justify the inconsistency is legally erroneous).
- *In re NuVasive*, 841 F.3d 966, 970-971 (Fed. Cir. 2016) (due process and Administrative Procedure Act require notice and a fair opportunity to be heard before an agency adopts a new basis of decision).
- *In re Skoll*, 523 F.2d 1392, 1397 (CCPA 1975) (“Expected beneficial results are evidence of obviousness of a claimed invention”).

Based on my professional judgment, I believe the decision is contrary to statute, precedent, Board rule, or other Board decisions, including the following:

- 35 U.S.C. §103 (obviousness determined from perspective of person of ordinary skill in the art)
- 37 C.F.R. §42.107(a), 42.108(c) (Institution decision to be based on

evidence, including any testimonial evidence, and petitioner should be granted a pre-institution reply to address the patent owner preliminary response when there is a good cause).

- *Nuseed Americas Inc. v. BASF Plant Sci. GmbH*, IPR2017-02176, Paper 16, 7 (2018) (“[I]t would be impractical to require petitioners to prove infinite negatives”); *Kashiv Biosciences, Inc. v. Amgen Inc.*, IPR2019-00797, Paper 16, 23 (2019) (explaining a petitioner cannot anticipate and refute every possible counter argument).
- *Google LLC v. Parus Holdings*, IPR2022-00805, Paper 7, 27-28 (2022) (“Petitioner’s showing is sufficient to satisfy the standard we apply at this stage of the proceeding. Patent Owner’s distinctions...are not, at this time, supported by testimonial or other extrinsic evidence, and such distinctions may meaningfully be developed during the trial.”).

Respectfully submitted,

/Richard Torczon/

Richard Torczon, Reg. No. 34,448
Counsel for Petitioner Mylan

WILSON SONSINI

Richard Torczon | Senior Counsel | Wilson Sonsini Goodrich & Rosati

1700 K Street NW Floor 5 | Washington DC 20006

direct: 202.973.8811 | RTorczon@WSGR.com

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