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Filed on Behalf Of:

Novartis Pharmaceuticals Corporation

By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MICHIGAN and
UNIVERSITY OF SOUTH FLORIDA,
Patent Owners.

Case IPR2023-01347
U.S. Patent No. 10,633,344

PETITIONER'S STATEMENT ON PARALLEL PETITIONS

Novartis Pharmaceuticals Corporation (“Petitioner”) has concurrently filed two *inter partes* review petitions against U.S. Patent No. 10,633,344 (“the ’344 patent”). In accordance with the Patent Trial and Appeal Board Consolidated Trial Practice Guide (“Consolidated Trial Practice Guide”), Petitioner submits this paper explaining why more than one petition is necessary and ranking the petitions. Consolidated Trial Practice Guide, November 2019 at 59-60. For the reasons set forth below, Petitioner respectfully requests that the Board exercise its discretion to institute both petitions.

I. Legal Standard

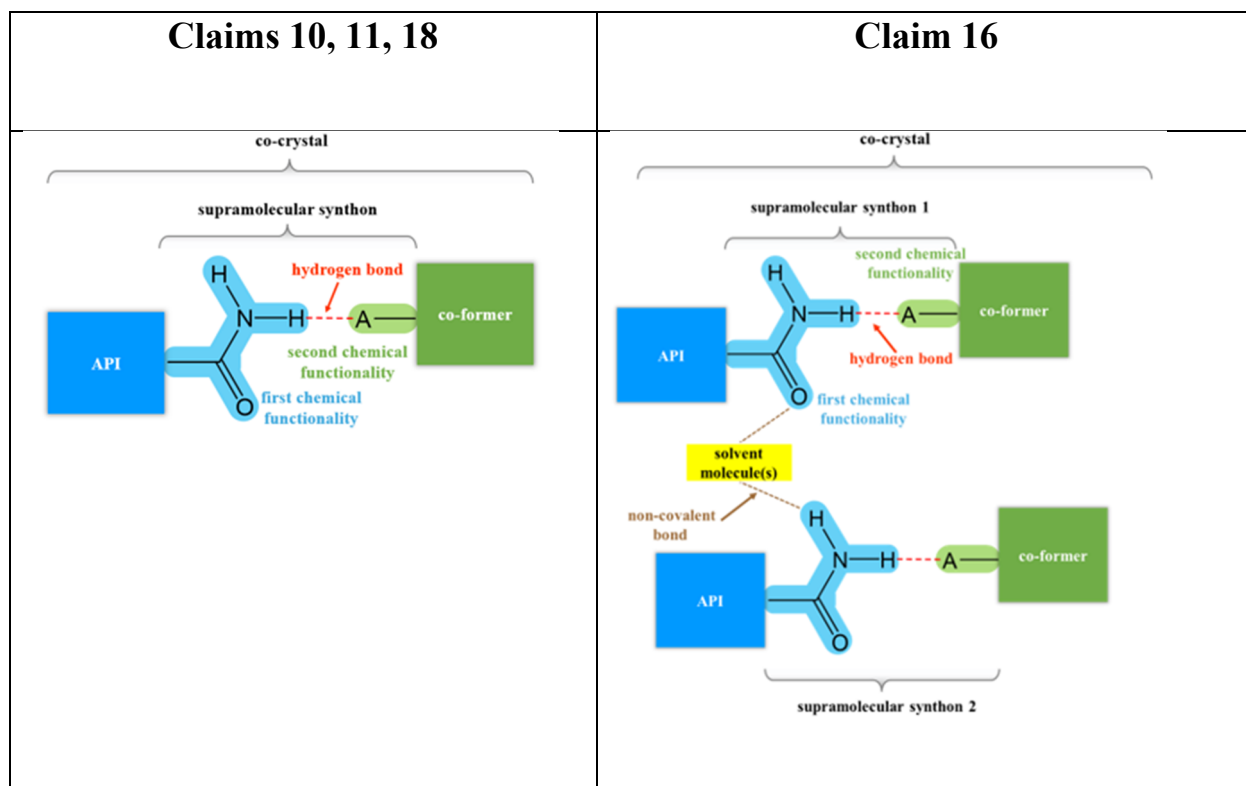
“[T]he Board recognizes that there may be circumstances in which more than one petition may be necessary” and can consider factors such as “the complexity of the technology in the case” and “the strength of the merits of the petition.” Consolidated Trial Practice Guide, November 2019 at 59; Fed. Reg. Vol. 88, No. 77, April 21, 2023 at 24513.

II. The Board Should Exercise Its Discretion to Institute Multiple Petitions

A. Material Differences Between The Petitions

IPR2023-01346 (“the ’346 Petition”) addresses claims 10, 11 and 18 of the ’344 patent, which are directed to a pharmaceutical composition comprising a co-crystal and a carrier, where the co-crystal comprises an API and a co-former that have certain properties and particular hydrogen bond interactions between them. IPR2023-01347 (“the ’347 Petition”) addresses claim 16 of the ’344 patent, which

is directed to a pharmaceutical composition comprising a co-crystal and a carrier, where the co-crystal comprises an API, a co-former, and a solvent molecule. In addition to the API and co-former having certain properties and particular hydrogen bonds between them, claim 16 also requires that the solvent interact in a particular way with certain portions of the API and co-former. The claimed co-crystals of claims 10, 11, 16 and 18 are depicted below.



Because of the material differences in the claim limitations between claims 10, 11 and 18 on one hand, and claim 16 on the other, different combinations of prior art are required in each petition, as shown below. There is no overlap in primary references between the two petitions.

IPR2023-01346 Claims 10, 11, 18	Ground 1: Hickey Ground 2: Almarsson alone, or in view of Hickey, Martindale 2011
IPR2023-01347 Claim 16	Ground 1: Ueto in view of Li, Martindale 2011, '006 Publication, Remington 2012 Ground 2: '408 Application and/or Sowa, in view of Li, Marini, '006 Publication, Remington 2012

B. The Complexity Of The Technology Justifies Multiple Petitions

Claims 10, 11 and 18 each include limitations describing the claimed pharmaceutical compositions, the properties of the co-crystals, the properties of the co-crystal components, and the specific bonding patterns required by the claims, using technical terms that require explanation. Claim 16 includes an additional limitation that introduces further complexity and requires lengthy explanation to fully set forth why such co-crystals were not disclosed in the priority applications, and why the prior art co-crystals meet that claim.

The Board requires Petitioners to fully explain their arguments for cancellation. *See Solaredge Techs. Ltd. v. Koolbridge Solar, Inc.*, IPR2022-00007, Paper 10 at 12-13 (PTAB April 19, 2022) (“A petition . . . may be considered *only if* . . . the petition identifies, in writing and *with particularity*, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” (quoting 35

U.S.C. § 312(a)(3)) (emphasis added) (also citing 37 C.F.R. § 42.22(a); 37 C.F.R. § 42.21(a)). The Board has also “recognize[d] that . . . in some cases[] it may be impossible to adequately present all legitimate grounds for cancelation in a single petition.” *Id.* Here, the four challenged claims have all been asserted against Petitioner in parallel litigation. In order to fully set forth the grounds for cancellation, two petitions are necessary. Because estoppel applies to Petitioner if the IPR is instituted, Petitioner should be afforded the opportunity to fully set forth its bases for finding the challenged claims unpatentable.

The Board has granted institution of multiple petitions where the length of the claims and the difference in claim scope necessitated lengthy arguments, like here. *Microsoft Corp. v. Synkloud Techs., LLC*, IPR 2020-01269, Paper 9 at 7-9 (PTAB April 7, 2021) (“[I]t is reasonable to conclude that the length of the claims, and the difference in scope . . . warranted the filing of two petitions. For instance, Petitioner’s showing for independent claims 1 and 16 occupies over forty-five pages of the Petition, which is reasonable in view of the length of those claims. Petitioner’s showing for independent claim 9, which is different in scope from that of independent claims 1 and 16, also occupies over forty-five pages of the other petition, which is also reasonable in view of the length of claim 9.”) (citations omitted). The Board has further instituted multiple petitions where complex claims were divided across petitions, as is the situation here. *Solaredge Techs. Ltd.*

v. Koolbridge Solar, Inc., IPR2022-00007, Paper 10 at 12-13 (PTAB April 19, 2022); *Uber Techs., Inc. v. AGIS Software Dev. LLC*, IPR2021-01308, Paper 11 at 13-14 (PTAB Jan. 7, 2022) (finding satisfactory Petitioner’s explanation that two petitions were required “to provide ‘the necessary specificity as to how the prior art meets the recited limitations within the word limit applicable to IPR petitions.’”). As such, the Board should exercise its discretion to institute both petitions.

III. Conclusion

Petitioner respectfully requests that for the foregoing reasons, the Board exercise its discretion to institute both the ’346 and ’347 Petitions.

IV. Ranking

Petitioner ranks the ’346 Petition first, and the ’347 Petition second.

Date: August 28, 2023

Respectfully Submitted

/s/ Nicholas N. Kallas
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Reg. No. 31,530

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), the undersigned certifies that on August, 28, 2023, a complete copy of the foregoing Statement on Parallel Petitions was served via Federal Express to the Patent Owner by serving the correspondence address of record indicated in the Patent Office's Patent Center for U.S. Patent No. 10,633,344:

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A courtesy copy of the foregoing was also served by email upon the following counsel of record for the Patent Owner in litigation pending before the United States District Court for the Northern District of California Case No. 3:22-cv-04913-AMO:

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