UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AYLA PHARMA LLC,
Petitioner

v.

NOVARTIS AG,
Patent Owner.

U.S. Patent No. 9,533,053 to Gamache *et al.*
Issue Date: January 3, 2017
Title: High Concentration Olopatadine Ophthalmic Composition

Inter Partes Review No.: IPR2020-00295

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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Cases

I. INSTITUTION SHOULD NOT BE DENIED BASED ON § 325(D)

A. Petitioner's Asserted Grounds Were Not Considered During Prosecution (*Becton* Factors (a-d))

There is no dispute that the Examiner never put forth **any** prior art rejection during the prosecution of the '053 patent, including the grounds advanced in the Petition and supporting declarations. The crux of Novartis' argument under § 325(d) is: (1) the Examiner "considered" Argentum's IPR petition to the '154 patent because it was disclosed in an IDS during prosecution of the '053 patent, and (2) the Examiner issued a *Schneider*-based rejection during the prosecution of the related '154 patent. POPR at 31. These arguments fail for several reasons.

First, Novartis presumes that its mere disclosure, in an IDS, of the *Argentum* IPR petition and/or the other prior art references, meant that the Examiner considered and relied on them. Presumptive awareness, however, is not enough for a § 325(d) denial. *TRW Automotive v. Magna Elecs.*, IPR2014-00261, Paper 19, 12 (June 26, 2014). "The Board has consistently declined to exercise its discretion under § 325(d) based on the mere citation of references in an IDS that were not applied by the Examiner." *Apotex v. UCB Biopharma*, IPR2019-00400, Paper 17, 24 (July 15, 2019); Petition, 12 (citing cases). Where, as here, the prior art is "simply being of record, but not applied in any rejection by the Examiner during examination … provides little impetus for [the PTAB] to exercise [its] discretion to deny institution under § 325(d)." *Hyperbranched Medical Tech. v. Confluent*

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