UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AYLA PHARMA LLC,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Case No. IPR2020-00295
Patent 9,533,053

PATENT OWNER'S SUR-REPLY

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Ayla does not dispute that the examiner and the Court previously considered the same references and arguments that Ayla advances; that they did so with respect to the same or "undisputedly similar" claims; that the examiner allowed the '053 patent over those same references and arguments; and that the Court rendered numerous factual findings that run directly contrary to Ayla's asserted grounds. Ayla nevertheless insists, without any valid justification, that the Board should retread that ground and institute Ayla's petition. The Board should not do so.

Institution under these circumstances would render meaningless the efficiency aims of the AIA. With respect to § 325(d), Ayla points to nothing in its petition or declaration that the examiner failed to consider. Without any genuine basis for alleging examiner error under *Advanced Bionics*, Ayla wholly ignores that case and resorts instead to misconstruing the prosecution record. With respect to § 314(a), despite conceding the close similarity of the claims of the related '154 and '053 patents, Ayla provides no reason to second-guess the Court's post-trial findings bearing directly on Ayla's art and arguments. And rather than addressing the known objective evidence of record, Ayla instead asserts unabashedly that the Court's findings are unsupported by "competent expert testimony" (which is untrue) and that "it is premature to address" those findings "at this stage" (which ignores several Board decisions holding precisely the opposite).

The Board thus should exercise its discretion and deny Ayla's petition.

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I. Ayla's Petition Should Be Denied under § 325(d)

Despite the issuance of *Advanced Bionics* being a principal basis for its request for a reply, Ayla's reply never once cites that decision or applies its two-part framework. *See, e.g.*, EX1044 (Hearing Tr.) at 22 ("the *Bionics* case put forth the two-factor test ... and we should be allowed to address that"). Untethered to the relevant Board precedent, Ayla instead argues (at 1) that the Board must institute because "'the mere citation of references in an IDS'" does not justify denial.

As an initial matter, Ayla fails to appreciate that "if *either condition*" of the first part of *Advanced Bionics* is satisfied, then the only remaining question is "whether the petitioner has demonstrated that the Office erred." IPR2019-01469, Paper 6, at 8 (emphasis added). Because Ayla does not dispute that every one of its relied-upon references was considered by the examiner, part one of *Advanced Bionics* is necessarily met. *Id.* at 20; *see* Pat. Owner Prelim. Resp. (POPR) 30-31.

Under part two of *Advanced Bionics*, Ayla has not demonstrated Office error. POPR 38-42. Unlike in Ayla's cited cases (at 1-2), Ayla's references were not simply listed on an IDS. Rather, Patent Owner disclosed to the examiner a complete IPR petition and two accompanying declarations—which discussed the relevant disclosures of each of Ayla's references; combined those references in the same way as Ayla; and presented Ayla's same unpatentability arguments directed to substantially the same claim limitations. POPR 14-15, 30-36; EX1021;

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