

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KELONIA THERAPEUTICS, INC.,
Petitioner

v.

INTERIUS BIOTHERAPEUTICS, INC.
Patent Owner

PGR2024-00008
Patent No. 11,767,366

Petitioner's Reply to Patent Owner's Preliminary Response

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A discretionary denial under 35 U.S.C. § 325(d) is inappropriate in this matter under the two-part framework set forth in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper No. 6 at 8-9 (P.T.A.B. Feb. 13, 2020) (precedential) for at least two reasons. First, there is no evidence that Petitioner’s primary reference, *Perkins*, was substantively considered by the Examiner. *Perkins* clearly discloses every limitation of the independent claims 1 and 2, which confirms that the Office materially erred under *Advanced Bionics* part two. Second, the Office never considered the *RCSB PDB* because the relevant disclosures of the *RCSB PDB* were not before the Examiner.

I. The Office Materially Erred by Allowing the Claims Over *Perkins*

Interius alleges that *Advanced Bionics* part one is satisfied with respect to *Perkins* and *Hwang* because they were cited in an Information Disclosure Statement. (POPR, 9.) Even if true, part two of the *Advanced Bionics* framework is not satisfied because “there is no indication that the Examiner appreciated the full scope of their disclosure.” *BioNTech SE et al. v. Moderna TX Inc.*, IPR2023-01358, Paper No. 19 at 14 (P.T.A.B. Mar. 19, 2024). For example, the Examiner did not make any rejections based on *Perkins* or *Hwang*, or offer any analysis of these references.

Interius’ allegation that “Kelsonia does not . . . point to a disclosure in the cited prior art that the Examiner misconstrued or ignored,” (POPR, 14) is simply incorrect. As the Petition and supporting testimony demonstrates, there is a compelling

argument that *Perkins* alone or in combination with the other prior art, renders the claims unpatentable because it discloses a mutation ***at position 182*** that the Examiner found missing from the prior art. (Petition, 14-15 (citing Ex. 1004, 1621).) The Petition explains that both the *Perkins* provisional and non-provisional ***expressly*** identify an I182 mutation, which necessarily includes the claimed I182E and I182D mutations (recited in claims 1 and 2) because ‘E’ and ‘D’ are among only 19 options for substituting the ‘I’ amino acid. (Petition, 32-34.) Interius disputes neither fact. (POPR, 22 (admitting that both the *Perkins* provisional and non-provisional expressly disclose an I182 mutation), *id.*, 26 (admitting that there are 19 possible mutations corresponding to I182).) Instead, Interius offers a litany of misleading arguments such as (1) the *Perkins* provisional does not support the I182 mutation disclosure in the non-provisional (POPR, 19-22), when in fact both the provisional and non-provisional have identical disclosures (Ex. 1005 at 20:29-21:14, 21:16-27; Ex. 1006 at 17-18), and (2) *Perkins* discloses a genus of “42 quadrillion” members (POPR, 28) when in fact Kelonia relied on a single disclosed genus (the I182 mutation) that undisputedly has only 19 species inclusive of I182D or I182E.

II. The Office Did Not Consider the *RCSB PDB* and Even If It Did, It Materially Erred by Allowing the Claims Over *Perkins* and *RCSB PDB*

Exercise of discretion is inappropriate here where two out of the four grounds are at least based in part on a reference that was not before the Office. Specifically, Petition grounds 3 and 4 rely on a combination of *Perkins* with the *RCSB PDB* that

addresses the specific deficiencies that Interius now alleges infect grounds 1 and 2. For example, grounds 3 and 4 explain why the *RCSB PDB* would have motivated a POSA to (a) select the I182 mutation in *Perkins* and (b) select the specific ‘E’ and ‘D’ substitutes for the ‘I’ amino acid at the 182 position. (Petition, 69-77.) The Examiner was not presented with the full 3D crystal structures that are only available from the *RCSB PDB* and are necessary to appreciate the disclosure of the *RCSB PDB* relevant to the *Perkins-RCSB PDB* combination. (E.g., Ex. 1002, ¶¶ 200-219.)

Interius’s allegation that the specific “VSV-G crystal structures” from the *RCSB PDB* were “considered by the Examiner” because they are referenced in Figures 1A and 1B of the ’366 patent, or in Nikolic (Ex. 1018), misses the mark. (POPR, 10-12.) The crystal structure snapshots in Figures 1A and 1B of the ’366 patent do not identify each of the nearby amino acid residues and distances needed to appreciate the desirability of the I182E and I182D mutations. (Ex. 1002, ¶ 219 fn. 17.) Nikolic also discloses snapshots, and does not illustrate I182. (Ex. 1018, 4-5.) Indeed, Dr. Rose’s testimony about the motivation to make an I182E or I182D mutation evaluated the nearby amino acid residues and distances, which are only visible in the full crystal structures from the *RCSB PDB*. (Ex. 1002, ¶¶ 200-219.) *Advanced Bionics* part one is thus not satisfied, and even if it was, the Examiner materially erred because there is clear motivation with a reasonable expectation of success to combine *Perkins* and the *RCSB PDB* to arrive at the claimed invention.

Respectfully submitted,

Dated: March 22, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2024, I caused a true and correct copy of the foregoing Petitioner's Reply to Patent Owner's Preliminary Response to be served by email at the following email addresses of record:

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