UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BLUEBIRD BIO, INC.
Petitioner

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Patent Owner

Case No. IPR2023-00070
Patent No. 7,541,179

PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE

On February 10, 2023, the Board authorized Petitioner to file a five-page Reply to address certain arguments raised in Patent Owner's Preliminary Response regarding the priority date of U.S. Patent No. 7,541,179 ("the '179 patent"). In its attempt to shore up deficient provisional applications, San Rocco Therapeutics ("SRT"), who filed the preliminary response: (1) misinterprets the prosecution record and provisional applications; (2) distorts the substance of Petitioner's argument; and (3) applies an incorrect legal standard.

I. SRT's Misinterpretation of the Prosecution History and Provisional Applications

SRT argues that the Examiner "already addressed the priority date" during prosecution of the '179 patent. (POPR, 21.) But SRT does not point to any analysis of the priority date issue by the Examiner. Rather, SRT suggests the Board may infer such an analysis because the Examiner treated the May Article as 35 U.S.C. § 102(a) prior art, and "accepted *Katz* declarations to traverse the rejection." (*Id.*) SRT draws the wrong inference from the Examiner's silence, which suggests only that the Examiner erred by failing to consider the priority date issue. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008) ("In the absence of an interference or rejection which would require the PTO to make a determination of priority, the PTO does not make such findings as a matter of course in prosecution."). Indeed, even if the Examiner silently considered the priority issue, there is no analysis upon which the Board may

discern whether the Examiner conducted a proper analysis. *See Smith & Nephew, Inc. v. Arthrex, Inc.*, IPR2016-00487, Paper 8 at 19 (P.T.A.B. July 27, 2016) ("We are not apprised of any statements the examiner made regarding priority. Silence is not a determination."). And the record in fact shows that the Examiner missed key issues (which SRT ignores), such as how, in response to repeated rejections regarding the "functional globin gene" claim language on written description grounds, Applicants pointed to specification passages from the full application that ***were not present*** in the provisional applications. (Pet., 16-17.)

SRT alleges the provisional applications disclose "tetramers of two murine α-globin and two human β-globin molecules." (POPR, 19; Ex. 1034, 4; Ex. 1035, 5.) But this sentence simply reports that, when human β-globin is expressed in mice from the vector, two of the human β-globin chains will bind to two of the native murine α-globin chains to form hemoglobin. (Ex. 1002 ¶ 18.) It does not indicate that the claimed vector can be used to express α-globin, as SRT alleges.[1]

[1] SRT also adds its own language to the provisional applications: "The vector of the invention is used in therapy for treatment of individuals suffering from hemoglobinopathies ***[disorders resulted from mutations in globin (alpha, beta, or gamma) genes]***." (POPR, 19 (emphasis added, brackets in original).) But SRT does not assert, nor could it, that the vector identified in the provisional

II. SRT's Distortions of Petitioner's Argument

The preliminary response fails to engage with the substance of Petitioner's priority argument. For example, SRT incorrectly asserts that the only dispute is over what it labels "Element 1.1" (the "functional globin gene"), and then represents that the Parties are in agreement over all remaining claim limitations, including what it terms "Element 1.8" ("said vector providing expression of the globin in a mammal *in vivo*"). (POPR, 21-23.) Petitioner explained, however, that the provisional applications do not inform a POSA that the alleged inventors "possessed all recombinant vectors ***that can express*** a 'functional globin' from the claimed 3.2-kb LCR ***in a mammal in vivo***." (Pet., 16 (emphasis added).) Notably, SRT does not provide proper support for "Element 1.8." Instead, it simply cites the provisional applications and its expert's conclusory assertion that these applications disclose that the "TNS9 vector was capable of providing expression of the globin in a mammal *in vivo*"—despite the provisional applications discussing only expression of human β-globin in mammals *in vivo*. (Ex. 2002 ¶ 75.)

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applications could be used to treat ***all*** hemoglobinopathies. Instead, the provisional applications discuss "β-thalassemia and sickle-cell disease"—disorders that specifically have mutations in ***human β-globin***. (Ex. 1034, 1; Ex. 1035, 1; *see also* Ex. 1002 ¶¶ 21, 23.)

In addition, SRT asserts that Petitioner does not dispute that the "[p]rovisionals provide sufficient support for the limitations of Claims 10, 19, and 22 of the '179 Patent." (POPR, 22-23.) Although Petitioner does not dispute this with respect to claim 10 (as it is limited to "human β-globin"), Petitioner clearly argued that claims 19 and 22 are ***not*** entitled to claim priority to the provisional applications. (Pet., 13 ("The Earliest-Possible Priority Date for Claims 1, ***19, and 22 of the '179 Patent*** Is July 1, 2002").)

III. SRT Applies the Wrong Legal Standard and Makes Categorical, Unsupported Statements

Finally, SRT makes a number of unsubstantiated categorical statements. *First*, SRT argues that a POSA "would understand [the provisional applications] to disclose an approach that ***could be*** used with different functional globin . . . to similar effect." (POPR, 23-24.) Here, SRT appears to apply an incorrect legal standard. As Petitioner explained, "[o]bviousness simply is not enough; the subject matter must be disclosed to establish ***possession***," and a single species may be insufficient to demonstrate ***possession*** of a genus even if it would invalidate a claim to that genus. (Pet., 13-14 (emphasis added).)

Second, SRT goes further in alleging that, "by substituting the nucleotide sequence of said globin gene(s) during the construction of the vector(s), different globin genes ***would be*** expressed" and "***would result*** in increased expression of said genes." (POPR, 24-25 (emphasis added).) Again, SRT appears to apply an

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