

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. IPR2023-00074
Patent No. 8,058,061

**PATENT OWNER'S SUR-REPLY
TO PETITIONER'S REPLY TO PRELIMINARY RESPONSE**

Petitioner's Reply presents unauthorized arguments, fails to show that SRT misinterpreted or misapplied the facts or the law, and confirms that the Petition should be denied since it does not remedy Petitioner's failure to demonstrate a reasonable likelihood of prevailing on at least one challenged claim. The Board authorized this Sur-Reply via email on February 10, 2023.

ARGUMENT

I. The Reply Presents Unauthorized Arguments and Should Be Struck.

Under the guise that SRT misinterpreted the prosecution history and provisional applications ("Provisionals") or applied an incorrect legal standard, Petitioner improperly presents new arguments. "Petitioner may not submit new [] argument in reply that it could have presented [in its Petition]." (PTAB Consolidated Trial Practice Guide (Nov. 2019) at 73-74 ("[A] reply [] that raises a new issue or belatedly presents evidence may not be considered.").)

For the first time, Petitioner argues that (1) the "Examiner missed" that the cited support for an amendment was not present in the Provisionals, (2) statements in the Provisionals do not indicate the vector design could express other globins, and (3) even if a POSITA substituted a different globin's nucleotide sequence, there are additional but unspecified changes to the vector needed to allow for the expression of the other globins. (*See* Reply at 2, 4-5.) Petitioner also never requested (or was granted) leave to address allegedly "categorical, unsupported statements." (*Id.* at

4-5.) Because these arguments could have been presented in the Petition and were not authorized by the Board, they should be rejected. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016) (affirming refusal to consider reply raising new arguments).

II. Petitioner Distorts Patent Owner’s Arguments to Erroneously Claim Patent Owner Misinterpreted the Prosecution History.

Petitioner does not point to any actual misinterpretation, but claims SRT simply drew the “wrong inference” from purported silence and Petitioner now argues the correct inference is that “the Examiner erred by failing to consider the priority date issue.” (Reply at 1.) There was no error here. The Office rejected the claims as anticipated by the *Nature* Article, (published July 6, 2000), under § 102(a), while simultaneously rejecting other art under § 102(b). (*See* POPR at 22 (citing Ex. 1032 at 63, 83-90, 104).) Thus, the Office necessarily determined priority when distinguishing between §§ 102(a) and 102(b) art. This was confirmed when the Office accepted traversal of the § 102(a) rejection with Katz declarations, which cannot traverse statutory bars, e.g., § 102(b). (*Id.*; *see also* MPEP § 716.10.) If the claims were only entitled to the filing date of the ‘221 Application (July 1, 2002), then the *Nature* Article would be § 102(b) prior art, preventing *Katz* declarations from removing this reference as prior art. (*See* POPR at 13-14, 22, 31-33.) Accordingly, the Office necessarily undertook the requisite priority analysis.

Petitioner makes two previously unrepresented arguments. First, Petitioner claims the Office missed that cited support is not present in the Provisionals. (Reply at 2 (citing Pet. at 17-18 (not alleging this).) Not true. Like the cited non-provisional support, the Provisionals explain that “large fragments” [i.e., nucleotide sequences] of the globin gene along with the LCR fragments allow for the “treatment [i.e., therapeutic benefits] of severe haemoglobinopathies.” (Ex. 1032 at 4; *Compare with* Ex. 1034 at 6 (explaining “the principles underlying inclusion of multiple genetic elements within this vector provide a paradigm for any stem cell therapy requiring stable and regulated expression of a [gene].”).)

Second, in rebuttal to SRT’s arguments, (POPR at 19-21), Petitioner attempts to explain away the Provisionals’ disclosures. (*See* Reply at 2.) But the only support for the alleged meaning of the α - and β -globin molecules provision is its expert’s testimony, which does not interpret the Provisionals’ disclosures. (*Id.* (citing Ex. 1002 ¶18).) This attorney argument should be rejected. In addition, SRT did not add to the provisional but simply provided an uncontested understanding of hemoglobinopathies, i.e., disorders resulting from mutations in (alpha, beta, or gamma) genes fully supported by the known scientific literature. (*See* Reply at 2-3, n.1; POPR at 20 (citations omitted).)

III. SRT Did Not Distort Petitioner’s Argument.

Contrary to Petitioner’s false claims, (Reply at 3), SRT provided support for

a POSITA's understanding from the Provisionals that a substituted globin is fully capable of being expressed *in vivo*. (See POPR at 24-27.) A POSITA knew the β -globin LCR was essential to expression of ϵ -, γ -, and β -globin genes and that substituting in one of these would result in expression of said gene. (See *id.* (citing Ex. 2011 at 1; Ex. 2002 at ¶¶61-68 (understanding of other globin expression)); Ex. 2009 at ¶¶14-15 (same); Ex. 2006 at ¶¶28-30 (explaining expectation of other globin expression); Ex. 2007 at ¶15 (same); Ex. 2008 at ¶17 (same).)

IV. SRT Applied the Correct Legal Standard and Supported Its Statements.

Contrary to Petitioner's suggestions, (Reply at 4-5), SRT applied the correct written description legal standard and fully supported its statements. (See POPR at 19-27.) Resorting to semantics, Petitioner suggests that just because SRT stated that a POSITA would understand that the teachings of the Provisionals "could be used" with other functional globins or that these other globin genes "would be expressed" by the disclosed TNS9 vector system, this somehow means that SRT was arguing obviousness instead of possession of the invention. Not so. A POSITA's understanding regarding the specification's disclosure, including whether the POSA would expect this disclosure to show possession of claimed embodiments, has always been the proper test for written description. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

Written description requires only a showing that a POSITA would have

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