

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

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I. INTRODUCTION

San Rocco Therapeutics (“SRT”) provides this sur-reply to Petitioner’s Reply (Paper 35, herein “Reply”) to Patent Owner’s Response to Petition (Paper 27, herein “POR”).

Petitioner’s Reply makes clear that Petitioner has effectively conceded Grounds 1, 2, 3, and 5 of its Petition, namely, that the May Thesis is not prior art that can anticipate claims 1, 2, 6-7, and 11 of the ’061 patent (Ground 1) and render claim 5 obvious (Ground 2), and that the Nature Article does not anticipate claims 1, 2, 6-7, and 11 (Ground 3) and render claims 5 obvious (Ground 5). Moreover, Petitioner never raised the Nature Article as a basis for challenging claims 8 and 15 of the ’061 patent, leaving only claims 1, 2, 6-7, and 11 as being challenged by this reference.

As to the remaining Ground 4, obviousness of claims 1, 2, 6-7, and 11 over the Nature Article, SRT maintains that the Nature Article is not prior art over these claims because these claims have an effective filing date of their Provisional Applications (“Provisionals”). Claim 7 is directed to the “ β globin gene,” and Petitioner does not dispute that this claim has *in haec verba* written description support from the Provisionals. (Ex. 1034, 2; Ex. 1035, 2-4). Despite the fact that the Provisionals consistently describe a “ β globin gene,” Petitioner’s only reply is that the POSA would recognize that “ β globin gene” is merely “shorthand” for

“human β globin gene,” which is the subject of claim 8 or claim 15, and which Petitioner concedes has priority and written description support from the Provisionals. But Petitioner cannot have it both ways. If the POSA believed from reviewing the Provisionals that the term “ β globin gene” is merely “shorthand” for “human β globin gene,” then that same POSA would also understand that the undisputed working examples of the “human β globin gene” within the claimed expression vector systems also indicated that the inventors were in possession of a vector system that could express a “ β globin gene,” including the many β globin gene mutants that were known at the time. Indeed, despite taking the depositions of the inventors of the '061 patent, Petitioner failed to impeach their sworn declarations submitted in these proceedings, which clearly state that by the filing dates of these Provisionals, these inventors possessed a vector systems system which would express not just β globin gene mutants, but other globin genes as well, such as the γ globin gene, which confirms that claims 1, 2, 6-7, and 11 also receive priority to their provisional application filing dates, and thus removing the Nature Article as prior art.

Even if the Nature Article is considered prior art against claims 1, 2, 6-7, and 11, Petitioner fails to explain how the POSA would have been motivated to arrive at the specific restriction enzyme fragments within the three hypersensitive regions

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