

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 OBJECTIONS TO PETITIONER'S
EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

Sloan Kettering Institute for Cancer Research (“SKI”) is the owner by assignment of U.S. Patent No. 8,058,061 (“the ’061 Patent”). SKI has granted San Rocco Therapeutics LLC (“SRT”) an exclusive but assignable license to — and for the entire term of — the ’061 Patent, entitling SRT to make, use, and sell the claimed invention, commence litigation for infringement, and defend any validity attack on the ’061 Patent.

Pursuant to 37 C.F.R. § 42.64 and the Federal Rules of Evidence, as applied by the Board, SRT (herein “Patent Owner”) provides the following objections to evidence submitted by Petitioner bluebird bio, Inc. (“Petitioner”). These objections are timely served within ten (10) business days. Patent Owner serves Petitioner with these objections to provide notice that Patent Owner may move to exclude the challenged evidence under 37 C.F.R. § 42.64(c) unless Petitioner cures the defects associated with the challenged evidence identified below. In addition, Patent Owner reserves the right to present further objections to this or additional evidence submitted by Petitioner, as allowed by the applicable rules or other authority.

Exhibit 1002 – Declaration of Jörg Bungert, Ph.D.

Patent Owner objects to Exhibit 1002 as lacking authentication as required under Fed. R. Evid. 901, which requires that “the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.”

Petitioner has failed to provide any evidentiary foundation for portions of this

document. For example, neither Petitioner nor its declarant, Dr. Bungert, identifies the source of certain images contained in this document or attempts to authenticate them. *See, e.g.*, Ex. 1002 at ¶¶ 152-154, 225-226. Dr. Bungert fails to provide a citation to any source for these images or the discussions related thereto. *See id.* Accordingly, this testimony is irrelevant, misleading, unduly prejudicial, and confusing under Fed. R. Evid. 401-403.

Patent Owner also objects to Exhibit 1002 as including “[e]xpert testimony that does not disclose the underlying facts or data on which the opinion is based” in violation of 37 C.F.R. § 42.55(a) and Fed. R. Evid. 702-703 and 705. For example, Dr. Bungert testifies that “[a] range of ± 20 bp would allow for minor changes in fragment length that resulted from the process of inserting the HS2, HS3, or HS4 fragment into the vector; this may result in the reported lengths of the fragment in the May Article being slightly different than the calculated length between recognition sites.” (Ex. 1002 at ¶ 152, n. 6.) Dr. Bungert provides no citation supporting this range or evidence that a POSA would consider it to be appropriate. (*See id.*) Patent Owner further objects to other portions of Exhibit 1002 to the extent it does not disclose the underlying facts or data on which statements and/or the opinion is based. (*See* Ex. 1002 at ¶¶ 32, 37-38, 45, 56-59, 64, 68, 87, 93, 125-127, 139, 145-146, 149-156, 171, 178, 181, 184, 190-192, 194, 195, 201-203, 215, 218-233, 235-236, 242, 245, 252, 256, 259-260, 262.) Similarly, Dr. Bungert identifies

various restriction sites, positions, and fragment lengths and then arbitrarily groups said fragments in the Appendices to his declaration. (*See* Ex. 1002 at Appendices A, B, and C.) No support is cited for the restriction site or position being known at the time of the invention and no basis is given for how the fragment lengths were determined and then grouped. (*See id.*)

Because these statements and opinions in Exhibit 1002 are unsupported and conclusory, Patent Owner further objects to this testimony as irrelevant, misleading, unduly prejudicial, and confusing under Fed. R. Evid. 401-403.

Exhibit 1005 – May, *et al.*, “Therapeutic Haemoglobin Synthesis in β -Thalassaemic Mice Expressing Lentivirus-Encoded Human β -globin,” *Nature*, 406:82-86 (2000) (“the *May Article*”)

Patent Owner objects to Exhibit 1005 to the extent it contains hearsay. Exhibit 1005 contains a date of July 6, 2000. (Ex. 1005 at 1.) Petitioner and its experts rely upon that date for the truth of the matter asserted, i.e., that the article was published and publicly available on July 6, 2000. (*See* Pet. at 20; Ex. 1002 ¶ 64; *see also* Ex. 1036 ¶¶ 44-45 (relying on similar evidence, including Appendix 1005D to declaration).) Because these statements are being offered for the truth of the matter asserted and do not fall under any exemption or exception, they are hearsay and should be excluded under Fed. R. Evid. 801-802.

Exhibit 1006 – May, et al., “Lentiviral-Mediated Transfer of the Human β -Globin Gene and Large Locus Control Region Elements Permit Sustained Production of Therapeutic Levels of β -Globin in Long-Term Bone Marrow Chimeras,” Mol. Therapy, 1(5):S248-49 (2000) (“the May Abstract”)

Patent Owner objects to Exhibit 1006 to the extent it contains hearsay. Exhibit 1006 contains a date of May 2000. (Ex. 1006 at 1.) Petitioner and its experts rely upon that date for the truth of the matter asserted, i.e., that the article was published and publicly available in May 2000. (See Pet. at 22-23; Ex. 1002 ¶ 71; see also Ex. 1036 ¶¶ 46-52 (relying on Ex. 1006 and similar evidence in Appendices 1006A and 1006B to declaration).) Because these statements are being offered for the truth of the matter asserted and do not fall under any exemption or exception, they are hearsay and should be excluded under Fed. R. Evid. 801-802.

Exhibit 1036 – Declaration of Ingrid Hsieh-Yee, Ph.D.

Patent Owner objects to Exhibit 1036 as including “[e]xpert testimony that does not disclose the underlying facts or data on which the opinion is based” in violation of 37 C.F.R. § 42.55(a) and Fed. R. Evid. 702-703 and 705. For example, Dr. Hsieh-Yee testifies that experts in the field would reasonably rely on the data described herein to form their opinions. (See Ex. 1036 at ¶ 17; see also *id.* at ¶¶ 6, 21, 24, 29, 32, 40, 49, 56, 59, 66.) She provides no support or even example to support such a statement. Patent Owner further objects to other portions of Exhibit 1036 to the extent it does not adequately disclose the underlying facts or data on

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