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Paper 8
Date: April 24, 2023

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.

IPR2023-00074
Patent 8,058,061 B2

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and JAMES A. WORTH, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

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I. INTRODUCTION

Bluebird bio, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1, 2, 5–8, 11, and 15 of U.S. Patent No. 8,058,061 B2 (Ex. 1001, "the '061 patent"). Paper 1 ("Petition" or "Pet."). Sloan Kettering Institute for Cancer Research ("Patent Owner") filed a Preliminary Response to the Petition. Paper 5 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply (Paper 6, "Reply") and Patent Owner filed a Sur-Reply (Paper 7, "Sur-reply").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018). Upon considering the parties' arguments and evidence, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

A. Real Parties in Interest

Petitioner identifies itself and Third Rock Ventures, LLC as the real parties-in-interest. Pet. 2.

Patent Owner identifies itself, San Rocco Therapeutics, LLC, formerly known as Errant Gene Therapeutics, LLC, and Memorial Sloan-Kettering Cancer Center as the real parties-in-interest. Paper 4, 1.

B. Related Matters

Petitioner and Patent Owner identify *San Rocco Therapeutics, LLC v. bluebird bio, Inc., et al.*, No. 1-21-cv-01478 (D. Del.)[1] as a related district court litigation. Pet. 2–3; Paper 4, 2–3. Patent Owner also identifies *Errant*

[1] Patent Owner captions this case "*Errant Gene Therapeutics, LLC v. Bluebird Bio, Inc.*, 1-21-cv-01478, (D. Del. October 21, 2021)." Paper 4, 2.

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Gene Therapeutics, LLC v. Memorial Sloan-Kettering Cancer Center and Sloan Kettering Institute of Cancer Research, 1-21-cv-08206 (S.D.N.Y.) as a related litigation involving the '061 patent. Paper 4, 3.

The parties further identify IPR2023-00070, challenging certain claims of U.S. Patent No. 7,541,179 B2 ("the '179 patent"), as a related matter. Pet. 2–3; Paper 4, 2–3. The '061 patent issued from a divisional application of U.S. application number 10/188,22 ("the '221 application"), which issued as the '179 patent. Ex. 1001, code (62).

C. The '061 Patent

The '061 patent relates to a recombinant vector, e.g., a lentiviral vector, incorporating a functional globin gene and large portions of the β-globin locus control region ("LCR"). Ex. 1001, 1:50–53. The Specification defines the "recombinant lentiviral vector" as "an artificially created polynucleotide vector assembled from a lentiviral-vector and a plurality of additional segments as a result of human intervention and manipulation." *Id.* at 2:40–43. The Specification defines "functional globin gene" as "a nucleotide sequence the expression of which leads to a globin that does not produce a hemoglobinopathy phenotype, and which is effective to provide therapeutic benefits to an individual with a defective globin gene." *Id.* at 2:44–48. "The functional globin gene may encode a wild-type globin," "a mutant form of globin," "α-globin, β-globin, or γ-globin." *Id.* at 2:48–56. The recombinant lentiviral vector is used as a gene therapy vector to provide "therapeutically meaningful levels of human globin for sustained periods of time." *Id.* at 1:41–46.

The Specification describes the recombinant vector as including "large portions of the locus control region (LCR) which include DNase I hypersensitive sites HS2, HS3 and HS4." *Id.* at 2:57–59. The Specification

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defines "large portions" as "portions of the locus control region which encompass larger portions of the hypersensitive sites as opposed to previously tested fragments including only the core elements." *Id.* at 2:63–67. In a specific vector, designated TNS9, the LCR is 3.2 kilobases ("kb") in size and "consists of an 840 [base pair ('bp')] HS2 fragment (SnaBI-BstXI), a 1308 bp HS3 fragment (HindIII-BamHI) and a 1069 bp HS4 fragment (BamHI-BanII)." *Id.* at 3:26–28. Figure 1, reproduced below, illustrates the TNS9 vector.

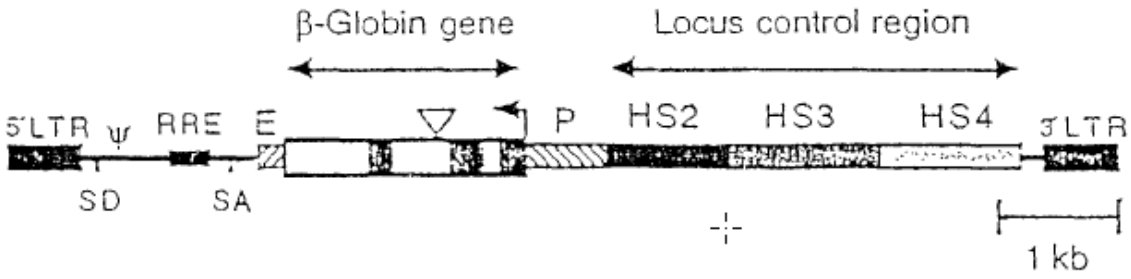

Fig. 1

Figure 1 illustrates the TNS9 vector with the exons represented by filled boxes and the introns represented by open boxes. *Id.* at 3:16–18. The TNS9 vector includes, from the 5′ end to the 3′ end, a splice donor (SD), packaging region (Ψ), rev-response element (RRE), splice acceptor (SA), 3'-β-globin enhancer (E), β-globin gene, human β-globin promoter (P), and LCR (including HS2, HS3, and HS4). *Id.* at 3:18–21. The 5′ and 3′ ends include long terminal repeat (LTR) sequences. *See* Fig. 1.

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D. Illustrative Claims

Petitioner challenges claims 1, 2, 5–8, 11, and 15 of the '061 patent. Claims 1 and 11, set forth below, are the only independent claims and are illustrative of the claimed subject matter.

> 1. An isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising a recombinant lentiviral vector which comprises a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three contiguous nucleotide fragments obtainable from a human β-globin locus control region (LCR), the three fragments being a BstXI and SnaBI, HS2-spanning nucleotide fragment of said LCR, a BamHI and HindIII, HS3-spanning nucleotide fragment of said LCR, and a BamHI and BanII, HS4-spanning nucleotide fragment of said LCR, said vector providing expression of the globin in a mammal in vivo.
>
> 11. A method for making a mammalian hematopoietic progenitor cell or a mammalian stem cell composition which comprises
>
> (a) preparing a recombinant lentiviral vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three contiguous nucleotide fragments obtainable from a human β-globin locus control region (LCR), the three fragments being a BstXI and SnaBI, HS2-spanning nucleotide fragment of said LCR, a BamHI and HindIII, HS3-spanning nucleotide fragment of said LCR, and a BamHI and BanII, HS4-spanning nucleotide fragment of said LCR, said vector providing expression of the globin in a mammal in vivo; and
>
> (b) obtaining hematopoietic progenitor cells or stem cells from the mammalian individual, and transducing the cells with the recombinant vector.

Ex. 1001, 11:56–67, 12:61–13:10. Dependent claim 2 recites the hematopoietic progenitor cell or stem cell of claim 1 being a human cell. *Id.* at 12:1–2. Claims 5–8 recite that the functional globin of claim 1 is a mutant

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