

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.

IPR2023-00070
Patent 7,541,179 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

I. INTRODUCTION

Bluebird bio, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 10, 19, and 22 of U.S. Patent No. 7,541,179 B2 (Ex. 1001, “the ’179 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.

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 '179 patent. Paper 4, 3.

The parties further identify IPR2023-00074, challenging certain claims of U.S. Patent No. 8,058,061 B2 (“the '061 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 10/188,221 (“the '221 application”), which issued as the '179 patent. Ex. 1001, code (21).

C. *The '179 Patent*

The '179 patent is directed 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, 1:47–51. The Specification defines a “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 2:36–40. 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 2:41–45. “The functional globin gene may encode a wild-type globin,” “a mutant form of globin,” “ α -globin, β -globin, or γ -globin.” *Id.* at 2:45–53. 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 1:36–44.

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 2:54–56. The Specification

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 2:60–64. 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 3:24–26. Figure 1, reproduced below, illustrates the TNS9 vector.

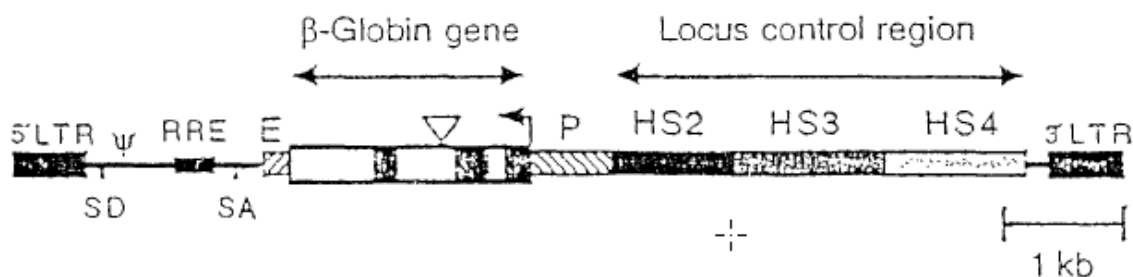


Fig. 1

Figure 1 illustrates the TNS9 vector with exons represented by filled boxes and introns represented by open boxes. *Id.* at 3:14–16. 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 3:16–19. The 5' and 3' ends include long terminal repeat (LTR) sequences. *See* Fig. 1.

D. Illustrative Claim

Petitioner challenges claims 1, 10, 19, and 22 of the '179 patent. Claim 1, set forth below, is the only independent claim and is illustrative of the claimed subject matter.

1. A recombinant 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.

Ex. 1001, 11:55–65. Dependent claim 19 recites that the functional globin is β -globin, and dependent claim 10 recites that the functional globin is human β -globin. *Id.* at 13:4–5, 14:6–7. Dependent claim 22 recites that the vector is a lentiviral vector. *Id.* at 14:12–13.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1, 10, 19 and 22 would have been unpatentable on the following four grounds:

Claims Challenged	35 U.S.C. § ²	Reference/Basis
1, 19, 22	102	May Thesis ³

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the '179 patent issued has an effective filing date before that date, the pre-AIA version of §§ 102 and 103 apply.

³ May, *Therapeutic Hemoglobin Synthesis in Beta-Thalassemic Mice Expressing Lentivirus-Encoded Human Beta-Globin*, Cornell University (2001) (Ex. 1004, “May Thesis”).

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