

Demonstratives of Petitioner bluebird

The United States Patent and Trademark Office – Before the Patent Trial and Appeal Board
bluebird bio, Inc., Petitioner / Sloan Kettering Institute for Cancer Research

**San Rocco Therapeutics responded on behalf of Patent Owner*

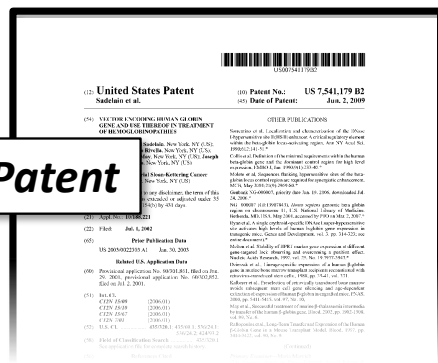
IPR2023-00070 (U.S. Patent No. 7,541,179)

IPR2023-00074 (U.S. Patent No. 8,058,061)

Oral Hearing: January 24, 2024

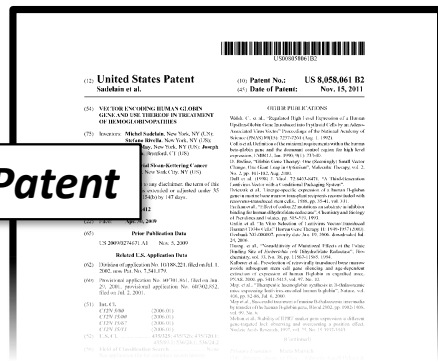
Representative Challenged Claims

'179 Patent



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 BspI and SnaBI HS2-spanning nucleotide fragment of said LCR and 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 functional globin in a mammal in vivo.

'061 Patent



1. An isolated mammalian hematopoietic progenitor cell comprising 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 BspI and SnaBI HS2-spanning nucleotide fragment of said LCR and 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 functional globin in a mammal in vivo.

Instituted Grounds

'179 Patent (IPR2023-00070)	Ground 1	The <i>May Thesis</i> Anticipates Claims 1, 19, and 22
	Ground 2	The <i>May Article</i> Anticipates Claims 1, 18, and 22
	Ground 3	The <i>May Article</i> Renders Claims 1, 19, and 22 Obvious
	Ground 4	The <i>May Abstract</i> Renders Claims 1, 10, 19, and 22 Obvious
'061 Patent (IPR2023-00074)	Ground 1	The <i>May Thesis</i> Anticipates Claims 1, 2, 6-7, and 11
	Ground 2	The <i>May Thesis</i> in View of <i>Himanen</i> Renders Claim 5 Obvious
	Ground 3	The <i>May Article</i> Anticipates Claims 1, 2, 6-7, and 11
	Ground 4	The <i>May Article</i> Renders Claims 1, 2, 6-7, and 11 Obvious
	Ground 5	The <i>May Article</i> in View of <i>Himanen</i> Renders Claim 5 Obvious
	Ground 6	The <i>May Abstract</i> Renders Claims 1, 2, 6-8, 11, and 15 Obvious
	Ground 7	The <i>May Abstract</i> in View of <i>Himanen</i> Renders Claim 5 Obvious

Agenda

- Lack of written description support in the provisional app
- The May Article invalidity grounds
- The May Abstract invalidity grounds
- The May Thesis invalidity grounds

Agenda

- **Lack of written description support in the provisional application**
- The May Article invalidity grounds
- The May Abstract invalidity grounds
- The May Thesis invalidity grounds

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