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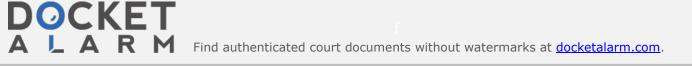
BLUEBIRD BIO, INC., Petitioner

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH, Patent Owner

Patent No. 7,541,179

DECLARATION OF JÖRG BUNGERT, Ph.D.



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	В.	Chad May, <i>et al.</i> , "Therapeutic Haemoglobin Synthesis in β-Thalassaemic Mice Expressing Lentivirus-Encoded Human β-Globin," Nature, 406(6791) (2000) (" <i>May Article</i> ") (Ex. 1005)29		
	C.	May <i>et al.</i> , "Lentiviral-Mediated Transfer of the Human $\beta$ -Globin Gene and Large Locus Control Region Elements Permit Sustained Production of Therapeutic Levels of $\beta$ -Globin in Long-Term Bone Marrow Chimeras," Mol. Therapy, 1(5) (2000), (" <i>May Abstract</i> ") (Ex. 1006)32		
X.		nd 1: The <i>May Thesis</i> Teaches f the Limitations of Claims 1, 19, and 22 of the '179 Patent		

			Declaration of Jörg Bungert, Ph.D. U.S. Patent No. 7,541,179
		1.	[1.pre] "A recombinant vector comprising"
		2.	[1.a] "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 $\beta$ -globin locus control region (LCR),"
		3.	[1.b] "the three fragments being a <i>BstXI</i> and <i>SnaBI</i> HS2-spanning nucleotide fragment of said LCR, a <i>BamHI</i> and <i>HindIII</i> HS3-spanning nucleotide fragment of said LCR and a <i>BamHI</i> and <i>BanII</i> HS4-spanning nucleotide fragment of said LCR,"37
		4.	[1.c] "said vector providing expression of the globin in a mammal <i>in vivo</i> ."
	В.		n 19: "The vector of claim 1, ein the functional globin is a β-globin."
	C.		n 22: "The vector of claim 1, ein the vector is a lentiviral vector"
XI.			The <i>May Article</i> Teaches All ations of Claims 1, 19, and 22 of the '179 Patent
	A.	Clain	n 1
		1.	[1.pre] "A recombinant vector comprising"
		2.	[1.a] "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 $\beta$ -globin locus control region (LCR),"40
		3.	[1.b] "the three fragments being a <i>BstXI</i> and <i>SnaBI</i> HS2-spanning nucleotide fragment of said LCR, a <i>BamHI</i> and <i>HindIII</i> HS3-spanning nucleotide fragment of said LCR and a <i>BamHI</i> and <i>BanII</i> HS4-spanning nucleotide fragment of said LCR,"42
		4.	[1.c] "said vector providing expression of the globin in a mammal <i>in vivo</i> ."
	В.		n 19: "The vector of claim 1, ein the functional globin is a β-globin."

#### Declaration of Jörg Bungert, Ph.D. U.S. Patent No. 7,541,179

	C.		n 22: "The vector of claim 1, ein the vector is a lentiviral vector"			
XII.		Ground 3: The <i>May Article</i> Teaches or Suggests All of the Limitations of Claims 1, 19, and 22 of the '179 Patent				
XIII.	. Ground 4: The <i>May Abstract</i> Teaches or Suggests All of the Limitations of Claims 1, 10, 19, and 22 of the '179 Patent					
	A. Claim 1					
		1.	[1.pre] "A recombinant vector comprising"56			
		2.	[1.a] "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 $\beta$ -globin locus control region (LCR),"			
		3.	[1.b] "the three fragments being a <i>BstXI</i> and <i>SnaBI</i> HS2-spanning nucleotide fragment of said LCR, a <i>BamHI</i> and <i>HindIII</i> HS3-spanning nucleotide fragment of said LCR and a <i>BamHI</i> and <i>BanII</i> HS4-spanning nucleotide fragment of said LCR,"			
		4.	[1.c] "said vector providing expression of the globin in a mammal <i>in vivo</i> ."68			
	В.		n 10: "The vector of claim 1, ein the functional globin is human β-globin."			
	C.	Clain where	n 19: "The vector of claim 1, ein the functional globin is a β-globin."			
	D.	Clain where	n 22: "The vector of claim 1, ein the vector is a lentiviral vector"			
XIV.	IV. Conclusion					

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#### List of Materials Considered<sup>1</sup>

Ex. 1001	U.S. Patent No. 7,541,179 to Sadelain et al. ("the '179 patent")
Ex. 1004	May, "Therapeutic Hemoglobin Synthesis in Beta-Thalassemic Mice Expressing Lentivirus-Encoded Human Beta-Globin," Cornell University (2001) ("the <i>May Thesis</i> ")
Ex. 1005	May, <i>et al.</i> , "Therapeutic Haemoglobin Synthesis in β-Thalassaemic Mice Expressing Lentivirus-Encoded Human β-globin," Nature, 406:82-86 (2000) ("the <i>May Article</i> ")
Ex. 1006	May, <i>et al.</i> , "Lentiviral-Mediated Transfer of the Human $\beta$ -Globin Gene and Large Locus Control Region Elements Permit Sustained Production of Therapeutic Levels of $\beta$ -Globin in Long-Term Bone Marrow Chimeras," Mol. Therapy, 1(5):S248-49 (2000) ("the <i>May</i> <i>Abstract</i> ")
Ex. 1007	Perutz, <i>et al.</i> , "Hemoglobin Structure and Respiratory Transport," Sci. Am., 239(6): 92-125 (1978)
Ex. 1008	Thein & Rochette, "Disorders of Hemoglobin Structure and Synthesis," <i>in</i> Principles of Mol. Med. 179 (Jameson, ed., 1998)
Ex. 1009	Bank, et. al, "Disorders of Human Hemoglobin," Science, 207:486-93 (1980)

<sup>1</sup> Non-patent publication citations are to the original page numbers of the

publication, and citations to U.S. patents are to the column:line number of the

patents. The only exception concerns to Exs. 1032 and 1037-39, as Petitioner

utilizes an asterisk (\*) to denote citation to the exhibit page.

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