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BLUEBIRD BIO, INC., Petitioner

v.

SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH, Patent Owner

Patent No. 8,058,061

DECLARATION OF JÖRG BUNGERT, Ph.D.

Table of Contents

Page

| I. | Introduction—U.S. Patent No. 8,058,0611 | | | | | |
|-------|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| II. | Qualifications2 | | | | | |
| III. | Summary of Opinions4 | | | | | |
| IV. | Pers | Person of Ordinary Skill in the Art | | | | |
| V. | Technological Overview | | | | | |
| | A. | Inherited Hemoglobin Disorders and Gene Therapies9 | | | | |
| | B. | A Predicate to Gene Therapy: Understanding the Regulation of Hemoglobin Genes12 | | | | |
| | C. | Development of Vectors for Gene Therapy17 | | | | |
| VI. | Overview of the '061 Patent21 | | | | | |
| VII. | Claim Construction | | | | | |
| VIII. | The Priority Date for the '061 Patent25 | | | | | |
| IX. | Over | rview of the Prior Art | | | | |
| | А. | Chad M. May, "Therapeutic Hemoglobin Synthesis in Beta-Thalassemic Mice Expressing Lentivirus-Encoded Human Beta-Globin," Cornell University (2001) (" <i>May Thesis</i> ") (Ex. 1004)31 | | | | |
| | B. | 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)32 | | | | |
| | C. | May <i>et al.</i> , "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) (2000), (" <i>May Abstract</i> ") (Ex. 1006)35 | | | | |
| | D. | Himanen, <i>et al.</i> , "A Recombinant Sickle HemoglobinTriple Mutant With Independent Inhibitory Effects on Polymerization," J. Biol. Chem., 271(41):25152-56 (1996) (Ex. 1047)36 | | | | |

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| Х. | Ground 1: The <i>May Thesis</i> Teaches All of the Limitations of Claims 1, 2, 6-7, and 11 of the '061 Patent | | | | |
|----|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| | A. | Clain | n 1 | | |
| | | 1. | [1.pre] "An isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising" | | |
| | | 2. | [1.a] "a recombinant lentiviral vector which comprises," | | |
| | | 3. | [1.b] "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)," | | |
| | | 4. | [1.c] "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,"41 | | |
| | | 5. | [1.d] "said vector providing expression of the globin in a mammal <i>in vivo</i> ."42 | | |
| | B. | Clain hema | n 2: "The cell of claim 1, wherein the mammalian topoietic progenitor cell or the stem cell is a human cell."43 | | |
| | C. | Clain where | n 6: "The cell of claim 1, ein said functional globin is a wild-type globin."43 | | |
| | D. | Claim 7: "The cells of claim 1, wherein said functional globin is a β -globin." | | | |
| | E. | Clain | n 11 | | |
| | | 1. | [11.pre] "A method for making a mammalian hematopoietic progenitor cell or a mammalian stem cell composition which comprises"44 | | |
| | | 2. | [11.a] "(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),"45 | | |

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| | | 3. | [11.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,"46 |
|------|---------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | 4. | [11.c] "said vector providing expression of the globin in a mammal <i>in vivo</i> ; and"47 |
| | | 5. | [11.d] "(b) obtaining hematopoietic progenitor cells or stem cells from the mammalian individual,"47 |
| | | 6. | [11.e] "and transducing the cells with the recombinant vector." |
| XI. | Grou or Sı | ind 2: iggests | The <i>May Thesis</i> in Combination With <i>Himanen</i> Teaches All of the Limitations of Claim 5 of the '061 Patent49 |
| | A. | Clair wher | n 5: "The cell of claim 1, ein said functional globin is a mutant globin." |
| XII. | Grou 1, 2, | ind 3: 6-7, ar | The <i>May Article</i> Teaches All of the Limitations of Claims nd 11 of the '061 Patent |
| | A. | Clair | n 151 |
| | | 1 | F1 7 (CA ' 1 / 1 1' |
| | | 1. | [1.pre] "An isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising" |
| | | 1. 2. | [1.pre] "An isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising" |
| | | 1. 2. 3. | [1.pre] "An isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising" |
| | | 1. 2. 3. | [1.pre] "An isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising" |

Declaration of Jörg Bungert, Ph.D. U.S. Patent No. 8,058,061

| | В. | Claim 2: "The cell of claim 1, wherein the mammalian hematopoietic progenitor cell or the stem cell is a human cell."64 | | | | |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| | C. | Claim 6: "The cell of claim 1, wherein said functional globin is a wild-type globin." | | | | |
| | D. | Claim 7: "The cells of claim 1, wherein said functional globin is a β -globin." | | | | |
| | Е. | Claim 11 | | | | |
| | | 1. | [11.pre] "A method for making a mammalian hematopoietic progenitor cell or a mammalian stem cell composition which comprises"66 | | | |
| | | 2. | [11.a] "(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),"67 | | | |
| | | 3. | [11.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,"68 | | | |
| | | 4. | [11.c] "said vector providing expression of the globin in a mammal <i>in vivo</i> ; and"69 | | | |
| | | 5. | [11.d] "(b) obtaining hematopoietic progenitor cells or stem cells from the mammalian individual,"69 | | | |
| | | 6. | [11.e] "and transducing the cells with the recombinant vector."70 | | | |
| XIII. | Groun the Li | nd 4: The <i>May Article</i> Teaches or Suggests All of imitations of Claims 1, 2, 6, 7, and 11 of the '061 Patent70 | | | | |
| XIV. | Ground 5: The <i>May Article</i> in Combination with <i>Himanen</i> Teaches or Suggests All of the Limitations of Claim 5 of the '061 Patent73 | | | | | |
| | A. | Clain where | n 5: "The cell of claim 1, ein said functional globin is a mutant globin." | | | |

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