

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.

Case No. IPR2023-00074

Patent No. 8,058,061

**DECLARATION OF DR. JAMES RILEY
IN SUPPORT OF PATENT OWNER'S RESPONSE**

Table of Contents

I.	Qualifications.....	4
II.	Relevant Field and Level of Ordinary Skill in the Art.....	6
III.	Materials Reviewed.....	8
IV.	The Understandings Applied to My Analysis.....	14
V.	State of the Art.....	21
	A. Background.....	21
	B. The β -globin gene was intensely studied.....	22
	1. While the LCR had been well-characterized, it was not known which regions were needed to provide consistent high-level expression.....	24
	C. Methods for assembling expression vectors were known.....	27
	1. Restriction Endonucleases.....	27
	2. PCR.....	31

D.	Despite all that was known about the β -globin gene, gene therapy vectors remained elusive	38
VI.	Vector Development and Testing is Slow	41
VII.	The Claimed Lentiviral Vector Represented a Major Advancement Towards Tenetic Treatment of Disorders such as Hemoglobinopathies.....	43
VIII.	The '179 and '061 Patents	46
A.	The Disclosures of the '061 Patent	47
B.	The Priority Date of the '061 Patent	53
C.	Prosecution History	65
IX.	The Asserted Art.....	66
A.	Summary of the Asserted Art.....	66
1.	May Abstract.....	66
2.	The Nature Article	69
3.	The May Thesis.....	72
B.	Use of the Asserted Art	74

X.	Claim Construction.....	76
XI.	Petitioner Fails to Show that (i) Each Limitation of the Claims is Disclosed in the Asserted Art or (ii) that the Clams Were Obvious in View of that Art.....	77
A.	The Nature Article Does Not Anticipate Claims 1, 2, 6, 7, and 11 of the '061 Patent	78
1.	A POSA would have understood that PCR could be used to generate the disclosed HS fragments	79
2.	None of the HS fragments generated using restriction enzymes are the sizes of the HS fragments disclosed in the Nature Article.....	85
XII.	The Asserted Art Fails to Render the Challenged Claims Obvious.....	105
1.	The Nature Article Does Not Render the Claims Obvious....	105
2.	The May Abstract Does Not Render the Challenged Claims Obvious.	111

I, James Riley, declare as follows:

1. I am over the age of 21 years and am fully competent to make this Declaration. I make the following statements based on personal knowledge and, if called to testify to them, could and would do so.

2. I understand these patents are being challenged in *inter partes* reviews in front of the Patent Trial and Appeal Board of the United States Patent and Trademark Office.

3. I understand that the validity of certain claims of U.S. Patent No. 7,541,179 (“the ’179 Patent”) and U.S. Patent No. 8,058,061 (“the ’061 Patent”) have been challenged in *inter partes review* (IPR) proceedings in front of the Patent Trial and Appeal Board of the United States Patent and Trademark Office. Specifically, in IPR2023-00070 the validity of claims 1, 10, 19, and 22 of the ’179 Patent have been challenged, and in IPR2023-0074 the validity of claims 1, 2, 5-8, 11, and 15 of the ’061 Patent have been challenged. I make this declaration in support of Patent Owner’s Preliminary Response in the above-captioned *inter partes* review.

I. Qualifications

4. I received my B.S. from Vanderbilt University in Molecular Biology in 1989. I received my Ph.D. from Emory University in Genetics and Molecular Biology in 1994 under the supervision of Dr. Jeremy Boss. I did my postdoctoral

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.