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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

UNIVERSITY OF UTAH RESEARCH FOUNDATION, et. al., Plaintiffs, vs. AMBRY GENETICS CORPORATION, Defendant.	**DECLARATION OF MARK ALLAN KAY, M.D., PH.D.** Case No. 2:13-cv-00640-RJS Judge Robert J. Shelby
UNIVERSITY OF UTAH RESEARCH FOUNDATION, et. al., Plaintiffs, vs. GENE BY GENE, LTD., Defendant.	

I, Mark Allan Kay, hereby declare that:

I. QUALIFICATIONS AND BACKGROUND

1. I am currently a tenured professor and Head of the Division of Human Gene Therapy at Stanford University School of Medicine. I am the Dennis Farrey Family Professor in the Departments of Pediatrics and Genetics at Stanford University. I am also the Associate Chair for Basic Research in the Department of Pediatrics at Stanford University School of Medicine. My qualifications, expertise, and list of publications are set forth in my curriculum vitae, which is attached as Exhibit A.

2. I received my Ph.D. in Developmental Genetics and my M.D. from Case Western Reserve University in 1986 and 1987, respectively. I completed my internship and residency in the Department of Pediatrics at the Baylor College of Medicine, Houston, Texas in 1990. Between 1990 and 1993, I joined the Department of Molecular and Human Genetics at Baylor College of Medicine as a medical genetics fellow where I completed clinical training to be Board eligible in both Clinical Medical Genetics and Biochemical Genetics. During those three years, I also completed my post-doctoral research on gene therapy for hepatic deficiencies at Baylor College of Medicine, Houston, Texas.

3. I was triple-boarded: Pediatrics from 1990 until 1997; Clinical Genetics, and Clinical Biochemical Genetics from 1993 until 2003. In my medical practice, I have seen many patients for diagnosis, recurrence risk, and/or treatment of genetic disorders between 1990 and 1998. I have been and continue to be involved in Phase I / II clinical trials in gene therapy.

4. My research focuses primarily on developing gene transfer technologies for gene therapy of genetic and acquired diseases of the liver. The second major focus of my research includes the role of small RNAs in mammalian gene regulation.

5. I keep abreast of ongoing research developments in the area of molecular biology and gene therapy by regular perusal of the relevant literature and my service on the editorial boards of several different scientific journals. In particular, I am or have been on the editorial boards of numerous scientific journals, including Gene Therapy, Human Gene Therapy, and Molecular Therapy. I am currently the Associate Editor of Human Gene Therapy and continue to be on the editorial boards of other scientific journals. Based on this work, I am familiar with the review process associated with publishing scientific articles. That process can involve multiple rounds of edits, including requests for authors to run additional experiments to generate more data to include in the manuscript before publication. In my experience, it is common for the content of manuscripts to change considerably between when an article is first submitted and when it is published.

6. I have been retained by attorneys for Plaintiffs to provide consultation and expert opinions regarding United States Patent Nos. 5,747,282 (the "'282 patent"); 5,837,492 (the "'492 patent"); 5,753,441 (the "'441 patent"); 6,033,857 (the "'857 patent"); 6,951,721 (the "'721 patent"); and 5,654,155 (the "'155 patent") (collectively, the "patents-in-suit") in support of Plaintiffs' Motion for a Preliminary Injunction. I have been asked to provide opinions in response to the declarations of Dr. Anne Bowcock ("Bowcock Declaration") and Dr. Simon Gregory ("Gregory Declaration"), both dated August 14, 2013.

7. This declaration and the opinions set forth herein are based on Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, the Bowcock Declaration, the Gregory Declaration, along with the references and other documents cited therein, documents cited herein, and my personal education, professional experience and general knowledge of the

field as of the early-to-mid-1990s and thereafter. A full list of the materials I considered in preparing this declaration is attached as Exhibit B.

8. In the past four years, I have testified at trial or by deposition in the following matter: Tekmira Pharmaceuticals Corp. and Protiva Biotherapeutics, Inc. v. Alnylam Pharmaceuticals, Inc. and Alcana Technologies, Inc., Civil Action No. 11-10-10-BLS2 (Mass. Super. Ct.).

9. I am being compensated at my normal consulting rate of $650 per hour for non-testimonial work, and $850 per hour for testimony at depositions, hearing and trial. My compensation is no way dependent on the outcome of this litigation.

10. I continue my investigation and study. I may review additional documents and information the parties provide or rely on after the submission of my declaration. If Defendants' experts provide additional opinions not expressed in their reports, I may supplement my report to respond to them. Therefore, I may expand or modify my opinions as my investigation and study continues, and supplement my opinions in light of any additional information I review, any matters Defendants raise, or any opinions Defendants' experts may provide.

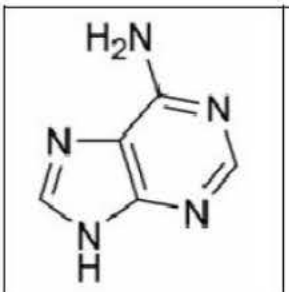
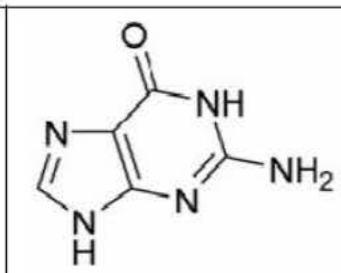
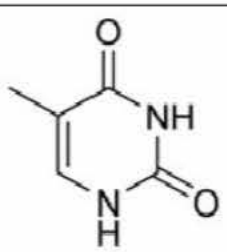
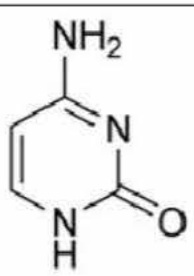
11. I reserve the right to make demonstratives for use at trial or hearings that include figures or text from any of the materials I have considered, as well as any other information that I believe may assist me in explaining issues relevant to this case.

II. TECHNOLOGY BACKGROUND

A. DNA

12. DNA, which stands for deoxyribonucleic acid, is a type of chemical compound called a nucleic acid. At its most basic level, a DNA molecule is composed of several chemical elements, namely Carbon, Hydrogen, Oxygen, Nitrogen, and Phosphorus. These chemical elements make up repeating units that are connected to form a strand or polymer of the DNA

molecule. These repeating units of DNA are known as nucleotides. The standard nucleotides in vertebrate DNA contain four different bases: Adenine, Thymine, Cytosine, and Guanine. These bases are linked together by chemical bonds via a sugar-phosphate backbone. As shorthand for convenience, scientists often denote nucleotides by the first letter of the names of their bases: "A" for Adenine; "G" for Guanine; "T" for Thymine; and "C" for Cytosine. Presented below are depictions of the chemical structures of the four nucleotides:

			
Adenine	Guanine	Thymine	Cytosine

13. A molecule of DNA is typically represented by the linear order of its nucleotides, i.e., its "nucleotide sequence" or simply – its "sequence." The nucleotide sequence defines important structure and chemical properties of a particular DNA molecule based on the linear order of nucleotides in that particular DNA molecule. The structure and chemical properties of a particular DNA molecule can help establish its function.

14. Generally, DNA exists as a double helix, which consists of two intertwined strands of DNA. This structure is made possible because each base in one strand is paired via hydrogen bonds with another base in the other, complementary strand (Adenine pairs with Thymine and Cytosine pairs with Guanine).

15. DNA as it is found in the human body, i.e., native DNA, is one integral component of chromosomes. Chromosomes are complex structures that carry genes and which are located in most cells of the human body. Historically, the term "gene" has been used to

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