

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANCESTRY.COM DNA, LLC.
Petitioner

v.

DNA GENOTEK, INC.
Patent Owner

Patent No. 8,221,381 B2

Inter Partes Review No. IPR2016-00060

DECLARATION OF JOHN M. COLLINS, Ph.D.

sd-683112

I, John M. Collins, declare as follows:

1. I make this declaration in support of DNA Genotek Inc.'s ("DNA Genotek's") Patent Owner's Response. The following declaration is based on my personal knowledge. If called to testify, I could testify competently as to the matters set forth herein.

I. INTRODUCTION AND QUALIFICATIONS

2. I hold a B.S. in mechanical engineering with a minor in economics from Rensselaer Polytechnic Institute. I also hold a Ph.D. and M.S. in Mechanical Engineering from the Massachusetts Institute of Technology, with a concentration on fluid mechanics, and heat and mass transfer, and I have over 30 years' experience in the design and development of medical products. Attached as Exhibit 1 is a copy of my curriculum vitae.

3. Since 2008, I have held a leadership position at the Consortia for Improving Medicine with Innovation and Technology ("CIMIT"). Founded by Massachusetts General Hospital, Massachusetts Institute of Technology, Brigham and Women's Hospital, and Draper Labs in 1998, CIMIT is a non-profit consortium of Boston's leading teaching hospitals and universities along with a growing list of national and international affiliates. CIMIT is directed to stimulating and accelerating translational medical research into patient care in the domain of devices, procedures, and clinical systems engineering. I am CIMIT's Chief Operating Officer.

4. Since 2008, I have also held the position of Chief Technology and Innovation Officer at Reed Collins, LLC, a company which provides consulting services for academic institutions and businesses in the fields of technology, commercialization, and business development.

5. I am a named inventor on over 20 U.S. patents, including 11 patents related to medical devices. I have designed many products, including minimally invasive surgical access devices, trocars, and a saliva testing device for female fertility monitoring.

6. I have provided expert opinions in 19 patent cases in my career, including one case involving a fluid collection device for chest drainage. I have testified in deposition approximately 25 times and at trial approximately 10 times.

7. Counsel for DNA Genotek contacted me and inquired whether I would help the Board to better understand the evidence in the *inter partes* review. Specifically, I was asked to consider (1) whether claims 1, 2, 4, 5, 8, 11, 12, 15-17, 20, 41, 44, and 49 are anticipated under 35 U.S.C. § 102(e)(2) by U.S. Patent 7,645,424 (“O’Donovan”); and (2) whether claim 7 is allegedly unpatentable under 35 U.S.C. § 103(a) over O’Donovan in view of WO 98/03265 (“KCCL”).

8. For my work as an expert, I am being compensated at the rate of \$400 per hour. My compensation is not contingent on the opinions I reach or on the outcome of any legal action, mediation, arbitration, or the terms of any settlement in this case.

9. I reserve the right to supplement my opinions to address any information obtained, or positions taken, based on any new information that comes to light throughout this litigation.

II. BASIS FOR OPINIONS

A. Materials Considered

10. I have reviewed and considered the ’381 Patent (Ex. 1001) and its prosecution history (Ex. 1002).

11. I have also reviewed and considered the following references, which I have been asked to assume for purposes of this declaration are prior art to the '381 Patent:

- Ex. 1007—O'Donovan;
- Ex. 1010—KCCL; and
- Ex. 1011—English translation of KCCL;

12. In addition, I have reviewed the following documents:

- Paper 5—Ancestry's Resubmitted Petition;
- Ex. 1003—Declaration of Terry N. Layton Ph.D. in support of Ancestry's Resubmitted Petition;
- Paper 19—Institution of *Inter Partes* Review;
- Ex. 2004—Transcript of Deposition of Terry Layton, Ph.D., May 25, 2016; and
- Ex. 2008—Declaration of Terry Layton, Ph.D. in Support of Petition for *Inter Partes* Review of U.S. Patent No. 8,221,381, filed June 3, 2016.
- Ex. 2001—ASTM D 1894-01, "Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting"

13. Additionally, I am aware of information generally available to, and relied upon by, persons of ordinary skill in the art at the time of the invention in this case and the references cited above, such as technical dictionaries and reference materials.

B. Legal Principles Applied

14. I have been informed by counsel and understand that the patent laws include a novelty requirement. If a device has been previously disclosed to the public, then it is not novel. If it is not novel, a claimed invention is said to be "anticipated" by the prior art. To demonstrate

anticipation, the party asserting invalidity must show that the claimed invention is “described in a printed publication,” meaning that each claim limitation is disclosed explicitly or inherently in a single prior art reference.

15. I have also been informed by counsel and understand that a claim is obvious, and therefore invalid, if the differences between the subject matter claimed and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the claims pertain. I have also been informed by counsel and understand that the analysis of the scope and content of prior art must consider the prior art as a whole; it is not proper to “pick and choose” or isolate portions of references from the whole, or to ignore portions of the reference that led away from obviousness.

16. I have considered the definition of a person of ordinary skill in the art set by Dr. Layton in his expert declaration. Dr. Layton stated that with respect to the '381 Patent, a person of ordinary skill in the art would have “at least a bachelor of science degree in an engineering field, such as mechanical engineering, and several years of experience designing collection devices for the medical field.” I do not think the level of skill in the art is quite that high. A person of ordinary skill in the art would have a Bachelor of Science degree in some scientific field, but not necessarily engineering, plus some experience with medical devices, but not necessarily “several years” of experience.

17. I consider myself to have at least such “ordinary skill in the art” with respect to the subject matter of the '381 Patent since at least 1983.

III. U.S. PATENT NO. 8,221,381

18. The '381 Patent describes several embodiments of container systems for releasably storing a “substance” in a “lid” before a “sample” is collected in a separate “vial.”

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