

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

DNA GENOTEK INC.,

Plaintiff,

v.

SPECTRUM DNA, SPECTRUM  
SOLUTIONS L.L.C., and SPECTRUM  
PACKAGING L.L.C.,

Defendants.

)  
)  
)  
) C.A. No. 15-cv-00661-SLR  
)  
) **JURY TRIAL DEMANDED**  
)  
)  
)

**DECLARATION OF TERRY LAYTON, PH.D. IN SUPPORT OF DEFENDANTS'  
OPPOSITION TO DNA GENOTEK'S MOTION FOR PRELIMINARY INJUNCTION**

**ANCESTRY EX. 1017**

I, Terry Layton, Ph.D., declare as follows:

1. I have been retained as an expert witness on behalf of Defendants Spectrum DNA, Spectrum Solutions L.L.C., and Spectrum Packaging L.L.C. (collectively, "Spectrum") in this case. I submit this declaration in support of Spectrum's Opposition to DNA Genotek Inc.'s ("Genotek's") Motion for a Preliminary Injunction.

2. For my work as an expert in this case, I am being compensated at the rate of \$250 per hour, except that for my work providing deposition or trial testimony, I am compensated at a rate of \$350 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.

3. I have been asked to give my opinions regarding whether the Spectrum DNA collection device infringes claim 1 of U.S. Patent 8,221,381 ("the '381 patent"), either literally or under the doctrine of equivalents. I have also been asked to give my opinions regarding the validity of claim 1 of the '381 patent in view of U.S. Patent No. 7,645,424 and WO 98/03265. This declaration contains my opinions resulting from that analysis.

4. In providing my opinions expressed below, I relied upon my education, my experience, and the documents referenced herein.

5. The analysis and opinions described in this report are based on the record that is currently available in this lawsuit. I am able to render an opinion at this time based on that information. However, my analysis is ongoing. I may revise or expand upon my opinions as additional information becomes available, including, but not limited to, views and opinions expressed by other expert witnesses, and additional documentary and testimonial evidence produced during ongoing discovery or at trial.

## **I. EDUCATION AND PROFESSIONAL BACKGROUND**

6. I studied Electrical Engineering at the University of Illinois at Urbana-Champaign and received a Bachelor of Science degree in Zoology/Physiology from the University of Wyoming in 1966. I earned a M.S. in Bioengineering from the University of Illinois at Chicago in 1972, and a Ph.D. in Biomedical Engineering from the University of Virginia in 1975.

7. I have worked in the medical device field for more than 35 years, and have been actively involved with the engineering, research, product design, development, and manufacturing of medical devices, including FDA regulated medical devices and medical fluid collection devices. A copy of my curriculum vitae is attached as Exhibit A.

8. From 1975 to 1988, I was employed by The Kendall Company, starting out as a research scientist, and ultimately being promoted to Manager of Medical & Sports Medicine Divisions. During that time, I designed, tested, developed, and/or managed a variety of products in the dental, medical, and sports fields. Several of these projects involved urine collection devices, lumbar puncture spinal fluid collection vials, and thoracentesis collection bags and specimen collection tubes and caps.

9. From 1988 to 1990, I was employed by Baxter Healthcare Corporation (“Baxter”), where I was a manager of the Advanced Device Technology group. During that time, I was involved in the design and management of products and components for IV systems and components, and blood collection products.

10. From 1991 to 1994, I was employed by Packer Engineering as its Director of Biomedical Engineering. During that time, I consulted on and made numerous technology assessments of a variety of health related products in the biomedical field and conducted failure mode investigations of medical devices.

11. From 1994 to 1999, I was employed by Integra and the NeuroCare Group as its Vice-President, Group Technical Officer. During this time, I was involved in developing and releasing to the market new products relating to neurosurgical implants and monitoring devices, assessing new technologies, licensing patents, and purchasing patents and companies. I was also involved in developing and releasing to the market medical devices such as cerebral spinal fluid (CSF) collection bags and valves.

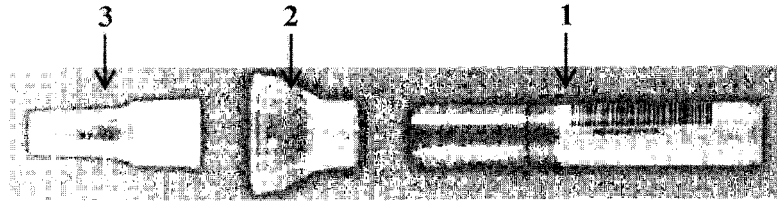
12. I am an inventor on eighteen issued patents, and have authored numerous publications and presentations related to medical devices. A list of my publications and patents is included in Exhibit A.

## **II. INFRINGEMENT ANALYSIS**

13. Genotek's expert, Dr. Lasheras, has asserted that Spectrum's DNA Saliva Collection Kit with Solution for DNA Preservation (the "Spectrum Product") infringes claim 1 of the '381 patent, either literally or under the doctrine of equivalents.

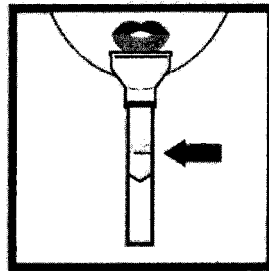
14. I have reviewed the '381 patent (attached as Exhibit B), the file history of the '381 patent, and the Spectrum Product. I have also reviewed pictures and materials relating to the Spectrum Product, including those on Spectrum's website, [www.spectrum-dna.com](http://www.spectrum-dna.com), and the exhibits attached to Dr. Lasheras' declaration. I have also reviewed WO 2015/017701 (attached as Exhibit J).

15. As shown on the information sheet for the Spectrum Product (attached as Exhibit C), the Spectrum DNA sample collection device includes three main components:

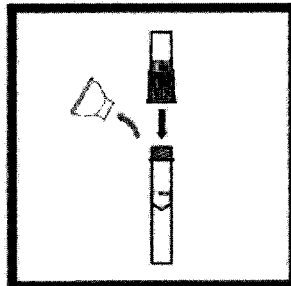


16. In the figure above, the collection tube of the Spectrum Product is labelled (1), the funnel is labelled (2), and the cap is labelled (3). As explained in more detail below, the cap (3) contains a piercing insert, a separate container with a stabilization liquid, and a membrane covering the opening of the separate container so the liquid does not spill out until the membrane is pierced by the piercing insert.

17. The instructions for the Spectrum Product (attached as Exhibit D) describe four steps. First, with the funnel (2) attached to the collection tube (1), the user fills the collection tube (1) with saliva to the black wavy line, as shown in the figure below:



Second, the funnel (2) is removed (see figure below) and the cap (3) is placed on the collection tube (1):



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