UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON DICKINSON AND COMPANY,
Petitioner

V.

ENZO LIFE SCIENCES, INC. Patent Owner

U.S. Patent No. 7,064,197

SYSTEM, ARRAY AND NON-POROUS SOLID SUPPORT COMPRISING FIXED OR IMMOBILIZED NUCLEIC ACIDS

DECLARATION OF DR. NORMAN NELSON



U.S. Patent No. 7,064,197 Declaration of Dr. Norman Nelson

- I, Norman Nelson, do hereby declare:
- 1. I am making this declaration at the request of Becton Dickinson and Company ("BD") in the matter of the *Inter Partes* Review of U.S. Patent No. 7,064,197 to Rabbani et al. ("the '197 patent").
- 2. My qualifications are established by my resume, which I understand is provided as Exhibit A to this Declaration.
- 3. I am being compensated for my work on this matter, but my opinions are based on my own views of the patented technology and the prior art. My compensation in no way depends on the outcome of this proceeding or the content of my testimony.
- 4. In preparing this Declaration, I reviewed and considered the '197 patent, the prosecution history of the '197 patent, and the documents listed at the end of this declaration. Importantly, I have reviewed the related Petition, which I understand BD will file at the United States Patent and Trademark Office (USPTO) at the same time as this Declaration is filed at the USPTO.

I. QUALIFICATION AND EXPERIENCE

5. I obtained a Ph.D. in Chemistry, with a focus in Biochemistry, in 1982 from University of California, San Diego. I also received a Bachelor of Science in Chemistry from California Institute of Technology in 1976.



- 6. I have nearly 31 years of experience in molecular diagnostics and nucleic acid chemistry, particularly nucleic acids analysis. I am and was very knowledgeable about conventional techniques for attaching nucleic acids to other moieties like solid supports or labels. I worked for Gen-Probe Incorporated (now acquired by Hologic, Inc.)—a pioneer and leader in molecular diagnostics—for 27 years (June 1985-August 2012). While at Gen-Probe, I co-invented, reduced to practice, and played a key role in commercialization of multiple core technologies involving nucleic acids analysis, which are currently in FDA-approved products.
- 7. I started my career at Gen-Probe as a scientist (1985-2005), where I developed and implemented key nucleic acids-based technologies and assays, including nucleic acids capture/immobilization and labeling techniques, hybridization, amplification and detection of nucleic acids. As the Director of Biochemistry at Gen-Probe (2005-2009), I led a multidisciplinary team in the development of multiplexed nucleic acids-based assays. And as the Senior Director of Discovery Research at Gen-Probe (2009-2012), I focused on the development and commercialization of various nucleic acids-based diagnostic products.
- 8. I have been working as a consultant in the field of nucleic acids-based diagnostics, DNA sequencing and Genomics since 2012.



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- 9. My research work has led to 37 issued U.S. patents and over 100 issued or pending patent applications worldwide.
- 10. I have co-authored over 20 peer-reviewed journal articles and over 35 technical poster presentations in field of nucleic acids-based diagnostics. I have also delivered numerous technical presentations at conferences. And I have also chaired or served in the program committee of many conferences and symposia related to my field of work.
- 11. I have extensive experience in the field of nucleic acid immobilization, hybridization, and detection—the technical field of the '197 patent. Upon joining Gen-Probe, I extensively researched and studied the existing field of nucleic acids analysis going back to the mid-1970s. Study and knowledge of the prevailing technologies was a requirement for my success as a scientist in developing novel or improved technologies. After BD retained me for preparing this Declaration, I have re-familiarized myself with the pre-1983 scientific literature and patent publications in the field of nucleic acid immobilization, hybridization, and detection (the earliest priority date listed on the face of the '197 patent).

II. RELEVANT LEGAL STANDARDS

12. The opinions I express in this declaration involve the application of my technical knowledge and experience to the evaluation of certain prior art



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- with respect to the '197 patent. In addition, I understand that the following legal principles apply, as explained to me by BD's legal counsel.
- 13. I understand that, in proceedings like this one before the USPTO, a claim in an unexpired patent shall be given its broadest reasonable interpretation in light of the specification of the patent in which it appears. I also understand that district courts may apply a different claim construction standard, and that claims there should be given their ordinary meaning to a person having ordinary skill in the art at the relevant timeframe in light of the claim language, patent specification, and prosecution history. I have read Section VIII of the Petition which sets out the interpretation of certain claim terms in the Petition. I agree with the statements made in that section. I have been informed of certain terms that have already been interpreted by a court. My opinions in this declaration remain the same under either claim construction standard discussed in the Petition or the claims construction standard from the court.
- 14. I understand that a patent claim can be unpatentable if it is anticipated in view of the prior art. I understand that anticipation of a claim requires that every element of a claim be disclosed expressly or inherently in a single prior art reference, arranged as in the claim.



DOCKET

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