

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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HOLOGIC, INC.

and BECTON, DICKINSON AND COMPANY,

Petitioners,

v.

ENZO LIFE SCIENCES, INC.,

Patent Owner

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Case No. IPR2016-00820

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

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**PETITIONERS' MOTION TO EXCLUDE EVIDENCE**

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**I. Requested Relief and Timely Objections**

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), Petitioners Hologic, Inc. and Becton, Dickinson and Company move to exclude the following:

- Exhibits 2035 and 2037-2041 under Federal Rules of Evidence (“FRE”) 901 for lack of authentication and under FRE 802 as improper hearsay;
- Paragraphs 3-10, 12, 14, 16, and 17 of Exhibit 2043 (Mr. Weiner’s Declaration) under FRE 602 for lack of personal knowledge and under FRE 802 as improper hearsay; and
- Paragraphs 146 and 165-181 of Exhibit 2042 (Dr. Buck’s Declaration) under FRE 602 for lack of personal knowledge, under FRE 802 as improper hearsay, and under FRE 702 and 703 as improper expert testimony.

Petitioners timely objected to these exhibits on those bases. Paper 24, at 2-4.

**II. The RTP Exhibits, And The Portions of Dr. Buck’s And Mr. Weiner’s Declarations Relying On Them, Are Inadmissible Evidence**

Enzo introduced Exhibits 2035, 2037, 2038, 2039, 2040, and 2041—purported to be copies of laboratory notebooks and other documents—as evidence of the conception and reduction to practice of the invention of the ’197 patent, in an effort to prove an invention date prior to October 1982 (collectively “the RTP Exhibits”). Paper 20, 40-41. These out of court statements in the RTP Exhibits have no indicia of reliability, and Petitioners have had no chance to cross-examine anyone with personal knowledge of the experiments and dates recorded in these

documents. Also, most of the pages of the RTP Exhibits are unsigned, undated, unwitnessed, and/or illegible. Enzo chose not to present any inventor or other competent testimony to suggest that those documents are what Enzo says they are or that they satisfy any hearsay exception. For the reasons stated below, the RTP Exhibits and the related testimony from Patent Owner's declarants, Dr. Gregory Buck and Mr. Barry Weiner (Exhibits 2042, 2043), should be excluded as inadmissible evidence. Each RTP Exhibit is summarized in turn before addressing evidentiary issues.

#### **A. Summary of the RTP Exhibits**

***Exhibit 2035.*** Enzo alleges that Exhibit 2035 is a document signed by co-inventors Barbara Thalenfeld and Kenneth Johnston, demonstrating “[conception] on approximately February 22, 1982 and that the first written record and experiment demonstrating the invention occurred on May 26, 1982.” Paper 20, at 41. The exhibit is neither dated nor witnessed. Ex. 2035, at 5.

***Exhibit 2037.*** Dr. Buck and Mr. Weiner describe Exhibit 2037 as inventor Dollie Kirtikar's notebook. *See* Ex. 2042, ¶¶ 167, 169, 170, 172, 174, 175; Ex. 2043, ¶¶ 10-11. This 306-page exhibit contains copies of removable sheets in a binder, which are in non-chronological order and are often undated and/or

unsigned. None of the pages are witnessed by a testifying declarant.<sup>1</sup> Ex. 1036, 140:10-144:3.

**Exhibits 2038 and 2039.** Enzo alleges that Exhibits 2038 and 2039 are inventor Barbara Thalenfeld's laboratory notebook. *E.g.*, Ex. 2043, ¶¶ 12, 14. Exhibit 2038 is non-chronological, unsigned, and unwitnessed, while Exhibit 2039 is neither signed nor witnessed. Both exhibits contain additional documents either "folded or stapled to the handwritten pages." Ex. 2043, ¶¶ 13, 15.

**Exhibit 2040.** Enzo asserts that Exhibit 2040 was prepared by inventors Barbara Thalenfeld and Kenneth Johnston and describes June 1982 experiments. Ex. 2042, ¶¶ 167-168; Ex. 2043, ¶ 16. It is not witnessed.

**Exhibit 2041.** Enzo describes Exhibit 2041 as a photocopy of photocopies of Dr. Thalenfeld's notebook, and the pages were "signed or initialed ... *after* the *copy* was made." Ex. 2043, ¶ 17 (emphasis added). Thus, the inventors did not sign the *original* notebook, and it is not witnessed.

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<sup>1</sup> Mr. Weiner alleged that certain pages were witnessed by a non-inventor, Dr. Norman Kelker. Ex. 1036, 64:1-16, 66:1-13, 68:11-24. Dr. Kelker consulted with Mr. Weiner prior to his deposition (*id.*, 10:4-7, 11:5-14:22), but Enzo chose not to present his testimony.

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