

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. IPR2016-00822

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

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**REPLY IN SUPPORT OF PETITIONERS' MOTION TO EXCLUDE  
EVIDENCE**

Petitioners' Motion to Exclude Evidence ("Mot.") established that the RTP Exhibits, and portions of Dr. Buck's and Mr. Weiner's Declarations concerning those Exhibits, are not admissible under the Federal Rules of Evidence ("FRE"). Enzo's Opposition fails to affect that showing.

**I. Mr. Weiner Lacks Personal Knowledge Of Reduction To Practice Dates In The RTP Exhibits, Which Are Otherwise Inadmissible Hearsay**

Enzo argues that Mr. Weiner had personal knowledge of Enzo's R&D activities during the January to September 1982 time frame, during which he was Vice President of Enzo Biochem. Enzo Opposition ("Opp."), 2-4. Petitioners, however, do not dispute that Mr. Weiner may have some personal knowledge of Enzo's R&D activities in 1982. Rather, Petitioners dispute Mr. Weiner's personal knowledge of the *date* when Enzo's activities resulted in the claimed invention, i.e., *the date when the claimed invention was purportedly reduced to practice*. His knowledge of the general nature of Enzo's R&D activities does not amount to personal knowledge of *when* the claimed invention was reduced to practice.

At his deposition, Mr. Weiner answered that he was aware of Enzo's R&D activities, was a liaison between Enzo's scientists and the business world, and had contact with the inventors on a daily basis (*see id.*), even though he did not oversee any R&D or work alongside the inventors (*e.g.*, Ex. 1036, 20:12-21:3, 24:6-10, 35:24-38:9, 48:17-49:12, 51:21-52:16, 56:5-57:4, 69:14-23). But when he was specifically asked whether he had any personal knowledge of *when* the claimed

subject matter was reduced to practice, independent of the RTP Exhibits, he stated “I cannot say that I was aware of the specific date” or “recall 30 years ago the specific date of an event.” *E.g.*, Ex. 1036, 136:11-137:6, 138:16-139:21. In fact, despite his alleged independent knowledge of Enzo’s R&D activities, Mr. Weiner identified the relevant R&D period as **1980 to 1984**—extending well beyond the relevant October 1982 publication date of the VPK reference. *Id.*, 138:16-139:5.

Unlike *In re Hall* where regular library practices were used to “approximate” a public accessibility date from a proven library receipt date, here Mr. Weiner’s testimony is not “competent evidence” to then “approximate” the date of invention based on Enzo’s business practices. 781 F.2d 897, 899 (Fed. Cir. 1986). And Enzo cannot rely upon *Palo Alto Networks*, where testimony about *regular* monthly publication practices was admitted to prove a publication date. *Palo Alto Networks, Inc. v. Finjan, Inc.*, IPR2015-01974, Paper 49, at 19-20, 35-36 (P.T.A.B. March 16, 2017). By contrast, Mr. Weiner failed to show that Enzo followed any regular business practice in maintaining the RTP Exhibits. *E.g.*, Ex. 1036, 51:12-20, 53:6-54:14. Indeed, Enzo effectively argues that it had ***no notebook maintenance policy***: “Enzo’s policy did not require that each notebook entry be signed and witnessed or that notebooks be bound and consecutively dated.” Opp., 8.

Mr. Weiner’s testimony that the inventors’ experiments occurred by certain ***dates*** is based on nothing more than the hearsay statements of the RTP Exhibits.

Mr. Weiner's purported knowledge of Enzo's R&D activities does not give rise to knowledge of the *dates* when such R&D activities resulted in reduction to practice of the claimed invention, and cannot be used to authenticate the RTP Exhibits.

## **II. The RTP Exhibits Are Neither Authentic Nor Admissible Hearsay**

Petitioners' Motion presented two separate grounds for excluding the RTP Exhibits. Enzo's opposition does nothing to overcome those grounds. *First*, the RTP Exhibits cannot be authenticated because Enzo has not established they *are what Enzo claims them to be*—documents created by September 1982 showing reduction to practice of the '197 patent claims. *See Opp.*, 7. Petitioners have shown that Mr. Weiner lacks personal knowledge of *when* the RTP Exhibits were created, and that the RTP Exhibits lack distinctive characteristics of reliable laboratory records, because they are not consistently dated, signed, or witnessed.

Enzo's corroboration arguments also fail. *See Opp.*, 9-10. Dr. Kirtikar's *2003* declaration (Ex. 2002) was not submitted to prove an invention date (it addressed a written description rejection). Also, *Blicharz* relates to the *weight* given to corroborative evidence, which included testimony from a witness who actually observed the experiments. *Blicharz v. Hays*, 496 F.2d 603, 605-606 (C.C.P.A. 1974). *Blicharz* does not support Enzo's efforts to *authenticate* the inconsistently dated, signed, and witnessed RTP Exhibits.

*Second*, the RTP Exhibits do not qualify as business records or other

exceptions to the hearsay rule. *See* Mot., 9-11. Enzo fails to demonstrate how the RTP Exhibits meet the business record exception requirements: without consistent dates, there is no way to confirm that the information was recorded “at or near the time the experiments were performed,” and without a clear notebook policy (*see supra*, p. 2), Enzo cannot demonstrate that there was a “regularly conducted activity of the business.” Further, *Corning Inc.* is not as limited as Enzo suggests. *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00043, Paper 97, at 5 (“Federal Circuit and Board precedent declines to invoke a Rule 803(6) exception to laboratory notebook documents,” citing several cases refusing to admit scientific research reports and tests under Rule 803(6)).

Moreover, the RTP Exhibits cannot qualify as authentic ancient documents under either FRE 901(8) or 803(16), because the documents lack the details expected in reliable notebook-keeping practice—consistent signing, dating, and witnessing (i.e., proof of review)—creating suspicion about their authenticity.

### **III. Portions of Dr. Buck’s Testimony Must Be Excluded**

Enzo never disputes that Dr. Buck lacks personal knowledge of *the dates* certain activities allegedly occurred. Instead, Enzo relies on *Broadcom* to argue that Dr. Buck can use inadmissible facts in the RTP Exhibits to “analyz[e] conception and reduction-to-practice questions.” Opp., 14. The *Broadcom* expert, unlike Dr. Buck, gave “detailed testimony at trial explaining his basis for

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