UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOLOGIC, INC.,
and BECTON, DICKINSON AND COMPANY,
Petitioners

v.

ENZO LIFE SCIENCES, INC.
Patent Owner

Case No. IPR2016-00820
U.S. Patent No. 7,064,197

CORRECTED PETITIONERS' REPLY

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Table of Contents

I. PRELIMINARY STATEMENT 1

II. ARGUMENTS 1

A. Claims anticipated by Fish. 1

1. Single-stranded (ss) nucleic acids fixed to a non-porous solid support. 1

2. Fish's immobilized ssDNA is in hybridizable form. 4

B. Claims obvious based on Fish. 9

1. Obviousness concerning sequence of interest. 9

2. Obvious to use Fish's binding technique for RNA. 10

C. Claims obvious based on Fish in view of Gilham. 10

D. Anticipation of challenged claims by VPK. 12

1. Enzo cannot claim priority to the 1983 application because it fails to comply with the written description requirement. 12

2. No reduction to practice before VPK's publication date. 14

E. It would have been obvious that the hybridization procedure of VPK could be performed on glass slides having wells or depressions as disclosed by Metzgar. 23

F. Obviousness based on Noyes, VPK, and Ramachandran. 24

1. Nucleic acids bound using the Noyes binding chemistry would remain in hybridizable form. 24

2. Motivation to combine Noyes and Ramachandran to covalently bind RNA in hybridizable form to the glass slides of VPK. 25

III. THE SECONDARY CONSIDERATIONS, IF ANY, FAIL TO OVERCOME THE EVIDENCE OF OBVIOUSNESS 25

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

A. Enzo's technical expert is not qualified to opine on secondary considerations. 26

B. Enzo has not established a nexus between the merits of the claimed invention and any secondary considerations. 27

IV. CONCLUSION....28

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

I. PRELIMINARY STATEMENT

The Institution Decision held that it is more likely than not that the challenged claims are unpatentable based on the grounds presented in Hologic's Petition. Nothing in Enzo's Patent Owner Response calls that into question. The conclusory and unsupported arguments of Enzo's technical expert, Dr. Gregory Buck ("Buck"), fail to alter the Board's reasoning in its Institution Decision. The Board should issue a Final Written Decision canceling the challenged claims.

II. ARGUMENTS

A. Claims anticipated by Fish.

1. Single-stranded (ss) nucleic acids fixed to a non-porous solid support.

The Decision properly concludes that Fish explicitly discloses binding ssDNA to PLL-coated wells. Decision, 12-13.

The Decision states that Fish "knew that ssDNA would bind to PLL-coated wells, because they were relying on such binding to carry out their experiment." Decision, 13. The Decision quotes the following supporting sentence from Fish: "[t]his positive control for the nuclease S_1 activity suggests that single-stranded nucleic acid, bound to PLL treated plastic, remains susceptible to the hydrolytic activity of the enzyme." Ex.1006, 538, right col.,¶1.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Enzo's alternative interpretation of the sentence—Fish *assumed* that ssDNA may have bound—does not make sense. Response, 5. The Decision got it right.

Enzo claims that "additional information" suggests Fish would not have known ssDNA bound. Response, 5. Enzo argues that prior hybridization methods involved ssDNA bound to porous materials or cells bound to non-porous materials. As a consequence, Enzo argues that a POSITA would not have expected ssDNA to bind to PLL-coated polyvinyl plates. *Id*. Enzo's alleged state of the art, which did not address nucleic acids binding to PLL, sheds no light on what the Fish authors knew about binding ssDNA to PLL-coated wells.

Enzo oddly asserts that Fish's doubt that DNA would bind to ***uncoated*** polyvinyl somehow counters the Decision's conclusion that Fish knew ssDNA would bind to ***PLL-coated*** polyvinyl. Response, 5.

Fish proves that dsDNA bound to the PLL-coated wells. Response, 4; Ex.1035, 56:25-57:5. Enzo argues that those dsDNA experiments were unreliable for assessing whether ssDNA would bind in view of unspecified differences between ssDNA and dsDNA. Ex.2042, ¶76. But both ssDNA and dsDNA have negatively-charged backbones, allowing them to bind to positively-charged PLL-coated wells. Ex.1002, ¶52. Thus, if dsDNA binds to PLL-coated plates, there is no reason to doubt that ssDNA would too. *Id*.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.