

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 IPR2016-00820
Patent 7,064,197 B1

Before MICHAEL J. FITZPATRICK, ZHENYU YANG, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a)

I. INTRODUCTION

The original sole Petitioner in this *inter partes* review, Hologic, Inc. (“Hologic”) filed a Petition to institute an *inter partes* review of claims 1, 6, 8, 9, 12–16, 27, 31–34, 38, 41, 61–64, 68–70, 72–74, 78, 79, 100, 101, 191–195, 212, 213, 218, 219, 222, 225–227, 230, 233, and 236 (“the challenged claims”) of U.S. Patent No. 7,064,197 B1 (Ex. 1001, “the ’197 patent”) pursuant to 35 U.S.C. § 311(a). Paper 1 (“Pet.”). Patent Owner, Enzo Life Sciences, Inc., filed a Preliminary Response pursuant to 35 U.S.C. § 313. Paper 7 (“Prelim. Resp.”). In an October 4, 2016, Decision, we granted the Petition. Paper 8 (“Inst. Dec.”).

During trial, Becton, Dickinson and Company (“Becton”) was joined as co-petitioner. Paper 32. Hologic and Becton are hereafter referred to collectively as “Petitioners.”

Patent Owner filed a Patent Owner Response (Paper 24, “PO Resp.”), to which Petitioners filed a Reply (Paper 38, “Reply”). Both sides filed Motions to Exclude. *See* Papers 43, 45. Both sides requested a hearing for oral arguments, and a consolidated hearing for this *inter partes* review and Case IPR2016-00822 was held June 1, 2017. A transcript of the hearing appears in the record. *See* Paper 51 (“Tr.”).

As discussed below, Petitioners have shown by a preponderance of the evidence that all of the challenged claims are unpatentable.

A. Related Matters

Co-petitioner Hologic successfully petitioned for two *inter partes* reviews of claims of the ’197 patent—the instant proceeding and Case IPR2016-00822. Co-petitioner Becton also filed two petitions for *inter*

partes reviews of the '197 patent, along with motions to join the already instituted Hologic-petitioned *inter partes* reviews. See IPR2017-00172; IPR2017-00181. Becton's petitions were denied, but Becton was joined as co-petitioner in this proceeding and as well as in Case IPR2016-00822. See Paper 32; IPR2016-00822, Paper 31.

The parties identify the following lawsuits as involving the '197 patent: *Enzo Life Sciences, Inc. v. Hologic, Inc.*, No. 1:15-cv-271 (D. Del.); *Enzo Life Sciences, Inc. v. Siemens Healthcare Diagnostics, Inc.*, No. 1:12-cv-505 (D. Del.); *Enzo Life Sciences, Inc. v. Affymetrix, Inc.*, No. 1:12-cv-433 (D. Del.); *Enzo Life Sciences, Inc. v. Agilent Technologies Inc.*, No. 1:12-cv-434 (D. Del.); *Enzo Life Sciences, Inc. v. Illumina Inc.*, No. 1:12-cv-435 (D. Del.); *Enzo Life Sciences, Inc. v. Abbott Laboratories et al.*, No. 1:12-cv-274 (D. Del.); *Enzo Life Sciences, Inc. v. Becton Dickinson and Company et al.*, No. 1:12-cv-275 (D. Del.); *Enzo Life Sciences, Inc. v. Life Technologies Corp.*, No. 1:12-cv-105 (D. Del.); and *Enzo Life Sciences, Inc. v. Roche Molecular Systems Inc. et al.*, No. 1:12-cv-106 (D. Del.). Pet. 2–3; Paper 23, 1.

B. The '197 Patent

The '197 patent relates generally to the detection of genetic material by polynucleotide or oligonucleotide probes. Ex. 1001, 1:23–24, 5:43–46. The '197 patent refers to the genetic material to be detected as an “analyte.” *Id.* at 1:37–39. An analyte may be present in a biological sample such as a clinical sample of blood, urine, saliva, etc. *Id.* at 5:47–50. If an analyte of interest is present in a biological sample, it is fixed, according to the invention of the '197 patent, “in hybridizable form to a solid support.” *Id.* at

5:58–60. In the challenged claims, the analyte is either “single-stranded nucleic acid” (claims 1, 6, 12, 13, 27), “DNA or RNA” (claims 8, 15), or “nucleic acid” (claims 9, 14). “Analytes in a biological sample are preferably denatured into single-stranded form, and then directly fixed to a suitable solid support.” *Id.* at 5:61–63. The ’197 patent states that it is preferred, and all of the challenged claims require, that the solid support be non-porous. *Id.* at 6:2–6; *e.g.*, *id.* at 15:51–53 (claim 1 reciting a “non-porous solid support”). To obtain fixation (or binding) to the non-porous solid support, the ’197 patent teaches treating the surface of the support with a chemical such as polylysine. *Id.* at 11:37–39.

Chemically-labeled probes are then brought into contact with the fixed single-stranded analytes under hybridizing conditions. The probe is characterized by having covalently attached to it a chemical label which consists of a signaling moiety capable of generating a soluble signal. Desirably, the polynucleotide or oligonucleotide probe provides sufficient number of nucleotides in its sequence, *e.g.*, at least about 25, to allow stable hybridization with the complementary nucleotides of the analyte. The hybridization of the probe to the single-stranded analyte with the resulting formation of a double-stranded or duplex hybrid is then detectable by means of the signalling moiety of the chemical label which is attached to the probe portion of the resulting hybrid. Generation of the soluble signal provides simple and rapid visual detection of the presence of the analyte and also provides a quantifiable report of the relative amount of analyte present, as measured by a spectrophotometer or the like.

Id. at 6:15–32.

C. The Challenged Claims

Petitioners challenge claims 1, 6, 8, 9, 12–16, 27, 31–34, 38, 41, 61–64, 68–70, 72–74, 78, 79, 100, 101, 191–195, 212, 213, 218, 219, 222, 225–227, 230, 233, and 236 of the '197 patent. Pet. 1. Of the challenged claims, claims 1, 6, 8, 9, 12–15, and 27 are independent. The remainder of the challenged claims all depend directly from at least one of the challenged independent claims, with several of them in multiple dependent form.

Claim 1 is illustrative and reproduced below.

1. A non-porous solid support comprising one or more amine(s), hydroxyl(s) or epoxide(s) thereon, wherein at least one single-stranded nucleic acid is fixed or immobilized in hybridizable form to said non-porous solid support via said one or more amine(s), hydroxyl(s) or epoxide(s).

D. Grounds of Unpatentability Tried

We instituted trial on the following grounds of unpatentability:

References	Basis ¹	Claims Challenged
Fish (Ex. 1006) ²	§ 102(b)	1, 6, 8, 9, 12–16, 27, 32–34, 41, 61–63, 69, 70, 72–74, 79, 100, 191, 193, 194, 212, 213, 219, 222, 225–227, 230, 233, and 236

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, enacted September 16, 2011, amended 35 U.S.C. §§ 102 and 103. AIA § 3(b)–(c). Their amendment became effective eighteen months later on March 16, 2013. *Id.* at § 3(n). Because the application from which the '197 patent issued was filed before March 16, 2013, any citations herein to 35 U.S.C. §§ 102 and 103 are to their pre-AIA versions.

² Falk Fish, et al., “A Sensitive Solid Phase Microradioimmunoassay For

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