

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

ENZO LIFE SCIENCES, INC.,
Appellant

v.

BECTON, DICKINSON AND COMPANY,
Appellee

UNITED STATES,
Intervenor

2018-1232, 2018-1233

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-00820, IPR2016-00822.

Decided: August 16, 2019

JUSTIN P.D. WILCOX, Desmarais LLP, New York, NY, argued for appellant. Also represented by KERRI-ANN LIMBEEK, KEVIN KENT MCNISH.

THOMAS SAUNDERS, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellee. Also represented by WILLIAM G. MCELWAIN, HEATHER M. PETRUZZI;

NANCY SCHROEDER, Los Angeles, CA; OMAR KHAN, New York, NY.

DENNIS FAN, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for intervenor. Also represented by KATHERINE TWOMEY ALLEN, SCOTT R. MCINTOSH, JOSEPH H. HUNT; THOMAS W. KRAUSE, JOSEPH MATAL, FARHEENA YASMEEN RASHEED, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

Before LOURIE, O'MALLEY, and CHEN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Enzo Life Sciences, Inc. appeals from two final written decisions of the United States Patent and Trademark Office (“PTO”) Patent Trial and Appeal Board (“the Board”) holding various claims of U.S. Patent 7,064,197 (“the ’197 patent”) unpatentable as anticipated or obvious. *See Hologic, Inc. v. Enzo Life Scis., Inc.*, No. IPR2016-00820, 2017 WL 4339646 (P.T.A.B. Sept. 28, 2017) (“’820 Decision”); *Hologic, Inc. v. Enzo Life Scis., Inc.*, No. IPR2016-00822, 2017 WL 4407743 (P.T.A.B. Oct. 2, 2017) (“’822 Decision”). The PTO intervened to defend the constitutionality challenge to *inter partes* review (“IPR”) proceedings as applied to patents issued before the enactment of the America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011). For the following reasons, we *affirm*.

BACKGROUND

Deoxyribonucleic acid (“DNA”) and ribonucleic acid (“RNA”) are nucleic acids made of a series of nucleotides. A nucleotide is composed of a sugar, a phosphate, and a nitrogenous base. DNA has four nitrogenous bases: adenine (A), guanine (G), cytosine (C), and thymine (T). RNA also has the bases adenine (A), guanine (G), and cytosine (C), but contains uracil (U) instead of thymine (T). A

polynucleotide refers to multiple nucleotides linked together in a chain. Two strands of polynucleotides can bind to one another, *i.e.*, hybridize, through hydrogen bonding between complementary nucleotides known as Watson-Crick base pairing: bases T or U pair with A, and G pairs with C. A strand of nucleotides that is not hybridized to another strand is said to be single-stranded, while two strands hybridized to each other are said to be double-stranded.

Enzo owns the '197 patent directed to “the detection of genetic material by polynucleotide probes.” '197 patent col. 1 ll. 23–24. The invention leverages hybridization techniques to detect the presence of an analyte, which may be “a DNA or RNA molecule,” “a molecular complex,” or “a biological system containing nucleic acids, such as a virus, a cell, or group of cells.” *Id.* col. 1 ll. 39–42. A polynucleotide probe that is complementary to a target analyte will hybridize with it and is thereby used to detect that analyte's presence. *See id.* col. 2 ll. 37–63. According to the invention, the analytes to be detected are “fixed . . . in hybridizable form to [a] non-porous solid support.” *Id.* col. 13 ll. 63–67; *see also id.* col. 5 ll. 58–60. The specification also discloses that a “technique for improving the fixing or uniformity of the plastic surface for fixing DNA involves treatment of the surface with polylysine.” *Id.* col. 11 ll. 37–39.

Independent claim 1 is representative of the claims challenged in IPR2016-00820 (“the '820 IPR”) and independent claim 17 is representative of the claims challenged in IPR2016-00822 (“the '822 IPR”):

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).

Id. col. 13 ll. 63–67 (emphases added).

17. An *array* comprising various single-stranded nucleic acids fixed or immobilized in *hybridizable form* to a non-porous solid support.

Id. col. 15 ll. 51–53 (emphases added).

Hologic, Inc. filed two petitions for IPR of the '197 patent. During both proceedings, Becton, Dickinson, & Company ("Becton") moved to join as a co-petitioner, and the Board granted the motions. See Joinder Order at 2, *Hologic, Inc. v. Enzo Life Scis., Inc.*, No. IPR2016-00820 (P.T.A.B. Mar. 27, 2017), Paper No. 32; Joinder Order at 2, *Hologic, Inc. v. Enzo Life Scis., Inc.*, No. IPR2016-00822 (P.T.A.B. Apr. 5, 2017), Paper No. 31. The Board instituted trial on all eight grounds of unpatentability across the two IPRs, which all rely on Fish¹ or VPK² as the primary reference.

The Board determined that all the challenged claims were unpatentable as anticipated by Fish or rendered obvious by Fish alone or in combination with other prior art references. '820 *Decision*, 2017 WL 4339646, at *11–15; '822 *Decision*, 2017 WL 4407743, at *10–15. The Board next determined that VPK qualified as a prior art reference. '820 *Decision*, 2017 WL 4339646, at *15–18; '822 *Decision*, 2017 WL 4407743, at *15–18. The Board found that the '197 patent could not claim priority from its original parent application's filing date of January 27, 1983,

¹ Falk Fish & Morris Ziff, *A Sensitive Solid Phase Microradioimmunoassay for Anti-Double Stranded DNA Antibodies*, 24 *Arthritis and Rheumatism* 534–43 (Mar. 1981), J.A. 1266–75 ("Fish").

² A.C. van Prooijen-Knegt et al., *In Situ Hybridization of DNA Sequences in Human Metaphase Chromosomes Visualized by an Indirect Fluorescent Immunocytochemical Procedure*, 141 *Experimental Cell Research* 397–407 (Oct. 1982), J.A. 1288–98 ("VPK").

because that application did not provide written description support for the claimed “non-porous solid support.” *See, e.g.*, ’197 patent col. 13 l. 63. Instead, the Board determined that the ’197 patent could only claim priority from the 1983 application’s child continuation-in-part application, which was filed on May 9, 1985. VPK was publicly available as of October 1982, more than a year before the critical date of May 9, 1985, and thus qualified as prior art. *See* 35 U.S.C. § 102(b) (2006). The Board then concluded that all the challenged claims were anticipated by VPK or would have been obvious over VPK in combination with other prior art references. ’820 *Decision*, 2017 WL 4339646, at *19–24; ’822 *Decision*, 2017 WL 4407743, at *20–23.

Enzo appeals. The PTO intervened pursuant to 35 U.S.C. § 143 to defend against Enzo’s constitutionality challenge to IPRs as applied to the ’197 patent because it issued on June 20, 2006, which is before the enactment of the AIA in 2011. Enzo argues that constitutes a violation of the Fifth Amendment. Before this case was argued, Hologic moved to withdraw as a party to this appeal, and this court granted the motion. *See Enzo Life Scis., Inc. v. Becton, Dickinson & Co.*, Nos. 2018-1232, 2018-1233 (Fed. Cir. Apr. 25, 2019), ECF No. 74. Becton remains as appellee. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board’s legal determinations *de novo*, and the Board’s factual findings underlying those determinations for substantial evidence. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Anticipation is a question of fact that we review for substantial evidence. *In re Rambus, Inc.*, 753 F.3d 1253, 1256 (Fed. Cir. 2014). A prior art document may anticipate a

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