

2018-1232, 2018-1233

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

ENZO LIFE SCIENCES, INC.,

Appellant,

– v. –

BECTON, DICKINSON AND COMPANY,

Appellee,

UNITED STATES,

Intervenor.

APPEALS FROM THE UNITED STATES PATENT AND
TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD
IN Nos. IPR2016-00820, IPR2016-00822

**COMBINED PETITION FOR REHEARING AND
REHEARING *EN BANC* BY PATENT OWNER-
APPELLANT ENZO LIFE SCIENCES, INC.**

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OCTOBER 30, 2019

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 26.1, 35(c)(1), and 47.4, counsel for appellant certifies the following:

1. The full name of every party or amicus represented by me is:

Enzo Life Sciences, Inc.
2. The name of the real party in interest (if the party is not identified in Question 3) represented by me is:

N/A
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Enzo Biochem, Inc.
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Desmarais LLP: Michael P. Stadnick (former); Timothy Q. Li (former)
5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal include:

Enzo Life Sciences, Inc. v. Hologic, Inc., C.A. No. 11:15-CV-00271-LPS-CJB (D. Del.)

Enzo Life Sciences, Inc. v. Becton, Dickinson & Co., et al., C.A. No. 1:12-cv-00275-LPS (D. Del.)

Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc., et al., C.A. No. 1:12-cv-00106-LPS (D. Del.)

Ex Parte Reexamination Control No. 90/014,270 (USPTO)

Ex Parte Reexamination Control No. 90/014,272 (USPTO)

Dated: October 30, 2019

/s/ Justin P.D. Wilcox

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TABLE OF CONTENTS

	<u>Page</u>
CERTIFICATE OF INTEREST	i
TABLE OF AUTHORITIES	iv
STATEMENT OF COUNSEL	1
POINTS OF LAW OVERLOOKED OR MISAPPREHENDED	2
INTRODUCTION	3
STATEMENT OF THE CASE.....	4
I. The '197 Patent Issued In 2006.....	4
II. The AIA Created <i>Inter Partes</i> Review In 2011.	5
III. The Board Found The Challenged '197 Patent Claims Unpatentable.....	6
IV. The Panel Affirmed The Board's IPR Decisions.....	7
REASONS FOR GRANTING REHEARING	8
I. The Panel Did Not Address Enzo's Due Process Clause Arguments, Misapprehending Them As A Takings Clause Challenge.....	8
II. The Panel's Decision Contravenes Supreme Court Precedents That Forbid The Retroactive Impairment Of Vested Property Rights.....	10
III. The Question Presented Is Exceptionally Important, And The Outcome Will Have Significant Implications.....	16
CONCLUSION	18
ADDENDUM	
CERTIFICATE OF SERVICE	
CERTIFICATE OF COMPLIANCE	

TABLE OF AUTHORITIES¹

	<u>Page(s)</u>
<u>Cases</u>	
<i>Arthrex, Inc. v. Smith & Nephew, Inc.</i> , 935 F.3d 1319 (Fed. Cir. 2019)	18
<i>Celgene Corp. v. Peter</i> , 931 F.3d 1342 (Fed. Cir. 2019)	7, 8, 10, 16
<i>Choate v. Trapp</i> , 224 U.S. 665 (1912).....	1, 9, 10, 11
<i>English v. Richardson</i> , 224 U.S. 680 (1912).....	11
<i>Gleason v. Wood</i> , 224 U.S. 679 (1912).....	11
<i>Graham v. Goodcell</i> , 282 U.S. 409 (1931).....	12
<i>Knick v. Township of Scott</i> , 139 S. Ct. 2162 (2019).....	9
<i>Lingle v. Chevron U.S.A. Inc.</i> , 544 U.S. 528 (2005).....	1, 8, 9
<i>McClurg v. Kingsland</i> , 42 U.S. 202 (1843).....	1, 11
<i>Medtronic, Inc. v. Mirowski Family Ventures, LLC</i> , 571 U.S. 191 (2014).....	1, 10, 13

¹ All emphasis has been added unless otherwise noted. Citations are to the current edition of the U.S. Code and Code of Federal Regulations unless otherwise noted.

	<u>Page(s)</u>
<i>Microsoft v. i4i Ltd. P’ship</i> , 564 U.S. 91 (2011).....	5, 12
<i>Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC</i> , 138 S. Ct. 1365 (2018).....	17
<i>OSI Pharms., LLC v. Apotex, Inc.</i> , No. 2018-1925, slip op. (Fed. Cir. Oct. 4, 2019)	16
<i>Par Pharm., Inc. v. TWi Pharms., Inc.</i> , 773 F.3d 1186 (Fed. Cir. 2014)	14
<i>Patlex Corp. v. Mossinghoff</i> , 758 F.2d 594 (Fed. Cir. 1985)	10, 13
<i>Pension Benefit Guar. Corp. v. R.A. Gray & Co.</i> , 467 U.S. 717 (1984).....	9, 12
<i>Raleigh v. Ill. Dep’t of Revenue</i> , 530 U.S. 15 (2000).....	13
<i>Usery v. Turner Elkhorn Mining Co.</i> , 428 U.S. 1 (1976).....	12
<i>Ward v. Bd. of Cty. Comm’rs</i> , 253 U.S. 17 (1920).....	1, 9, 11
<i>XY, LLC v. Trans Ova Genetics</i> , 890 F.3d 1282 (Fed. Cir. 2018)	14
 <u>Constitutional Provisions</u>	
U.S. Const. amend. V.....	1, 7, 8, 9

Page(s)

Statutes

35 U.S.C. § 154.....17

35 U.S.C. § 282 (2006) 2, 5, 12

35 U.S.C. § 311 note (2006)5

35 U.S.C. § 316(e) 6, 14, 15

Leahy-Smith America Invents Act,
Pub. L. No. 112-29, 125 Stat. 284 (2011)5, 6

Regulations

37 C.F.R. pt. 4213

Other Authorities

U.S. Patent Statistics Chart: Calendar Years 1963-2015,
U.S. Patent & Trademark Office,
https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm
(last updated June 15, 2016)16

STATEMENT OF COUNSEL

Based on my professional judgment, I believe this appeal requires an answer to a precedent-setting question of exceptional importance: Whether subjecting patents that issued before the enactment of the Leahy-Smith America Invents Act (“AIA”) to *inter partes* review (“IPR”) violates the Due Process Clause of the Fifth Amendment.

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States: *Ward v. Bd. of Cty. Comm’rs*, 253 U.S. 17 (1920); *Choate v. Trapp*, 224 U.S. 665 (1912); *McClurg v. Kingsland*, 42 U.S. 202 (1843); *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191 (2014); *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528 (2005).

/s/ Justin P.D. Wilcox

*Attorney of Record for
Patent Owner-Appellant
Enzo Life Sciences, Inc.*

POINTS OF LAW OVERLOOKED OR MISAPPREHENDED

These appeals arose from *inter partes* review proceedings concerning a patent that issued before the enactment of the AIA (a “pre-AIA patent”). Appellant Enzo Life Sciences, Inc. (“Enzo”) challenged the retroactive application of IPR as unconstitutional under the Due Process Clause of the Fifth Amendment. A panel of this Court misconstrued Enzo’s constitutional argument as a Takings Clause challenge and provided no due process analysis in its decision.

The panel also overlooked Supreme Court precedents, holding that substantive provisions of statute governing a grant, such as a patent, vest at issuance, and therefore, may not be retroactively impaired under the Fifth Amendment. The presumption of validity in 35 U.S.C. § 282 (2006) is a substantive, not procedural, provision. As explained *infra*, the panel decision is contrary to multiple precedents of the Supreme Court.

INTRODUCTION

The AIA violates the Due Process Clause of the Fifth Amendment by subjecting pre-AIA patents to IPR. Retroactive application of IPR to pre-AIA patents eviscerates substantive vested rights, namely the presumption of validity and the concomitant clear-and-convincing evidence standard for revoking patent rights in an adversarial proceeding.

Here, the Patent Trial and Appeal Board (“Board”) instituted two IPRs on U.S. Patent No. 7,064,197 (“the ’197 patent”)—which issued in 2006, long before the AIA’s enactment—violating Enzo’s due process rights. At the end of those IPRs, the Board concluded that petitioners Hologic, Inc. (“Hologic”)² and Becton, Dickinson and Company (“BD”) proved by a preponderance of evidence that the challenged claims of the ’197 patent are unpatentable. A panel of this Court affirmed, rejecting, *inter alia*, Enzo’s argument that the AIA is unconstitutional because subjecting the ’197 patent to IPR destroyed Enzo’s vested right in the standard of proof required to revoke the ’197 patent.

The panel erred. In its one-paragraph analysis, the panel rejected Enzo’s constitutional challenge because the Court previously ruled that subjecting pre-AIA

² Hologic was dismissed from these appeals on its unopposed motion to withdraw. D.I. 73-74.

patents to IPR is not a Fifth Amendment taking. Slip op. at 14-15 (Fed. Cir. Aug. 16, 2019), D.I. 89. But Enzo argued that “the Due Process Clause” is “the basis of Enzo’s constitutional challenge.” (D.I. 88.) Because the panel misapprehended Enzo’s argument, it never actually considered or addressed Enzo’s Due Process Clause challenge. Furthermore, allowing the panel’s decision to stand would contravene Supreme Court precedent, including that the presumption of validity and the concomitant elevated burden of proof is substantive law. That outcome would give Congress *carte blanche* to change patent law retroactively—for example, retroactively shortening the term, or outright replacing district-court invalidity cases with agency proceedings with a lower burden of proof. Therefore, Enzo’s constitutional challenge should be reheard by the panel or *en banc*.

STATEMENT OF THE CASE

I. The ’197 Patent Issued In 2006.

Founded in 1979 by Dr. Elazar Rabbani, Enzo sought to develop groundbreaking nucleic acid detection technology using an interdisciplinary team of chemists and molecular biologists. From those efforts, Enzo filed, in 1983, the first patent application in a chain that eventually issued as the ’197 patent, claiming nucleic acid detection techniques involving non-porous solid supports. Appx112. The patented techniques can be used to diagnose disease by detecting the presence or quantity of certain genetic material, such as nucleotide sequences in a sample

being tested, using non-radioactive detection. Appx116(1:27-32), Appx118(5:40-44, 6:23-32).

The '197 patent issued on June 20, 2006. Appx112. When it issued, the Patent Act bestowed upon Enzo certain substantive rights in the '197 patent. In particular, the Patent Act secured a presumption of validity and a concomitant burden of proof: any “party asserting ... invalidity” must prove invalidity by clear and convincing evidence. 35 U.S.C. § 282 (2006); *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91 (2011). Under the Patent Act, from the '197 patent’s issuance until 2011, there existed only one adversarial proceeding available to challenge the validity of the '197 patent—district court litigation that employed the clear-and-convincing burden of proof.³

II. The AIA Created *Inter Partes* Review In 2011.

Five years after the '197 patent issued, Congress made sweeping changes to patent law with the enactment of the AIA on September 16, 2011. Pub. L. No. 112-29, 125 Stat. 284 (2011). The AIA created IPR, allowing parties to challenge patentability in adversarial proceedings before an agency tribunal—the Board. *See* § 6(a), 125 Stat. at 299-304. The IPR provisions expressly “apply to any patent

³ The '197 patent was never subject to *inter partes* reexamination, which applied prospectively to applications filed on or after enactment. 35 U.S.C. § 311 note (2006).

issued *before*, on, or after” the effective date of September 16, 2012. § 6(c)(2)(A), 125 Stat. at 304. Unlike a patent challenger in district court subject to the clear-and-convincing evidence standard, an IPR petitioner need prove unpatentability by only a preponderance of the evidence to secure the revocation of a patent. 35 U.S.C. § 316(e). Thus, while the AIA did not alter the statutory presumption of validity or the clear-and-convincing standard for proving invalidity in district court proceedings, an accused infringer may avoid that heightened standard by initiating a parallel IPR before the Board.

III. The Board Found The Challenged '197 Patent Claims Unpatentable.

After Enzo filed suit for infringement of the '197 patent against Hologic and BD in district court, Hologic filed two IPR petitions in 2016. Appx137; Appx3790. The Board instituted trial on both and allowed BD to join as co-petitioner. Appx300-301; Appx614; Appx3949; Appx4185. In IPR2016-00820, the Board found that Hologic and BD proved by a preponderance of the evidence that 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 are unpatentable. Appx1-56. In IPR2016-00822, the Board found that Hologic and BD proved by a preponderance of the evidence that claims 17, 19, 25, 105, 106, 113, 114, 116, 119, 120, 128-131, 150-152, 154, 178, 180, 185-187, and 189 are unpatentable. Appx57-111.

IV. The Panel Affirmed The Board’s IPR Decisions.

These appeals followed. Enzo argued that the Board had erred in its findings of anticipation, obviousness, and the status of a reference as prior art. (D.I. 31 at 1-6.) Enzo further argued that the application of IPR to the ’197 patent is unconstitutional under the Fifth Amendment because it retroactively impaired rights that vested at issuance. (*Id.* at 59-61; D.I. 60 at 25-30.) After oral argument (D.I. 86), another panel of this Court held that the retroactive application of IPR did not violate the Takings Clause in *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. July 30, 2019). The Government subsequently filed a notice of supplemental authority, citing *Celgene*. (D.I. 87.) Enzo responded, explaining that the Takings Clause (at issue in *Celgene*) is distinct from “the Due Process Clause, the basis of Enzo’s constitutional challenge.” (D.I. 88.)

The panel affirmed. *Enzo Life Scis., Inc. v. Becton, Dickinson & Co.*, slip op. (Fed. Cir. Aug. 16, 2019), D.I. 89 (hereinafter “Panel Op.”). Specifically, it upheld the Board’s findings of anticipation and obviousness based on various grounds employing the “Fish” reference, on substantial evidence review. *Id.* at 5-14. Regarding constitutionality, the panel construed Enzo’s Fifth Amendment challenge as solely a Takings Clause challenge. The panel then rejected it, explaining that the same issue had been “recently addressed” in *Celgene*: “the retroactive application of IPR to the ’197 patent, which issued before the enactment of the AIA, is not an

unconstitutional taking under the Fifth Amendment.” Panel Op. at 14-15. No part of the opinion discussed due process or vested rights. *See generally id.*

REASONS FOR GRANTING REHEARING

I. The Panel Did Not Address Enzo’s Due Process Clause Arguments, Misapprehending Them As A Takings Clause Challenge.

The panel misapprehended Enzo’s arguments as a Takings Clause challenge. *See* Panel Op. at 15 (“[R]etroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment.” (quoting *Celgene*, 931 F.3d at 1362)). But Enzo’s arguments invoke the Due Process Clause. (*See, e.g.*, D.I. 60 at 27 & n. 6 (“This appeal does not arise ... from a cause of action seeking compensation for a past taking.”); D.I. 88 (distinguishing *Celgene* because “*Celgene* did not address the Due Process Clause, the basis of Enzo’s constitutional challenge”).) In fact, the Government addressed Enzo’s due process arguments, devoting seven pages in opposition. (D.I. 55 at 24-31.) Yet the panel never addressed due process.

The panel erred because the Due Process Clause and the Takings Clause of the Fifth Amendment provide separate and distinct protections. As the Supreme Court explained in *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528 (2005), whether legislation passes muster under a due process analysis “is logically prior to and distinct from the question whether a regulation effects a taking.” *Id.* at 543; *see also id.* at 540-41 (reviewing “substantially advances” test “derived from due process”).

The Takings Clause “does not bar government from interfering with property rights, but rather requires compensation in the event of ... a taking.” *Id.*; *Knick v. Township of Scott*, 139 S. Ct. 2162, 2170 (2019). By contrast, the Due Process Clause acts as a prohibition on unreasonable, arbitrary, or capricious action; “[n]o amount of compensation can authorize such action.” *Lingle*, 544 U.S. at 543. In other words, if a government action violates due process, it is void; if the action is a taking, the remedy is compensation.

Enzo’s challenge to the retroactive application of the IPR statute to a pre-AIA patent is grounded in due process. Although the Supreme Court’s vested rights cases did not specifically identify which clause of the Fifth Amendment applied, they invoked due process remedies. *See, e.g., Choate v. Trapp*, 224 U.S. 665, 673-74 (1912) (citing “the provisions of the 5th Amendment”); *Ward v. Bd. of Cty. Comm’rs*, 253 U.S. 17, 20 (1920) (citing the Fifth Amendment). For instance, in *Choate*, the Court declared that the tax-exemption rights in grants of land were “protected from repeal” and remanded for an injunction barring enforcement of the new legislation. 224 U.S. at 678-79. More recently, the Supreme Court has indicated that the Due Process Clause is the correct legal lens for assessing the validity of retroactive civil legislation. *See Pension Benefit Guar. Corp. v. R.A. Gray & Co.*, 467 U.S. 717, 730 (1984).

In spite of the due process issues raised in these appeals, the panel skipped the analysis and relied on *Celgene*, which addressed only a Takings Clause challenge, 931 F.3d at 1355-63. Respectfully, the panel or *en banc* Court should grant rehearing to consider Enzo's Due Process Clause challenge.

II. The Panel's Decision Contravenes Supreme Court Precedents That Forbid The Retroactive Impairment Of Vested Property Rights.

The panel's reliance on *Celgene* to reject Enzo's due process arguments is also error. In *Celgene*, the Court rejected a Takings Clause challenge to retroactive IPR based upon, *inter alia*, its decision in *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985). *Celgene*, 931 F.3d at 1358 n.13. The Court reasoned in *Patlex* that what the government gives through legislation, it may also take away by later legislation. *See* 758 F.2d at 605. Based on that reasoning, the Court held that the § 282 presumption of validity is "a procedure created by statute"—not "a property right subject to the protection of the Constitution." *Id.* On both points, *Patlex*, *Celgene*, and the panel's decision contravene Supreme Court precedent.

Due process forbids subsequent changes in law from diminishing vested rights in a government grant. Fundamentally, vested rights are not limited to the grant itself (e.g., a utility patent's right to exclude others), but also include the substantive statutory provisions that define the terms of the grant. *Choate*, 224 U.S. at 673-74. For utility patents, the burden of proof required to revoke a patent is a vested right because burdens of proof are substantive law. *Medtronic, Inc. v. Mirowski Family*

Ventures, LLC, 571 U.S. 191, 199 (2014). Therefore, subjecting the '197 patent to IPR, with a lowered burden of proof, unconstitutionally vitiated a vested right.

1. When the government grants property rights, the substantive provisions of statutes that govern the terms of the grant are “vested property right[s] arising out of a law of Congress and protected by the Constitution of the United States,” “which Congress could not repeal consistently with the Fifth Amendment.” *Ward v. Bd. of Cty. Comm’rs*, 253 U.S. 17, 20-21 (1920). Land patents are a historical example. When the government granted land patents bearing statutory tax exemptions, the Supreme Court upheld those tax exemptions as vested rights that could not be diminished by subsequent legislation. *Id.* (citing *Choate*, 224 U.S. at 665; *Gleason v. Wood*, 224 U.S. 679 (1912); *English v. Richardson*, 224 U.S. 680 (1912)). Because the tax exemption was among the bundle of rights the government granted to the patent-holder with the land, it could not later deprive the patent-holder of that right. *Choate*, 224 U.S. at 673-74 (“The patent issued in pursuance of those statutes gave ... as good a title to the exemption as it did to the land itself. Under the provisions of the 5th Amendment there was no more power to deprive him of the exemption than of any other right in the property.”). These principles equally apply to utility patents. *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843) (stating that a repeal “can have no effect to impair the right of property then existing in a patentee” that was created under the statute before its repeal).

The Supreme Court has never overruled the vested rights cases. Although it has used rational basis review when faced with due process challenges to interstate commerce legislation that attached monetary liability to past acts, none of those legislative due process cases involved rights that had previously been *conveyed, issued, or granted* by the government pursuant to statute.⁴ *E.g., Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15-20 (1976) (upholding retroactive legislation requiring employers to pay benefits to former employees); *Pension Benefit Guar. Corp.*, 467 U.S. at 728-34 (upholding retroactive legislation requiring employers to pay penalties for withdrawal from multiemployer pension plans during the timeframe when Congress had been debating the provision). Thus, the Supreme Court's land patent and vested-rights precedents continue to bind this Court.

2. The burden of proof required to revoke a patent is not a mere procedural provision; it is substantive law. The § 282 presumption of validity codifies a burden of proof on the challenger to show invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95, 100-07 (2011). In *Medtronic*, the Supreme Court acknowledged "settled case law" that "the burden of proof is a

⁴ Similarly, the cases about "curative" or "remedial" legislation did not repudiate protections of vested rights in grants from the government. In *Graham v. Goodcell*, 282 U.S. 409 (1931), the asserted vested right was the overall prior tax scheme, untethered from any particular statutory provision that governed a past government issuance.

substantive aspect of a claim.” 571 U.S. at 199 (quoting *Raleigh v. Ill. Dep’t of Revenue*, 530 U.S. 15, 20-21 (2000)) (internal quotation marks omitted). Thus, this Court’s pronouncement in *Patlex* that § 282 is a **procedural** provision directly contradicts Supreme Court precedent. *See* 758 F.2d at 605.

In short, the right to a clear and convincing burden of proof in adversarial proceedings against the ’197 patent is a substantive right that vested when the ’197 patent issued. For that reason, it is a property interest protected under due process.

3. The AIA retroactively deprived Enzo of that vested burden of proof by subjecting the ’197 patent to IPR where unpatentability may be established by a mere preponderance of the evidence. When the ’197 patent issued in 2006, the only adversarial proceeding available to challenge it was district court litigation, which demands clear and convincing evidence from a patent challenger. After enactment of the AIA, parties like BD can and do avail themselves of adversarial IPRs to challenge patents while circumventing the higher burden of proof in district court.

IPR permits accused infringers, like BD, to bring adversarial challenges in the Patent Office with a lower burden of proof than in district court litigation. For example, BD submitted expert testimony, cross-examined Enzo’s witness, objected using the Federal Rules of Evidence to testimony or exhibits, and participated in oral argument—all hallmarks of adversarial litigation. *See, e.g.*, 37 C.F.R. pt. 42. But BD established unpatentability by only a preponderance of the evidence, 35 U.S.C.

§ 316(e), which this Court reviewed under the deferential substantial evidence standard. Successful IPR petitioners, like BD, may then assert collateral estoppel in district court litigation. *E.g., XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1294 (Fed. Cir. 2018).

This common scenario shows the evisceration of vested patent rights due to retroactive IPR. Like Enzo in this case, a patent owner may sue for infringement in court, but find its patent revoked in a proceeding that bypasses the clear and convincing evidence standard. IPR has made the elevated burden of proof to revoke a patent into a dead letter—even in court.

4. This case demonstrates the practical consequences of lowering the burden of proof to revoke a patent to a preponderance of the evidence. Hologic’s and BD’s unpatentability theories based on the Fish reference relied on an inherency theory. Both contended that Fish inherently discloses nucleic acids in “hybridizable form” that are fixed or immobilized to a non-porous solid support. Appx20-24, Appx76-78. Inherency is ordinarily a high bar: this Court has stated that the allegedly inherent disclosure must be “necessarily” or “unavoidably” present. *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014). But the preponderance of the evidence standard lowers that high bar such that inherency can be established before the Board—and the revocation of a patent achieved—by a paucity of evidence.

As Enzo explained to the Board and the panel, nucleic acids fixed or immobilized to a non-porous solid support are not necessarily fixed or immobilized in hybridizable form. Appx420-432, Appx4064-4073. For example, the nucleic acid strands may form loops and coils (i.e., secondary structures) that restrict the availability of the bases for Watson-Crick pairing. *E.g.*, Appx3631(¶95); D.I. 31 at 25. Or a nucleic acid could be bound to a solid support along its length such that the bases are bound and unavailable for hybridization. *E.g.*, Appx3630-3631(¶95); D.I. 60 at 5, 9-10.

Fish not only failed to disclose expressly that its nucleic acids were bound in hybridizable form, but also failed to disclose where its nucleic acids were bound and what the environmental conditions were. Appx422. And, the expert testimony from petitioners' expert that the Board invoked in its decisions shed no light on either issue. *See* Appx21, Appx24, Appx75, Appx78. But the Board nonetheless found that Hologic and BD had proven, by a preponderance of the evidence, that Fish inherently discloses the "hybridizable form" limitations. Appx22-24, Appx76-78.

On that scant evidence, no reasonable factfinder could have found that Fish inherently discloses nucleic acids bound or immobilized to a solid support in hybridizable form—under the clear and convincing standard. But the Board does not apply that elevated standard. 35 U.S.C. § 316(e). Because they brought their unpatentability case to the Board, Hologic and BD enjoyed the benefits of—and

Enzo suffered the consequences of—the lower preponderance standard. And, those consequences extended to these appeals because this Court’s review incorporates the burden of proof employed by the Board. *OSI Pharms., LLC v. Apotex, Inc.*, No. 2018-1925, slip op. at 11-12 (Fed. Cir. Oct. 4, 2019).

The panel’s decision, relying on *Celgene*, overlooked these implications. *Celgene* had narrowly compared the successive changes from *ex parte* reexamination to *inter partes* reexamination to *inter partes* review. See 931 F.3d at 1360-61. That analysis misses the big picture: IPR provides a full-blown adversarial proceeding with no presumption of validity, and other features advantaging challengers (e.g., no need for standing), eviscerating vested rights in pre-AIA patents.

This Court should grant rehearing or rehearing *en banc* to correct the erroneous conclusion that the retroactive application of IPR in this case was not unconstitutional.

III. The Question Presented Is Exceptionally Important, And The Outcome Will Have Significant Implications.

Determining the constitutionality of retroactive IPR is exceptionally important and will have widespread impact because pre-AIA patents account for a significant portion of IPRs. About two million utility patents issued before 2011 remain unexpired today. See <https://www.uspto.gov/web/offices/ac/ido/oeip/taf/>

[us_stat.htm](#). Thus, the question of unconstitutional retroactivity will persist if this Court does not resolve Enzo's due process challenge.

Virtually no retroactive change concerning utility patent rights would be limited by the Fifth Amendment under the panel's application of *Celgene*. Consider, for example, that the term of a patent is determined by statute. 35 U.S.C. § 154. The term—a substantive provision of law—is fixed once the patent issues. But, between *Celgene* and the panel's rejection of due process and vested rights, Congress could retroactively diminish the term of issued patents by subsequent legislation, contrary to *McChurg*, *Ward*, and *Choate*.

Furthermore, with respect to Patent Office proceedings for cancelling issued patents, what principle would restrict Congress from advancing its incrementalism one step further? Could a future law require *all* challenges to an issued patent be decided with a lower standard of proof at the Board instead of in court? The hostility to retroactivity enshrined in the Due Process Clause exists to restrict such drastic Congressional action.

The question of retroactivity left open by the Supreme Court in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018) is now before this Court in several appeals. This case is an ideal vehicle to answer that question. For example, while the Court also rejected a challenge to the retroactive application of *inter partes* review in *Arthrex, Inc. v. Smith & Nephew*,

Inc., 935 F.3d 1319 (Fed. Cir. 2019), *Arthrex* involved a patent that issued *after* the AIA's enactment. *Id.* at 1331. Further, the *Arthrex* appellant did not raise a vested-rights theory, instead arguing that the AIA upset the *quid pro quo* of disclosing an invention in a then-pending patent application in exchange for exclusivity. (No. 2018-1584, Opening Br. at 62-65; Reply Br. at 22-29.) Because this Court has yet to address a vested-rights Due Process Clause challenge involving a pre-AIA patent, this case provides a perfect opportunity for the Court to take up that exceptionally important constitutional question. The panel's decision should be vacated and Enzo's appeal sustained.

CONCLUSION

Accordingly, this Court should vacate its affirmance of the Board's final written decisions and grant rehearing or rehearing *en banc* in Enzo's appeals.

Dated: October 30, 2019

Respectfully submitted,

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ADDENDUM

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

ENZO LIFE SCIENCES, INC. v. BECTON, DICKINSON AND
COMPANY

3

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”).

ENZO LIFE SCIENCES, INC. v. BECTON, DICKINSON AND
COMPANY

5

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

claim if it describes every element of the claimed invention, either expressly or inherently. *Husky Injection Molding Sys. Ltd. v. Athena Automation Ltd.*, 838 F.3d 1236, 1248 (Fed. Cir. 2016). Whether there are inherent teachings in a prior art reference is a question of fact. *See In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Obviousness is a question of law based on underlying factual findings, including “the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any objective indicia of non-obviousness.” *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007)).

I. ANTICIPATION BY FISH

The Board determined that claims 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 in the ’820 IPR and claims 17, 19, 25, 105, 106, 114, 116, 119, 128, 129, 150, 152, 178, 180, 186, and 187 in the ’822 IPR were anticipated by Fish. ’820 *Decision*, 2017 WL 4339646, at *11–12; ’822 *Decision*, 2017 WL 4407743, at *10–11. Fish teaches a microradioimmunoassay for detecting antibodies that bind to double-stranded DNA (“dsDNA”). *See* J.A. 1266. It further notes the use of poly-L-lysine (“PLL”) “to facilitate the binding of pure dsDNA to plastic surfaces.” *Id.* Fish also discloses experiments using single-stranded DNA (“ssDNA”) in the form of a mixture of synthetic polymers deoxyadenosine (“poly-dA”) and deoxycytidine (“poly-dC”) or “denatured calf thymus DNA.” J.A. 1268.

All of the challenged independent claims in both the ’820 IPR and ’822 IPR require the single-stranded nucleic acid to be “fixed or immobilized in *hybridizable form*” (the “hybridizable form limitation”). *See, e.g.*, ’197 patent col. 13 l. 65, col. 15 l. 52. The Board construed “hybridizable form” to mean “*capable of binding through Watson-Crick base pairing*,” adopting the parties’ agreed-upon

ENZO LIFE SCIENCES, INC. v. BECTON, DICKINSON AND
COMPANY

7

construction. *'820 Decision*, 2017 WL 4339646, at *5 (emphasis added).³ The Board further clarified the construction in its final written decisions to mean that “it has bases available for base-pairing.” *Id.* at *6.

Based on its construction, the Board found that Fish disclosed the hybridizable form limitation. The Board found that Fish teaches ssDNA bound to the PLL-coated wells. *See id.* at *8. The Board further found that being capable of hybridizing is the inherent result of ssDNA being fixed to PLL-treated non-porous solid supports. *See id.* at *10–11. The Board rejected Enzo’s argument that Fish failed to disclose hybridization and found that “actual hybridization is not a requirement of any challenged claim.” *Id.* at *10. The claims only recite “hybridizable form,” and the Board noted that the parties’ stipulated construction required that the single-stranded nucleic acid be “capable of binding through Watson-Crick base pairing” and did not require “actual hybridization.” *Id.* (citations omitted). The Board thus concluded that the challenged claims were anticipated by Fish. *Id.* at *11–12.

On appeal, Enzo argues that Fish does not disclose nucleic acid hybridization, but instead describes “binding radioactively-labeled antibodies” to dsDNA. Appellant’s Br. 24 (emphasis omitted). Moreover, Enzo contends, as it did before the Board, that the nucleic acids in Fish did not actually hybridize in any of the experiments, and thus the finding that Fish discloses hybridization lacks substantial evidence. According to its expert, Dr. Buck, the fact that a single-stranded nucleic acid exists does not mean it is in hybridizable form. For example, Dr. Buck testified that “a nucleic acid may be ‘restricted by the bonds formed between the nucleic acid and the support’ or inhibited by

³ The claim construction discussions of the two Board opinions are identical. Thus, citations regarding the Board’s claim construction will only be to the *'820 Decision*.

‘entanglement of the nucleic acid strands themselves, which may form loops and coils, called secondary structures, restricting the diffusion of other nucleic acid strands available for hybridization.’” *Id.* at 25 (quoting J.A. 3630–31 ¶ 95, 5605–06 ¶ 95). Enzo also argues that Dr. Nelson, the petitioners’ expert, failed to apply the modified claim construction and thus his testimony cannot constitute substantial evidence for the Board’s findings.

Becton responds that the Board correctly found that Fish inherently discloses the hybridizable form limitation. Relying on Dr. Nelson’s testimony, Becton argues that the positively-charged amines on the surface of the solid support coated with PLL, as disclosed in Fish, will bond with the negatively-charged phosphate groups in the DNA backbone leaving the bases free to hybridize. Becton criticizes Enzo for “deliberately sabotaging the experiment” in order to describe a situation where someone using Fish’s PLL binding chemistry would not create a hybridizable single-stranded nucleic acid. Appellee’s Br. 37. Becton contends that inherency cannot be defeated by “interfer[ing] with the natural result of a process.” *Id.* at 38.

We agree with Becton that Fish’s disclosure of a ssDNA bound to a solid support coated with PLL inherently discloses that the single-stranded nucleic acid is in hybridizable form. “A reference includes an inherent characteristic if that characteristic is the ‘natural result’ flowing from the reference’s explicitly explicated limitations.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001) (quoting *Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991)).

Here, substantial evidence supports the Board’s finding that the single-stranded nucleic acid of Fish is inherently hybridizable. The Board reasonably relied on testimony from both experts that a characteristic of single-stranded nucleic acids is that their bases are available to pair with complementary bases through Watson-Crick

pairing. See '820 Decision, 2017 WL 4339646, at *11 (citing J.A. 891 ¶ 64); '822 Decision, 2017 WL 4407743, at *9; see also J.A. 874–75 ¶ 24, 891 ¶ 64 (Dr. Nelson's testimony); J.A. 3705–06 ¶ 189 (Dr. Buck's testimony). That is what a single-stranded nucleic acid does in the presence of complementary bases. Unless purposely prohibited, the binding capability is inherent in the nature of a single-stranded nucleic acid. The Board's finding that Fish's disclosure of a ssDNA fixed to a PLL-treated support inherently teaches the hybridizable form limitation is thus based on substantial evidence.

Enzo also argues that in the '822 IPR, the Board erred in finding that Fish disclosed an "array" of "single-stranded nucleic acids." See, e.g., '197 patent col. 15 ll. 51–53. All of the challenged independent claims in the '822 IPR recite an "array" of "single-stranded nucleic acids." See, e.g., *id.* The Board construed "array" to include "an orderly grouping or arrangement of wells or depressions." '822 Decision, 2017 WL 4407743, at *4. The Board then found that Fish teaches this limitation because "it discloses microtitration trays having wells of ssDNA." *Id.* at *7 (citing J.A. 1268).

Enzo contends that Fish fails to disclose an "array" of "single-stranded nucleic acids." See, e.g., '197 patent col. 15 ll. 51–53 (emphasis added). According to Enzo, the Board erred in reading the term "array" in isolation from "single-stranded nucleic acids," and thus erred in finding that a container with wells or depressions without any nucleic acids would meet the claim language.

Becton responds, and we agree, that the Board's finding was supported by substantial evidence. Fish describes supports having rows of wells coated with ssDNA. See J.A. 1268. The Board also credited Dr. Nelson's testimony that Table 1 in Fish provides evidence that the ssDNA bound effectively to the PLL-coated wells of the microtitration tray. '822 Decision, 2017 WL 4407743, at *7 (citing J.A. 1268). That constitutes substantial evidence to support the

Board's finding that Fish teaches an "array" of "single-stranded nucleic acids." *See, e.g.*, '197 patent col. 15 ll. 51–53.

Enzo does not raise any arguments with respect to any other claim limitation, nor does it separately argue the dependent claims. Thus, the dependent claims stand or fall together with the independent claims. *See In re Kaslow*, 707 F.2d 1366, 1376 (Fed. Cir. 1983). We therefore conclude that the Board did not err in finding that Fish anticipates claims 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 in the '820 IPR and claims 17, 19, 25, 105, 106, 114, 116, 119, 128, 129, 150, 152, 178, 180, 186, and 187 in the '822 IPR.

II. OBVIOUSNESS GROUNDS BASED ON FISH

The Board determined that claims 31, 64, 68, 101, 192, and 195 in the '820 IPR and claims 130, 131, 151, and 154 in the '822 IPR would have been obvious over Fish. '820 *Decision*, 2017 WL 4339646, at *12–14; '822 *Decision*, 2017 WL 4407743, at *11–14. Those claims add one of the following limitations: "wherein said nucleic acid comprises a nucleic acid sequence complementary to a nucleic acid sequence of interest sought to be identified, quantified or sequenced," *see, e.g.*, '197 patent col. 17 ll. 1–4; or "wherein said nucleic acid is RNA," *see, e.g., id.* col. 18 ll. 38–39; or "wherein said nucleic acids comprise a gene sequence or pathogen sequence," *id.* col. 22 ll. 42–43. Enzo does not separately argue the challenged dependent claims and relies on the arguments it raised for anticipation by Fish. Thus, for the same reasons that Fish anticipates the aforementioned claims, we also hold that Fish renders obvious claims 31, 64, 68, 101, 192, and 195 in the '820 IPR and claims 130, 131, 151, and 154 in the '822 IPR.

The Board next determined that claims 38, 78, and 218 in the '820 IPR and claims 113 and 185 in the '822 IPR

would have been obvious over Fish and Gilham;⁴ and claims 120 and 189 in the '822 IPR would have been obvious over Fish, U.S. Patent 3,572,892 (“Metzgar”), and Sato.⁵ Enzo argues that the Board’s findings of a motivation to combine Fish and Gilham, and Fish, Metzgar, and Sato, are not based on substantial evidence. We take the arguments asserted for each ground in turn.

A. Obviousness over Fish and Gilham

The Board determined that claims 38, 78, and 218 in the '820 IPR and claims 113 and 185 in the '822 IPR would have been obvious over Fish and Gilham. *'820 Decision*, 2017 WL 4339646, at *14–15; *'822 Decision*, 2017 WL 4407743, at *14–15. The challenged claims add the limitation “wherein said fixation or immobilization to said non-porous solid support is *covalent*.” *See, e.g.*, '197 patent col. 17 ll. 24–26 (emphasis added). Gilham teaches a method of covalently binding RNA to cellulosic supports. *See* J.A. 1592–93. The Board found that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to apply Gilham’s method of covalently binding RNA to Fish’s non-porous supports, such as the microtitration plates, “because covalent binding provides a stronger linkage between the immobilized nucleic acids and the solid substrate.” *'820 Decision*, 2017 WL 4339646, at *15 (internal citation omitted).⁶

⁴ P.T. Gilham, *Immobilized Polynucleotides and Nucleic Acids*, *Immobilized Biochemicals and Affinity Chromatography* 173–85 (1974), J.A. 1592–1604 (“Gilham”).

⁵ Chikako Sato et al., *Cell Surface Charge and Cell Division in Escherichia coli after X Irradiation*, 87 *Radiation Research* 646–56 (1981), J.A. 4422–32 (“Sato”).

⁶ The analyses of Fish and Gilham are identical in the two Board opinions. Thus, citations will only be to the *'820 Decision*.

Enzo argues that the Board failed to identify why a person of ordinary skill would have been motivated to use the covalent binding method for RNA in Gilham with the procedures for using DNA of PLL-coated plates to detect antibodies described in Fish. Moreover, according to Enzo, not only was there insufficient motivation to combine, but there would not have been an expectation of success. Enzo contends that Gilham teaches away from the use of non-porous supports like those in Fish, and that Gilham's covalent binding would likely negatively affect the nucleic acid's ability to hybridize.

Becton responds that the Board's finding of a motivation to combine Fish and Gilham was supported by substantial evidence. We agree. Dr. Nelson, whom the Board credited, explained that both Fish and Gilham disclose nucleic acids bound to solid support surfaces with amine groups. *See id.* at *13–14. The Board then found that a person of ordinary skill in the art would have been motivated to use the covalent binding from Gilham on Fish's non-porous solid supports. *See id.* at *15. We also agree with Becton that Enzo's teaching away arguments improperly attack the references individually. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.”). However, as the Board determined, it is the combined teachings of Gilham's chemistry for binding RNA in hybridizable form and Fish's methods of attaching nucleic acids to non-porous supports that render the claims obvious. *See '820 Decision*, 2017 WL 4339646, at *15. Accordingly, the Board did not err in holding that claims 38, 78, and 218 in the '820 IPR and claims 113 and 185 in the '822 IPR would have been obvious over Fish and Gilham.

ENZO LIFE SCIENCES, INC. v. BECTON, DICKINSON AND
COMPANY

13

B. Obviousness over Fish, Metzgar, and Sato

The Board determined that claims 120 and 189 in the '822 IPR would have been obvious over Fish, Metzgar, and Sato. '822 *Decision*, 2017 WL 4407743, at *13–14. The challenged claims add the limitation “wherein said non-porous solid support comprises *one or more hydroxyls*.” *See, e.g.*, '197 patent col. 21 ll. 10–12 (emphasis added). Metzgar teaches a “multiple well tissue culture microscope slide” where the microscope slide is “glass or other transparent material.” Metzgar col. 1 l. 2, col. 2 ll. 28–29. Sato discloses treating glass slides with PLL. *See* J.A. 4423. Dr. Nelson testified that “glass necessarily includes hydroxyl groups.” '822 *Decision*, 2017 WL 4407743, at *14 (citing J.A. 5789 ¶ 83 (“The glass slides of . . . Metzgar necessarily include hydroxyl groups, because that is a known property of glass.”)). The Board determined, based on Dr. Nelson’s testimony, that a person of ordinary skill in the art would have been motivated to use the glass trays from Metzgar “as an alternative to Fish’s polyvinyl trays.” *Id.* (citing J.A. 5789 ¶ 83). In combination with Sato’s teaching of treating glass slides with PLL, the Board concluded that the challenged claims would have been obvious over Fish, Metzgar, and Sato. *Id.*

Enzo argues that the Board failed to identify why a person of ordinary skill in the art would have been motivated to substitute glass plates for the polyvinyl microtitration trays disclosed in Fish. According to Enzo, the Board erred in failing to credit Dr. Buck’s uncontested testimony that a person of ordinary skill would not combine those references because they would not work for their intended purposes.

Becton responds that substantial evidence supported the Board’s finding of a motivation to combine Fish, Metzgar, and Sato, and we agree. The Board found that glass slides having wells or depressions were well-known at the time of the invention. *See id.* The Board further found, based on Dr. Nelson’s testimony, that a person of

ordinary skill in the art would have been motivated to immobilize nucleic acids using the methods described in Fish on the glass slides disclosed in Metzgar. *See id.* Additionally, the Board found that Sato teaches “treatment of glass slides with PLL prior to fixing cells on the slides.” *Id.* The Board ultimately credited Dr. Nelson’s testimony that a person of ordinary skill in the art would have been motivated to perform the nucleic acid immobilization procedure disclosed in Fish on the glass slides in Metzgar treated with PLL as disclosed in Sato. *Id.* The Board’s finding of a motivation to combine was thus based on substantial evidence. Accordingly, the Board did not err in determining that claims 120 and 189 in the ’822 IPR would have been obvious over Fish, Metzgar, and Sato.

In conclusion, we determine that the Board did not err in holding that claims 1, 6, 8, 9, 12–17, 19, 25, 27, 31–34, 38, 41, 61–64, 68–70, 72–74, 78, 79, 100, 101, 105, 106, 113, 114, 116, 119, 120, 128–131, 150–152, 154, 178, 180, 185–187, 189, 191–195, 212, 213, 218, 219, 222, 225–227, 230, 233, and 236 of the ’197 patent are invalid as anticipated by Fish or obvious over Fish alone or in combination with other prior art references.

III. OTHER ISSUES

Enzo argues that the Board erred in finding that VPK qualifies as prior art, and thus the claims are not unpatentable as anticipated or obvious over grounds that include VPK. Because we have determined that the Board did not err in concluding that all of the challenged claims are unpatentable on grounds based on Fish, we need not reach the arguments involving VPK. *See Oral Arg.* at 12:14–12:49, 25:58–26:11, *Enzo Life Scis., Inc. v. Becton, Dickinson & Co.*, Nos. 2018-1232, 2018-1233 (Fed. Cir. July 9, 2019), <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-1232.mp3>.

Enzo also argues that the IPR process as applied retroactively to patents that issued before the enactment of the

ENZO LIFE SCIENCES, INC. v. BECTON, DICKINSON AND
COMPANY

15

AIA violates the Fifth Amendment. We recently addressed this issue in *Celgene Corp. v. Peter*, No. 18-1167, 2019 WL 3418549, at *12–16 (Fed. Cir. July 30, 2019), which is now precedent that governs this case. *Celgene* held that “retroactive application of IPR proceedings to pre-AIA patents is not an unconstitutional taking under the Fifth Amendment.” *Id.* at *16. Accordingly, we hold that the retroactive application of IPR proceedings to the ’197 patent, which issued before the enactment of the AIA, is not an unconstitutional taking under the Fifth Amendment.

CONCLUSION

We have considered Enzo’s remaining arguments but find them unpersuasive. For the foregoing reasons, we *affirm* the decisions of the Board.

AFFIRMED

CERTIFICATE OF SERVICE

I hereby certify that on October 30, 2019, I served a complete copy of the foregoing on all counsel of record by filing it with the United States Court of Appeals for the Federal Circuit using the CM/ECF system.

Dated: October 30, 2019

Respectfully submitted,

/s/ Justin P.D. Wilcox

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

The undersigned certifies that this petition complies with the type-volume limitation set forth in Fed. R. App. P. 35(b)(2). Excluding exempt portions, this petition contains:

- **3,891** words as counted by Microsoft Word 2016, the word-processing system used to prepare this paper; and
- **0** words in the illustrations, counted manually.

This petition's total word count, excluding exempt portions, is **3,891** words, which complies with the 3,900-word limit set by Fed. R. App. P. 35(b)(2).

The undersigned further certifies that this petition complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 and 14-point Times New Roman type.

Dated: October 30, 2019

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