IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC., Plaintiff. v. GEN-PROBE INCORPORATED Defendant.	C.A. No. 12-104-LPS
ENZO LIFE SCIENCES, INC., Plaintiff. v. ROCHE MOLECULAR SYSTEMS, INC.; ROCHE DIAGNOSTICS CORPORATION; ROCHE DIAGNOSTICS OPERATIONS, INC.; and ROCHE NIMBLEGEN, INC. Defendants.	C.A. No. 12-106-LPS
ENZO LIFE SCIENCES, INC., Plaintiff. v. BECTON, DICKINSON AND COMPANY; BECTON DICKINSON DIAGNOSTICS INC.; and GENOHM SCIENCES, INC. Defendants.	C.A. No. 12-275-LPS

UNSEALED ON JUNE 30, 2017

ENZO LIFE SCIENCES, INC.,	)	
	)	
Plaintiff.	)	
	)	
v.	)	C.A. No. 12-276-LPS
	)	
HOLOGIC, INC.,	)	
	)	
Defendant.	)	
	)	

Brian E. Farnan, FARNAN LLP, Wilmington, DE
John M. Desmarais, Michael P. Stadnick, Justin P.D. Wilcox, Jordan Malz, Peter C. Magic, DESMARAIS LLP, New York, NY
Attorneys for Plaintiff Enzo Life Sciences, Inc.

Karen L. Pascale, Pilar G. Kraman, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE
Matthew M. Wolf, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, DC
Jennifer Sklenar, Wallace Wu, Marty Koresawa, ARNOLD & PORTER KAYE SCHOLER LLP, Los Angeles, CA
Attorneys for Defendants Hologic, Inc., and Gen-Probe Incorporated

Frederick L. Cottrell, III, Katharine L. Mowery, Nicole K. Pedi, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE
William G. McElwain, Jamie T. Wisz, Heather M. Petruzzi, WILMER CUTLER PICKERING HALE AND DORR LLP, Washington, DC
Robert J. Gunther, Jr., Christopher R. Noyes, Omar A. Khan, Jonathan E. Barbee, Jeffrey Coleman, WILMER CUTLER PICKERING HALE AND DORR LLP, New York, NY
Jason H. Liss, Michael R. Heyison, WILMER CUTLER PICKERING HALE AND DORR LLP, Boston, MA
William W. Kim, Nancy L. Schroeder, WILMER CUTLER PICKERING HALE AND DORR LLP, Palo Alto, CA
Attorneys for Defendants Becton, Dickinson and Company; Becton Dickinson Diagnostics Inc.; Geneohm Sciences, Inc.; Roche Molecular Systems, Inc.; Roche Diagnostics Operations, Inc.; Roche Diagnostics Corporation; and Roche NimbleGen, Inc.

MEMORANDUM OPINION

June 28, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court are: (i) Defendants Gen-Probe Inc. ("Gen-Probe"); Roche Molecular Systems, Inc, Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., and Roche Nimblegen, Inc. (collectively, "Roche"); Becton, Dickinson and Company, Becton Dickinson Diagnostics Inc., and Geneohm Sciences, Inc. (collectively, "BD"); and Hologic, Inc.'s ("Hologic," and collectively, with Gen-Probe, Roche, and BD, "Defendants") Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,992,180 (the "'180 patent") for Failure to Comply with the Written Description Requirement (C.A. No. 12-104-LPS D.I. 227),[1] and (ii) Gen-Probe's and Hologic's Motion for Summary Judgment of Invalidity of the '180 Patent for Nonenablement (D.I. 221).

For the reasons set forth below, the Court will deny Defendants' motion with respect to the written description requirement and will grant Gen-Probe's and Hologic's motion with respect to nonenablement.

I. BACKGROUND

Plaintiff Enzo Life Sciences, Inc. ("Plaintiff" or "Enzo") filed patent infringement actions against Defendants, alleging infringement of the '180 patent as well as U.S. Patent No. 7,064,197 ("the '197 patent"). "The '180 patent generally relates to non-radioactive nucleic acid detection technology," while "[t]he '197 patent generally relates to nucleic acid hybridization technology involving non-porous solid supports." (C.A. No. 12-106-LPS D.I. 260 at 3)

The '180 patent, which is the subject of the pending motions, was issued on January 31, 2006 and claims priority to June 23, 1982. (D.I. 247 at 3) Defendants' motions focus on

[1]Unless otherwise noted, all citations to the docket are to C.A. No. 12-104-LPS.

representative claim 1 of the '180 patent, which states, in relevant part:

> An oligo- or polynucleotide which is complementary to a nucleic acid of interest or a portion thereof, said oligo- or polynucleotide comprising at least one modified nucleotide or modified nucleotide analog having the formula
>
> Sig-PM-SM-BASE
>
> wherein . . . said Sig comprises a non-polypeptide, non-nucleotidyl, non-radioactive label moiety which can be directly or indirectly detected when attached to PM or when said modified nucleotide is incorporated into said oligo- or polynucleotide or when said oligo- or polynucleotide is hybridized to said complementary nucleic acid of interest or a portion thereof, and wherein Sig comprises biotin, iminobiotin, an electron dense component, a magnetic component, a metal-containing component, a fluorescent component, a chemiluminescent component, a chromogenic component, a hapten or a combination of any of the foregoing.

'180 patent col. 59 ll. 62-67, col. 60 ll. 1-21.[2]

On December 15, 2016, Defendants moved for summary judgment of invalidity of the '180 patent for lack of written description (D.I. 227) and enablement (D.I. 221). Enzo filed its briefs in opposition to Defendants' motions on February 16, 2017 (D.I. 251 (written description), D.I. 247 (enablement)), and Defendants filed their reply briefs on March 20, 2017 (D.I. 269 (written description), D.I. 266 (enablement)). The Court heard oral argument on both motions on April 4, 2017. (*See* Transcript ("Tr."))[3]

---

[2]All asserted claims include, or depend from claims that include, the pertinent limitations in representative claim 1. (*See* D.I. 228 at 7 n.6)

[3]The Court heard argument at the same time on the parties' other motions, which will be resolved by separate opinion(s).

II. LEGAL STANDARDS

A. Summary Judgment

Under Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory

allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson*, 477 U.S. at 252.

B. Patent Validity Under 35 U.S.C. § 112

Paragraph 1 of 35 U.S.C. § 112[4] states in pertinent part:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

The statute sets out separate requirements for written description and enablement. *See*

---

[4]The patent statute was amended in September 2011 by the America Invents Act ("AIA"). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 300-01 (2011). The pre-AIA version of § 112 applies in this case. The post-AIA version of this portion of the statute (§ 112(a)) is identical to the pre-AIA verison.

Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (holding that written description and enablement requirements are separate). Nonetheless, these requirements "often rise and fall together." *Id.* at 1352.

1. Written Description

Whether a specification satisfies the written description requirement is a question of fact. *See GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014); *see also Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 468 (D. Del. 2009) ("Satisfaction of the written description requirement is a fact-based inquiry, depending on 'the nature of the claimed invention and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.'") (quoting *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). Despite being a question of fact, the issue of invalidity for lack of written description can be amenable to summary judgment. *See, e.g.*, *Carnegie Mellon*, 541 F.3d at 1126-28 (affirming summary judgment of invalidity for lack of written description); *see also Helicos Biosciences Corp. v. Illumina, Inc.*, 888 F. Supp. 2d 519, 530-31 (D. Del. 2012) ("While compliance with the written description requirement is a question of fact, the issue is 'amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party.'") (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

To comply with the written description requirement, a patent's specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad*, 598 F.3d at 1351 (internal brackets and quotation marks omitted). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those

skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "[T]he hallmark of written description is disclosure. Thus, 'possession as shown in the disclosure' is a more complete formulation" of the written description requirement. *Id.* "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* "[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." *Id.* at 1352. However, "a description that merely renders the invention obvious does not satisfy the requirement." *Id.*

2. Enablement

"Enablement is a question of law based on underlying factual findings." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Id.* (internal quotation marks omitted). "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *Id.* at 1380-81. "Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.* at 1381. "The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Id.* (internal quotation marks omitted).

"Whether undue experimentation is needed is not a single, simple factual determination,

but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* Although "a specification need not disclose what is well known in the art," "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech*, 108 F.3d at 1366. A patent "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010).

III. DISCUSSION

A. Written Description

1. Written Description for the Functional Limitations of Claim 1

Defendants seek summary judgment that the '180 patent lacks adequate written description for the functional limitations of claim 1: "(1) the labeled polynucleotide is hybridized to a nucleic acid sequence of interest, and (2) . . . the label is detectable when the labeled polynucleotide is so hybridized." (D.I. 228 at 6) In Defendants' view, the specification does not adequately describe these limitations because Example V – which, according to Defendants, is "the only example anywhere in the intrinsic record that purports to describe the manufacture or synthesis of a phosphate labeled polynucleotide" – "undisputed[ly] . . . provides [no] description relating to hybridization or detectability upon hybridization." (*Id.* at 7) Defendants further contend that Enzo's technical expert admitted that the rest of the specification contains "no

example, experiment, or data . . . to suggest that the product of Example V could hybridize or that its label is detectable when hybridized." (*Id.* at 11; *see also* D.I. 229-1 Ex. 5 at 131-32)

Enzo responds that "[a] person of ordinary skill [('POSA')] would have understood" the words "probe" and "hybridization probe" in the '180 patent specification "to (1) be capable of hybridizing and (2) be detectable upon hybridization." (D.I. 251 at 4) In Enzo's view, a POSA would have also understood that "hybridization and detection is the plain purpose to which Example V is directed." (*Id.* at 9) In addition to Example V, Enzo argues that the specification's "explicit disclosures of phosphate attachment[s], labels, linkages, and exemplary chemistry for making the labeled nucleic acids . . . would have served as common structural features that allowed [POSAs] to recognize that the inventors possessed phosphate-labeled polynucleotides capable of hybridization and subsequent detection." (*Id.* at 10) At oral argument, Enzo additionally pointed to column 54 line 18 – a portion of the specification in addition to Example V – as supplying the method for probes that is "useful for hybridization and detection." (Tr. at 95; *see also* '180 patent col. 54 ll. 18-23 ("A particularly important and useful aspect of the special nucleotides of this invention is the use of such nucleotides in the preparation of DNA or RNA probes. Some probes would contain a nucleotide sequence substantially matching the DNA or RNA sequence of genetic material to be located and/or identified."))

The record demonstrates genuine disputes of material fact with respect to whether the '180 patent contains adequate written description to support the functional limitations of claim 1. A reasonable jury could find, as Defendants assert, that neither Example V nor the rest of the specification "provides any description relating to hybridization or detectability upon hybridization." (D.I. 228 at 7) Alternatively, a reasonable jury could instead find, as Enzo

contends, that Example V and/or the rest of the specification would allow a POSA "to recognize that the inventors possessed phosphate-labeled polynucleotides capable of hybridization and subsequent detection." (D.I. 251 at 10) Hence, the record contains sufficient evidence from which a reasonable jury could find for either Defendants or Enzo on written description with respect to claim 1's functional limitations. (*See, e.g.*, D.I. 228 at 11; D.I. 229-1 Ex. 5 at 131-32; D.I. 251 at 9-10; '180 patent col. 54 ll. 18-23)

Accordingly, the Court must deny this portion of Defendants' motion for summary judgment.

2. Written Description for Making Internal Phosphate-Labeled Polynucleotides

Defendants argue that the Court should grant summary judgment that the specification of the '180 patent lacks adequate written description for "making . . . internal phosphate-labeled oligonucleotides" (D.I. 228 at 9) (emphasis omitted); that is, nucleic acids "having a label positioned internally rather than at the end of the nucleic acid" (*id.* at 1). In support of their motion, Defendants note "[i]t is undisputed that, if the synthesis scheme of Example V worked at all, it would only succeed in attaching a biotin to [a] terminal phosphate," not an internal phosphate. (*Id.* at 8) (emphasis omitted) Defendants further contend that, "[w]ith respect to Example V, Enzo told the Patent Office that Example V resulted in a terminal label – and not an internal label." (*Id.* at 13) In Defendants' view, the rest of the specification similarly lacks an "example, experiment, or model of any specific species of [an] internal phosphate-labeled polynucleotide." (*Id.*)

Enzo counters that "Example V of the '180 [p]atent specification discloses a method that

attaches biotin at phosphate moieties, whether terminal or internal, by way of the amine groups on biotinylated poly-L-lysine and biotinyl-1,6-diaminohexane." (D.I. 251 at 15; *see also* D.I. 252 Ex. 9 at A307 (expert testimony)) Enzo further contends that a POSA "would have been aware of art showing how to incorporate moieties such as aryl, alkyl, and methyl phosphonates at internal positions that would have been understood as suitable chemistry for likewise incorporating a signaling moiety (and linkage) at internal positions." (D.I. 251 at 16; *see also* D.I. 252-1 Ex. 38 at A807-08, 813-14) Thus, in Enzo's view, "at a minimum, a dispute of material fact exists as to whether Example V discloses internal labeling" and whether a POSA would have been aware of "suitable chemistry for . . . incorporating a signaling moiety . . . at internal positions." (D.I. 251 at 16)

The Court agrees with Enzo that genuine disputes of material fact preclude summary judgment on this issue. The parties disagree as to whether Example V discloses a method that attaches biotin to internal phosphate moieties. (*Compare* D.I. 228 at 8, 13 *with* D.I. 251 at 15) The parties further disagree on whether a POSA would have been aware of suitable chemistry for internal labeling. (*Compare* D.I. 228 at 17 *with* D.I. 251 at 16) Both sides cite record evidence for their contentions, including expert opinions, such that a reasonable jury could find for either side: finding insufficient written description for internal phosphate labeling or, alternatively, adequate written description for internal phosphate labeling. Therefore, the record demonstrates genuine disputes of material fact with respect to whether Example V discloses internal phosphate labeling and whether the chemistry for internal phosphate labeling was known in the art.

Accordingly, the Court must deny this portion of Defendants' motion for summary judgment.

B. Enablement

Defendants Gen-Probe and Hologic (collectively, hereinafter, "Hologic")[5] request that the Court grant summary judgment that the '180 patent is invalid for nonenablement because the specification lacks any "meaningful disclosure . . . on how to make and use the vast number of phosphate-labeled polynucleotides covered by the asserted claims." (D.I. 222 at 7) In support of its argument, Hologic points to the following statement in the '180 patent about a phosphate-modified nucleotide:

> The special nucleotides of this invention include a phosphoric acid P moiety (also designated hereinbelow as "PM"), a sugar or monosaccharide S moiety (also designated hereinbelow as "SM"), a base B moiety (also designated hereinbelow as "BASE"), a purine or a pyrimidine and a signal[]ing chemical moiety Sig covalently attached thereto, e[it]her to the P, S or B moiety.

(D.I. 222 at 7) (quoting '180 patent at col. 48 ll. 60-66)

Hologic argues that "[t]he above disclosure does not indicate . . . any specific nucleotide, any specific label, any specific linker, any specific position of a phosphate-modified nucleotide within the polynucleotide, or any specific sequence of length of the polynucleotide." (D.I. 222 at 7) In Hologic's view, the rest of the specification similarly "provides no guidance on how to select, among numerous possibilities, the sequence and length of the polynucleotide, the location and number of internal phosphate labels, or the location and number of nucleotide analogs." (*Id.* at 12)

Hologic further argues that the unpredictability in the state of the art contributes to rendering the '180 patent invalid for nonenablement. (*See id.* at 8-9, 13-15) Hologic cites

---

[5]Gen-Probe became a part of Hologic in August 2012. (D.I. 222 at 1 n.1)

testimony of Enzo's expert, Dr. Backman, who opined that, as of the priority date, "it was commonly thought that . . . chemically labeling the phosphate group would interfere with hybridization." (*Id.* at 8) (internal quotation marks omitted) Hologic additionally cites the testimony of one of the '180 patent inventors, Dr. Stavrianopoulos, who acknowledged that internal labeling "required methods and principles of organic chemistry [that were] unknown" as of the priority date (*id.* at 14) and remain "difficult . . . even today" (*id.* at 10) (internal quotation marks omitted). In Hologic's view, making an internal-phosphate-polynucleotide would have also required "extensive experimentation" because, while "each asserted claim covers all polynucleotides up to 100,000 DNA nucleotides long" (*id.* at 6), yet "the maximum length for chemical synthesis of a polynucleotide in 1982 was 15 nucleotides" (*id.* at 9) (citing Dr. Stavrianopoulos's testimony). Furthermore, according to Hologic, "[t]he synthesis of a polynucleotide longer than 100,000 nucleotides was not achieved until 2008." (*Id.*)

Enzo responds that "[t]he '180 [p]atent specification discloses signaling moieties, . . . provides several examples of chemical linkages, . . . discloses exemplary lengths of the claimed polynucleotides (*e.g.*, 5 to 500 nucleotides), . . . [a]nd . . . discloses that the label is detectable." (D.I. 247 at 7) In particular, Enzo contends that Example V "describes a method for attaching biotin at terminal and internal phosphate moieties of DNA polynucleotides." (*Id.* at 7-8) ("Example V . . . appl[ies] chemistry known in the art to create an embodiment of the invention") Enzo further contends that a POSA attempting to practice the invention "would not have considered every conceivable variation" or sequence of the claimed polynucleotide (*id.* at 12) (emphasis omitted), because "the specific sequence of the claimed polynucleotide is . . . no[t] germane to the claimed inventions" (*id.* at 1) (emphasis omitted). Finally, in Enzo's view,

practicing the inventions would have required, "at most, routine [experimentation]," as the chemistry for internal labeling "w[as] known in the art" and a polynucleotide longer than 15 nucleotides "could be joined together through ligation." (*Id.* at 14-15; *see also id.* at 6 ("The inventions of the '180 [p]atent . . . pertain to nucleic acid hybridization and detection, which was a decades-old field by the time of the original application for the '180 [p]atent."))

In its reply, Hologic argues that "Enzo's contention that . . . claim scope is 'irrelevant' . . . turns the enablement requirement on its head," as "[t]he law makes clear that a specification must enable the full scope of the claimed invention." (D.I. 266 at 4) (emphasis omitted) Hologic notes that "the claims are not limited to the preferred embodiments" – but, even if they were, "[n]othing in the [specification] teaches one how to select the length and sequence of a polynucleotide within the preferred 5 to 500 nucleotides or how to decide where to place the 1 to 100 phosphate-labeled nucleotides within the polynucleotide of 5-to-500 nucleotides long." (*Id.* at 6-7) In Hologic's view, the specification also "fails to describe" other aspects of the invention – for example, a "phosphate-labeled polynucleotide[] that maintain[s] hybridizability and detectability." (*Id.* at 5) Hologic further argues that Example V "does not describe any actual phosphate labeling" (*id.* at 1), does not disclose "the sequence or the length of the precipitated DNA" (*id.* at 2), and does not "indicat[e] whether the reaction is complete or successful" (*id.*).

While Enzo asserts that "the missing information could be found within the knowledge of a skilled artisan," Hologic replies that "the specification . . . must supply the novel aspects of an invention in order to constitute adequate enablement." (*Id.* at 5) (internal quotation marks omitted) Moreover, even taking into account what a POSA knew at the pertinent time, that still "fails to show any actual example of internal phosphate labeling by any method prior to June

1982." (*Id.* at 3) (discussing Dr. Backman's testimony; emphasis omitted) Finally, Hologic disputes Enzo's assertion that the inventions of the '180 patent pertain to a "decades-old field." (D.I. 247 at 6) In Hologic's view, "the field of the claimed invention . . . is the phosphate labeling of a polynucleotide," which was "new" and "highly unpredictable" as of the priority date. (D.I. 266 at 6) (citing testimony of Dr. Backman, Enzo's expert, that "[t]here was ignorance in the art about non-radioactively labeling a nucleic acid probe . . . before [the priority date]") (internal emphasis and quotation marks omitted; first alteration in original)

"To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 188 (Fed. Cir. 2014) (quoting *Wands*, 858 F.2d at 736-37). The Court finds that there is no genuine dispute of fact that the '180 patent specification lacks enablement. A reasonable jury simply could not find for Enzo. Instead, the only conclusion a reasonable jury could reach is that clear and convincing evidence proves the '180 patent is invalid for noneablement.

"[T]he specification must teach those of skill in the art how to make and how to use the invention ***as broadly as it is claimed***." *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (internal quotation marks omitted; emphasis added). Here, the claims are extremely broad. Even limiting claim scope to the preferred embodiments (for argument's sake), Hologic correctly points out that the specification does not teach "one how to select the length and sequence of a polynucleotide within the preferred 5 to 500 nucleotides or how to decide where to place the 1 to 100 phosphate-labeled nucleotides within the polynucleotide of 5-to-500 nucleotides long." (D.I.

266 at 7) Moreover, even if the Court accepts Enzo's contentions that Example V discloses internal labeling and that "[t]he inventions of the '180 patent . . . pertain to . . . hybridization and detection" (D.I. 247 at 6), neither Example V nor other parts of the specification indicates whether an internal phosphate-labeled polynucleotide "maintain[s] hybridizability and detectability" (D.I. 266 at 5; *see also generally Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) ("Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.")) As such, again as Hologic explains, a POSA "would have no choice but to make and test a vast number of possible variants to the claimed invention." (D.I. 266 at 7) That is, undue experimentation would be required, rendering the claims non-enabled.

The Court agrees with Hologic's comparison of the present situation to that confronted by the Federal Circuit in *Wyeth v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013). In *Wyeth*, the Federal Circuit affirmed a grant of summary judgment based on nonenablement. *See id.* at 1386. Here, "(1) the claims are far broader than in *Wyeth*,[6] (2) the disclosures here are far less than in *Wyeth*,[7] (3) the relevant field is even more unpredictable than in *Wyeth*, and (4) the trial-and-error process would have taken even longer than in *Wyeth*." (D.I. 266 at 4) It follows that, here, as in *Wyeth*, there is no genuine dispute that the claims are invalid due to nonenablement.

This same conclusion is supported by consideration of the *Wands* factors. *See* 858 F.2d at

---

[6]As Hologic argues, the "millions (or more) of phosphate-labeled polynucleotides with varying sequences and lengths covered by each asserted claim of the '180 patent far exceed the tens of thousands of sirolimus analogs in *Wyeth*." (D.I. 222 at 11)

[7]As Hologic argues, "[w]hile the specification in *Wyeth* disclosed at least one working example of the claimed invention (sirolimus), the '180 patent discloses none." (D.I. 222 at 12)

737. Based on the record, a reasonable factfinder could only find: (1) the quantity of experimentation necessary to arrive at embodiments equal to the full scope of the claims is undue; (2) insufficient direction or guidance is presented in the patent to allow a POSA to avoid undue experimentation; (3) insufficient working examples are present;[8] (4) the invention arises in a field of art that was highly unpredictable at the time of the invention; (5) the prior art showed that the pertinent field was unpredictable; (6) even though the relative skill of those in the art was high, POSAs at the time did not have sufficient knowledge to "fill in" all that is missing from the patent; (7) the art was, as already noted, highly unpredictable; and (8) the claims are extremely broad. (*See* D.I. 223-1 Ex. 1 ¶¶ 503-33)

Enzo opposes this conclusion, arguing that "chemistries . . . known in the art at the relevant time . . . could have been used to create a polynucleotide" that meets claim 1's limitations. (D.I. 247 at 14) Enzo's argument, however, "ignore[s] the essence of the enablement requirement." *Genentech*, 108 F.3d at 1366. "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." *Id.* "[W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required." *Id.* Thus, Enzo's references as to what "wa[s] known in the art" (D.I. 247 at 14) are unavailing; "a failure to meet the enablement requirement . . . cannot be

---

[8]Enzo admitted during prosecution of the '180 patent that Example V is a "'paper,' rather than 'working example[] . . . .'" (D.I. 223-3 Ex. 17 at ENZO-0096256) In this litigation, Enzo attempts to create a dispute of fact by pointing to testimony that one inventor has some recollection of Example V being performed "around '82, I don't remember that now." (D.I. 250 at A294) Even assuming a reasonable finder of fact could conclude, on this record, that some version of Example V was carried out by the inventors, the overall record remains one on which a reasonable finder of fact could only find that the claims are not enabled.

rectified by asserting that all the disclosure related to the process is within the skill of the art," *Genentech*, 108 F.3d at 1366.[9]

Accordingly, the Court will grant Hologic's motion for summary judgment that the '180 patent is invalid for nonenablement.[10]

IV. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' motion with respect to the written description requirement and will grant Hologic's motion with respect to nonenablement. An appropriate Order follows.

---

[9]Additionally, even if the Court were to consider Enzo's assertions as to the state of the art at the priority date, the record indisputably establishes that "there was ***ignorance*** in the art about non-radioactively labeling a nucleic acid probe (including non-radioactively labeling any oligo- or polynucleotide in a probe) at a phosphate moiety before June 23, 1982." (D.I. 267-1 Ex. 30 at 20) (emphasis added) Enzo's assertions, therefore, do not conclusively establish that the relevant chemistries were "well known in the art" at the time the '180 patent was filed. *Genentech*, 108 F.3d at 1366.

[10]The Court recognizes that, during prosecution, Enzo overcame a nonenablement rejection. (*See* D.I. 247 at 3-4) (citing D.I. 250-1 at A583-623, 636-49, 651-58, 660-66, 668-75, 677-83, 685-91, 693-775, 777-84, 786-802, 804-23) However, as Hologic aptly observes, "the Examiner only considered Enzo's argument and was not presented with the overwhelming evidence of nonenablement set forth in Defendants' summary judgment briefing." (D.I. 266 at 4 n.4)