United States Court of Appeals for the Federal Circuit

ENZO LIFE SCIENCES, INC.,
Plaintiff-Appellant

v.

ROCHE MOLECULAR SYSTEMS, INC., ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC., ROCHE NIMBLEGEN, INC., BECTON, DICKINSON AND COMPANY, AKA BECTON DICKSON AND COMPANY, BECTON DICKINSON DIAGNOSTICS INC., AKA BECTON DICKSON DIAGNOSTICS, GENEOHM SCIENCES INC., ABBOTT LABORATORIES, ABBOTT MOLECULAR, INC.,
Defendants-Appellees

2017-2498, 2017-2499, 2017-2545, 2017-2546

Appeals from the United States District Court for the District of Delaware in Nos. 1:12-cv-00106-LPS, 1:12-cv-00274-LPS, 1:12-cv-00275-LPS, 1:13-cv-00225-LPS, Chief Judge Leonard P. Stark.

SEALED OPINION ISSUED: June 20, 2019
PUBLIC OPINION ISSUED: July 5, 2019*

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* This opinion was originally filed under seal and has been unsealed in full.

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MATTHEW WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, argued for defendants-appellees Roche Molecular Systems, Inc., Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., Roche NimbleGen, Inc., Becton, Dickinson and Company, Becton Dickinson Diagnostics Inc., GeneOhm Sciences Inc.

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for defendants-appellees Abbott Laboratories, Abbott Molecular, Inc. Also represented by MICHAEL PEARSON, JASON M. WILCOX; JAMES F. HURST, AMANDA J. HOLLIS, Chicago, IL; BENJAMIN ADAM LASKY, New York, NY.

OMAR KHAN, Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY, for defendants-appellees Roche Molecular Systems, Inc., Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., Roche NimbleGen, Inc., Becton Dickinson and Company, Becton Dickinson Diagnostics Inc., GeneOhm Sciences Inc. Also represented by ROBERT J. GUNTHER, JR., CHRISTOPHER R. NOYES; WILLIAM G. MCELWAIN, THOMAS SAUNDERS, Washington, DC.

Before PROST, *Chief Judge,* REYNA and WALLACH, *Circuit Judges.*

PROST, *Chief Judge*.

Enzo Life Sciences, Inc. ("Enzo") appeals the decision of the U.S. District Court for the District of Delaware granting summary judgment against Enzo and holding that the asserted claims are invalid for lack of enablement.

We affirm as to non-enablement and do not reach the other issues presented on appeal.

I

Deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA") are nucleic acids. They are made of a series of building blocks, called nucleotides, linked together in a chain. A single nucleotide is made up of a sugar, a phosphate, and a nitrogenous base. DNA nucleotides have one of four nitrogenous bases: adenine (A); guanine (G); cytosine (C); and thymine (T). RNA has the same bases, except it uses uracil (U) instead of thymine (T).

A polynucleotide refers to multiple nucleotides linked together in a chain.[1] The nucleotides located at each end of a polynucleotide chain are referred to as terminal nucleotides. All other nucleotides in a polynucleotide chain are referred to as internal nucleotides.

Two strands of polynucleotides can pair with each other, i.e., hybridize, through hydrogen bonding between the bases on each polynucleotide strand. The bases T and U pair with A, while G pairs with C. This is referred to as complementary base pairing or "Watson-Crick base pairing," and this pairing is how the now-familiar double helix shape is formed. Two polynucleotide strands will hybridize if the arrangement of nucleotides in each strand is such that enough bases can pair with each other. For example, whether two strands will hybridize depends in part on the number of complementary base pairs that exist between the two polynucleotides.

Hybridization techniques are used to detect the presence of certain nucleic acid sequences of interest, i.e., target sequences, such as genetic alterations. In such procedures,

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[1] An oligonucleotide is simply a shorter polynucleotide (e.g., just a few nucleotides in length).

scientists use a hybridization "probe"—i.e., a labeled polynucleotide that is hybridizable and remains detectable after hybridization occurs—that is sufficiently complementary to the target sequence. The probe will hybridize with the target sequence if the target sequence is present, and the label on the probe then allows scientists to detect the hybridized probe.

Nucleic acid hybridization was well understood by June 1982, which is the claimed priority date of the patents at issue in this appeal. The prevailing method of labeling probes at that time was via radioactive labeling. Radioactive labeling generally involved replacing certain atoms in the nucleotide sequence with corresponding radioactive isotopes.

Non-radioactive labeling was just developing at the time of the claimed inventions. In 1981, Dr. David Ward and others at Yale University successfully developed a non-radioactive probe by attaching a label to a polynucleotide via a chemical linker at a base position of a nucleotide. *See* J.A. 4129–33 (publication by Dr. Ward and others titled "Enzymatic synthesis of biotin-labeled polynucleotides: Novel nucleic acid affinity probes"). Dr. Ward demonstrated that attaching labels at certain positions of the nucleotide ("the Ward positions") would not disrupt the polynucleotide's ability to hybridize and be detected upon hybridization.

In December 1981, Enzo licensed the exclusive rights to the patent portfolio covering Dr. Ward's discovery. *See* J.A. 4258–75. Shortly thereafter, in June 1982, Enzo filed a patent application covering non-radioactive labeling at additional positions on a nucleotide. The two patents in this appeal issued from applications filed in 1995 that claim priority from this 1982 application.

Both patents in this appeal generally relate to the use of non-radioactively labeled polynucleotides in nucleic acid hybridization and detection applications. The patents

share the same specification in relevant part. *See* J.A. 90 n.6.

A

U.S. Patent No. 6,992,180 ("the '180 patent") relates to non-radioactive labeling of polynucleotides where the label is attached at the *phosphate* position of a nucleotide. The claims are not directed to any specific polynucleotide, nor do they focus on the chemistry or linker used to attach a label, the number of labels to attach to a polynucleotide, or where within the polynucleotide to attach those labels. Instead, the claims encompass *all* polynucleotides with labels attached to a phosphate, as long as the polynucleotide remains hybridizable and detectable upon hybridization. Claim 1 of the '180 patent is representative:

> 1. 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 PM is a phosphate moiety, SM is a furanosyl moiety and BASE is a base moiety comprising a pyrimidine, a pyrimidine analog, a purine, a purine analog, a deazapurine or a deazapurine analog wherein said analog can be attached to or coupled to or incorporated into DNA or RNA ***wherein said analog does not substantially interfere with double helix formation or nucleic acid hybridization***, said PM being attached to SM, said BASE being attached to SM, and ***said Sig being covalently attached to PM*** directly or through a non-nucleotidyl chemical linkage, and 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 claim 1 (emphases added).

"Sig" represents a signaling moiety (i.e., a label); PM represents a phosphate moiety; SM represents a sugar moiety; and BASE represents a base moiety.

B

The asserted claims of U.S. Patent No. 8,097,405 ("the '405 patent") fall into two categories: (1) *in situ* hybridization claims; and (2) liquid phase hybridization claims.

The *in situ* hybridization claims (claims 63, 64, 65, 95, 103, 128, and 144) describe a process that uses a probe non-radioactively labeled at any non-Ward position to identify chromosomes. *In situ* hybridization is where probes are hybridized to a target that is fixed, usually on a glass slide. Claim 64 is exemplary.

The liquid phase hybridization claims (claims 196 and 198) describe a process that uses a non-radioactively labeled probe to hybridize and detect a target sequence in a liquid medium, rather than on a glass slide. These claims cover using probes labeled non-radioactively at *any position* on the nucleotide, *including* the three Ward positions. The asserted liquid phase hybridization claims depend from claim 189.

C

This consolidated appeal involves four district court cases.[2] The '180 patent is at issue in all four cases, while the '405 patent is at issue only in the cases against Abbott.

In January 2012, Enzo filed suit against Roche Molecular Systems, Inc., Roche Diagnostics Corp., Roche Diagnostics Operations, Inc., and Roche Nimblegen, Inc. (collectively, "Roche") alleging infringement of the '180 patent. J.A. 1212–16 (Compl.) (Case No. 1:12-cv-106). In March 2012, Enzo filed separate suits against Becton, Dickinson and Co., Becton Dickinson Diagnostics Inc., and GeneOhm Sciences, Inc. (collectively, "BD"); and Abbott Laboratories and Abbott Molecular, Inc. (collectively, "Abbott") alleging infringement of the '180 patent. J.A. 2833–36 (Compl.) (Case No. 1:12-cv-275 against BD); J.A. 1964–67 (Compl.) (Case No. 1:12-cv-274 against Abbott). In February 2013, Enzo filed a second suit against Abbott alleging infringement of the '405 patent. J.A. 3973–77 (Compl.) (Case No. 1:13-cv-225).

In June 2017, in the cases against Roche and BD, the district court denied summary judgment with respect to written description, but granted summary judgment in favor of the defendants, holding that all asserted claims of the '180 patent were invalid as not enabled. *See* J.A. 59–77, 99–117. The district court entered partial final judgment of invalidity pursuant to Federal Rule of Civil Procedure 54(b) with respect to the claims of the '180 patent in the cases against BD and Roche. J.A. 14–18 (BD), 5–9 (Roche).

In the two Abbott cases, Enzo agreed that the district court's earlier enablement ruling as to the '180 patent would be deemed to apply to the claims of that patent

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[2] Appeal Nos. 17-2354 and 17-2355 were dismissed by agreement of the parties in those appeals. ECF No. 98.

asserted against Abbott. J.A. 23, 14950–51. As to the '405 patent, in August 2017, the district court denied Abbott's motion as to written description but granted summary judgment in favor of Abbott, holding the claims invalid for lack of enablement. J.A. 78–98. The district court entered final judgment of invalidity of all asserted claims of the '180 and '405 patents on September 1, 2017. J.A. 10–13, 23–26.

Enzo timely appealed each judgment. This court consolidated the appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

In reviewing a grant of summary judgment, we apply the law of the regional circuit. *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 676 (Fed. Cir. 2015). The Third Circuit reviews a district court's grant of summary judgment de novo. *Melrose, Inc. v. City of Pittsburgh*, 613 F.3d 380, 387 (3d Cir. 2010). "Summary judgment is appropriate only where, drawing all reasonable inferences in favor of the nonmoving party, there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." *Id.* (quoting *Ruehl v. Viacom, Inc.*, 500 F.3d 375, 380 n.6 (3d Cir. 2007)). "[U]nless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party," there is no need for a trial, and summary judgment is appropriate. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

III

The enablement requirement asks whether "the specification teach[es] those in the art to make and use the invention without undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). To satisfy this requirement, "[t]he specification must contain sufficient disclosure to enable an ordinarily skilled artisan to make and use the entire scope of the claimed invention at the time of filing."

MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012). "Enablement is a question of law based on underlying factual findings." *Id.* at 1380.

"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, 1188 (Fed. Cir. 2014) (quoting *In re Wands*, 858 F.2d at 736–37).[3] In analyzing undue experimentation, we consider factors such as: "(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." *In re Wands*, 858 F.2d at 737.

In our view, the issue in this appeal is not simply whether the specification enables labeling; the question is whether it enables creation of a labeled probe that is both hybridizable and detectable upon hybridization. Many of the alleged factual disputes raised by Enzo and many of the arguments raised by Appellees relate to the details of *creating* the labeled polynucleotide. For example, Roche and BD contend that the specification fails to sufficiently disclose internal phosphate labeling. But even if we assume that the specification teaches one of skill in the art how to create the broad range of labeled polynucleotides covered by the claims, as explained below, the specification still fails to teach one of skill in the art which combinations will

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[3] In this case, the parties agree that the relevant person of ordinary skill in the art is a scientist with a doctorate in chemistry, biochemistry, biophysics, molecular biology, or a similar field. Appellant's Br. 30 (noting the parties' agreement).

produce a polynucleotide that is hybridizable and detectable upon hybridization, as required by the claim language.

With this focus on the functionality required by the claims, we agree with Appellees that our decision in *Wyeth and Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013), controls this case. In *Wyeth*, we affirmed a grant of summary judgment and held the asserted claims invalid for lack of enablement because it would have required undue experimentation to determine which compounds in the claimed class would have the required functionality. *Id.* at 1385–86. The claims in *Wyeth* were construed to require a compound having certain functionality (e.g., immunosuppressive effects). *Id.* at 1383. The claims covered a class of compounds that met those functional requirements. *Id.* at 1385. The patentee's witnesses testified that minor alterations to the molecule disclosed in the specification could impact the required functionality. *Id.* The patent challengers in that case thus argued that a person of ordinary skill in the art would need to screen each compound to determine what candidates would have the claimed functionality. *Id.* We agreed. *Id.* We noted the breadth of the claims, the limited guidance provided in the specification, the large number of possible candidates falling within the claimed genus (tens of thousands), and the fact that it would be necessary to first synthesize and then screen each of those candidates to determine whether it had the required functionality. *Id.* We further noted that one of the patentee's scientists had confirmed the unpredictability in the art by testifying that one would need to test each compound to understand whether it would have the desired functionality. *Id.* We thus concluded that there was no genuine dispute that practicing the full scope of the claims would require undue experimentation. *Id.*

The facts in this appeal largely mirror those in *Wyeth*. As in *Wyeth*, the asserted claims here require not just a particular structure, but a particular functionality (i.e., the labeled polynucleotides must be hybridizable and

detectable upon hybridization). As explained below, the specification fails to teach one of skill in the art whether the many embodiments of the broad claims would exhibit that required functionality.

The scope of the claims is quite broad. Claim 1 of the '180 patent encompasses all phosphate-labeled polynucleotides that are hybridizable and detectable. The claim places almost no limitations on the structure of the claimed polynucleotide, other than the fact that the label is attached to the phosphate portion of the nucleotide. It does not restrict the chemistry used to attach the label, the chemical linker used, the number of labels within a probe, or the location of the labels on the probe (i.e., whether they are terminal or internal). As to the type of non-radioactive label used, the claim provides broad categories, such as any "electron dense component" or "magnetic component."

The specification's guidance as to how such variables would or would not impact the functionality of the claimed probes is sparse. For example, Enzo directs our attention to a sentence in the specification that states that "[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." '180 patent col. 54 ll. 18–20; *see also id.* col. 54 ll. 18–33 (describing generally how a probe works). Enzo's expert, Dr. Backman, explained that a skilled artisan would have understood this reference to using the polynucleotide as a "probe" as meaning a polynucleotide that is capable of hybridizing and being detected upon hybridization. J.A. 5840–41 ¶ 57 (Backman Decl.). But at the time of the invention, the art was highly unpredictable. As Enzo's expert explained:

> At the time of the inventions of the '180 patent, it was commonly thought that the addition of a non-radioactive label to a nucleic acid sequence at positions other than a few known as 'non-disruptive positions' . . . would interfere with or disrupt the

> hybridization process, rendering the nucleotide ineffective for diagnostic purposes.

J.A. 4728 ¶ 74 (Backman Opening Report).

Given the unpredictability of the art at the time and the serious doubts held by those of skill in the art regarding whether labels could be attached to non-Ward positions without disrupting hybridization, merely stating that a labeled polynucleotide will work as a probe is not sufficient to enable one of skill in the art to know that it would indeed function as a probe—i.e., be hybridizable and detectable upon hybridization.

Enzo also presents Example V as an example of an internal phosphate-labeled polynucleotide that is hybridizable and detectable. Appellant's Br. 32–33. Example V states in full:

> Biotin and polybiotinylated poly-L-lysine were coupled to oligoribonucleotides using a carbodiimide coupling procedure described by Halbran and Parker, *J. Immunol.*, 96 373 (1966). As an example, DNA (1 ug/ml), 1 ml) in tris buffer pH 8.2, sheared with 0.1 N sodium hydroxide was denatured by boiling for 10 minutes and quick cooling in an ice bath. Biotinyl-1,6-diaminohexane amide (2 mg, 6 umol) or polybiotinylated poly-L-lysine (2 mg) and l-ethyl-3-diisopropylaminocarboimide HCl (10 mg, 64 umol) were added, and the pH readjusted to 8.2. After 24 hours at room temperature in the dark, the mixture was dialyzed against 10 mM tris buffered saline. DNA was precipitated ethanol.

'180 patent col. 33 ll. 33–44.

Appellees contend that Example V is not a working example. During prosecution, Enzo admitted that Example V is a "'paper', rather than [a] 'working example[].'" J.A. 4703 (stating in an amendment made during prosecution that "Applicants have determined that the examples

set forth . . . [except certain examples other than Example V] are 'paper', rather than 'working examples'"); J.A. 6657 (same). Additionally, Enzo's expert testified that he was not aware of Enzo having ever tested a phosphate-labeled probe for hybridizability and detectability. J.A. 8547–48 p. 84 l. 5–p. 85 l. 16 (Backman deposition); J.A. 8551–52 p. 124 l. 10–p. 125 l. 11 (Backman deposition); *see also* J.A. 6441 p. 133 ll. 6–15 (Backman deposition) ("Q: . . . is there any bench experiment disclosed in the '180 patent in which the '180 inventors attempted to determine whether the product of Example V, that is, the Sig moiety attached to an oligo- or polynucleotide could be detected after it had hybridized to a compl[e]mentary nucleic acid of interest? A. . . . no, they did not do an actual bench experiment to that effect."); *id.* p. 131 ll. 7–19. Regardless, even viewing Example V as a working example, Example V is insufficient to enable the breadth of the claims here, especially in light of the unpredictability in the art.[4]

The deficiencies in the description as to enablement cannot be cured in this case by looking to the knowledge of those skilled in the art at the time of the invention. Although "a specification need not disclose what is well known in the art," that rule is "not a substitute for a basic enabling disclosure." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). As we have said before, a patentee "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.,*

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[4] Nothing stated herein would necessarily disallow proper constructive examples, which are intended to fulfill both written description and enablement requirements. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984) ("Use of prophetic examples, however, does not automatically make a patent nonenabling.").

LLC, 603 F.3d 935, 941 (Fed. Cir. 2010). And, more importantly, all parties acknowledge that serious doubts existed in the art as to whether the use of non-radioactive probes at non-Ward positions would be useful as probes. For example, an inventor of the '180 patent who is also Enzo's CEO explained that, at the time, it was thought "aggressive chemical modification of nucleic acid would lead to destruction of his [sic] content." J.A. 6470 p. 1265 l. 5–p. 1266 l. 15 (Dr. Rabbani deposition); *see also* J.A. 6465 p. 31 l. 12–p. 33 l. 13 (Dr. Rabbani explaining how more aggressive modification of the nucleic acid was considered "breaking the dogma"). Enzo's expert, Dr. Backman, also pointed out the view of the art at the time, stating that "[a]t the time of the inventions of the '180 patent, it was commonly thought that the addition of a nonradioactive label to a nucleic acid sequence at positions other than [the Ward positions at the base] would interfere with or disrupt the hybridization process." J.A. 4728 ¶ 74 (Backman's Opening Report); J.A. 4184 ll. 10–24 (Dr. Rabbani deposition). Indeed, Enzo's expert explained that for one of skill in the art to be comfortable that a particular polynucleotide would work as a probe, "they would need to actually make the compound and test it in a hybridization experiment, which they would have been dissuaded from doing because of Ward." J.A. 8454 p. 150 ll. 8–15 (Sherman deposition) (discussing a polynucleotide labeled at the terminal phosphate and using carbodiimide chemistry and biotin); *see also* J.A. 8456 ll. 3–11 (Sherman deposition) ("Q: . . . But if they had been motivated to make this probe, non-Ward labeled probe, your view is that they would have to make it and test it in order to predict whether it would actually hybridize as of June 1982, right? A: Well, they would have to make it and assure against the prevailing wisdom that it could work."); J.A. 8454–55 p. 150 l. 17–p. 151 l. 18 (Sherman deposition).

Given such unpredictability in the art, and considering the testimony of Enzo's expert that each labeled

polynucleotide would need to be tested to determine whether it is hybridizable and detectable upon hybridization, the breadth of the claims here is particularly concerning in the enablement inquiry. *See In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."). Appellees contend that millions of embodiments of the claims exist based on the many variables involved in creating one of the claimed labeled polynucleotides. Enzo disputes this number, arguing it is improperly inflated because it counts every possible polynucleotide sequence that could exist as a separate embodiment. Even assuming Enzo is correct that the length and sequence of the polynucleotide do not give rise to separate embodiments, the other variables (such as the type of label, the type of linker used to attach the label, and the location of the labels within the polynucleotide) still result in an extremely large number of possible embodiments. Indeed, Enzo's expert explained that the number of possible polynucleotides that would fit within the limitations of claim 1 would be at least "tens of thousands." J.A. 6438 p. 120 l. 20–p. 121 l. 11 (Backman deposition).

In sum, even if Example V describes one working embodiment with the claimed functionality, undue experimentation would still be required with regard to the many other embodiments of the claims based on the number of possible embodiments and the unpredictability in the art. *See Genentech*, 108 F.3d at 1366 ("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.").

We conclude by briefly addressing the asserted claims of the '405 patent. Those claims are broader than the asserted claims of the '180 patent; rather than covering only *phosphate*-labeled polynucleotides, they also cover labeling

at other locations on a nucleotide. Like the claims of the '180 patent, the asserted claims of the '405 patent require the claimed polynucleotides to be hybridizable and detectable upon hybridization. Because the specification does not enable the narrower scope of polynucleotides claimed in the '180 patent, it also cannot enable the broader scope of polynucleotides claimed in the '405 patent. As such, even though the asserted claims of the '405 patent pertain to certain processes, the claims are still not enabled for the reasons described with respect to the '180 patent.

In sum, viewing the evidence in the light most favorable to Enzo, we agree with the district court's grant of summary judgment.

IV

For the foregoing reasons, we affirm the district court's grant of summary judgment that the asserted claims of the '180 patent and the '405 patent are invalid for lack of enablement.

AFFIRMED