IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC., Plaintiff. v. ABBOTT LABORATORIES and ABBOTT MOLECULAR, INC., Defendants.	)	C.A. No. 12-274-LPS

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MEMORANDUM OPINION

August 15, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court are: (i) Defendants Abbott Laboratories and Abbott Molecular Inc.'s (collectively, "Abbott" or "Defendants") Motion for Summary Judgment of Invalidity of U.S. Patent No. 8,097,405 (the "'405 patent") for Failure to Comply with the Written Description Requirement (D.I. 413 at 6-16), and (ii) Abbott's Motion for Summary Judgment of Invalidity of the '405 Patent for Nonenablement (D.I. 458). For the reasons set forth below, the Court will deny Abbott's motion with respect to written description and will grant Abbott's motion with respect to nonenablement.

I. BACKGROUND

Plaintiff Enzo Life Sciences, Inc. ("Enzo" or "Plaintiff") filed this patent infringement action against Abbott, alleging infringement of the '405 patent as well as U.S. Patent No. 6,992,180 ("the '180 patent").

The '405 patent, which is the subject of the pending motions, generally pertains to non-radioactive labeling and "relate[s] to nucleic acid[[1]] detection technology that relies upon the ability of nucleic acid (DNA or RNA) strands to hybridize – or bind together." (D.I. 430 at 7) (internal quotation marks omitted) While "the prevailing perception in the art [at the time of the invention] was that specific base moieties (the so-called 'Ward' positions) were the only possible positions for labeling," the '405 patent discloses that nucleotides "with non-radioactive labels attached to certain positions of a nucleotide – the phosphate moiety, sugar moiety, or non-Ward positions on the base moiety – could . . . be used as detectable nucleic acid probes." (D.I. 423 at

[1]"Nucleic acids (DNA or RNA) are made up of 'nucleotide[s],' each of which 'typically consists of three parts: a base, a sugar, and a phosphate.'" (D.I. 430 at 7) (quoting D.I. 431-2 Ex. 16 at 9)

5-6 (emphasis omitted); *see also* D.I. 427 at A2130)

The '405 patent was issued on January 17, 2012 and claims priority to June 23, 1982. (*See* D.I. 423 at 6) The asserted claims of the '405 patent "fall into two categories: the *in situ* hybridization claims and the liquid phase claims." (D.I. 430 at 8) The *in situ* hybridization claims – claims 63, 64, 65, 94, 103, 128, and 144 – "recite processes for counting or identifying chromosomes through 'specific hybridization' to a 'locus or loci' of a chromosome, using probes labeled at specified positions." (*Id.*) The liquid phase claims – claims 196 and 198 – "specify permissible Sigs [detectable labels] and detection methods, respectively."[2] (*Id.* at 9)

Abbott moved for summary judgment of invalidity of the '405 patent for lack of written description on May 12, 2017 (D.I. 410 at 6-16; D.I. 413 at 6-16),[3] and the parties completed briefing on July 7, 2017 (D.I. 413, 423, 448). On June 28, 2017, while summary judgment briefing was underway, the Court issued a Memorandum Opinion in a related case, *Enzo Life Sciences, Inc. v. Gen-Probe Inc.*, C.A. No. 12-104-LPS, granting a defense motion for summary

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[2]Claims 94, 103, 128, and 144 depend from independent claims 63, 64, and 65, among other claims. Claims 196 and 198 depend from independent claims 188 and 189, both of which recite the following limitations that are pertinent here:

> A process for detecting the presence of a nucleic acid of interest in a sample, comprising: providing or generating (i) a detectable non-radioactively labeled oligonucleotide or polynucleotide, . . . and (ii) a sample that may contain said nucleic acid of interest; forming in liquid phase, hybrids comprising said detectable non-radioactively labeled oligonucleotide or polynucleotide specifically hybridized with said nucleic acid of interest; and detecting hybrids non-radioactively to detect the presence of said nucleic acid of interest.

('405 patent col. 54 ll. 31-67, col. 55 ll. 1-10)

[3]D.I. 413 is an amendment to Abbott's opening brief, D.I. 410, and was filed on May 12, 2017. When citing to Abbott's opening brief, this Memorandum Opinion refers to D.I. 413, not D.I. 410.

judgment that the asserted claims of the '180 patent are invalid for nonenablement. (C.A. No. 12-104-LPS D.I. 284) ("Gen-Probe Opinion" or "GP Op.") On the same day, the Court issued an oral order in the instant case, requiring the parties to submit a joint status report discussing their respective position(s) on how the Court should proceed with respect to the summary judgment motions pending here. (D.I. 441)

In their July 10 status report, the parties agreed that the Gen-Probe Opinion invalidated all of the '180 patent claims asserted against Abbott and that all pending motions pertaining to the '180 patent were now moot. (*See* D.I. 450 at 4-5) The status report also included Abbott's request for leave to file a motion for summary judgment of invalidity of the '405 patent for nonenablement. (*See id.* at 6) In Abbott's view, good cause was established by the Gen-Probe Opinion, because "the '405 patent is related to and has essentially the same specification as the '180 patent." (*Id.* at 5)

The Court granted Abbott's request for leave. (D.I. 451) Thereafter, between July 18 and August 1, 2017, the parties submitted additional letter briefing with respect to enablement. (D.I. 459, 461, 462) The Court heard oral argument on August 8, 2017. (*See* Transcript ("Tr."))

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

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