IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN MANUFACTURING, LTD, and AMGEN USA INC.,

Plaintiffs;

v.

SANOFI, SANOFI-AVENTIS U.S. LLC, AVENTISUB LLC, f/d/b/a AVENTIS PHARMACEUTICALS INC., and REGENERON PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 14-1317-RGA

MEMORANDUM OPINION

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January 18, 2019

ANDREWS, U.S. DISTRICT JUDGE:

Currently pending before the Court are Plaintiffs' Motion for Partial Summary Judgment (D.I. 634), Defendants' Cross-Motion for Summary Judgment on Estoppel (D.I. 673), and Defendants' Motion for Summary Judgment on Invalidity. (D.I. 630). The Parties have fully briefed the issues. (D.I. 631, D.I. 635, D.I. 674, D.I. 678, D.I. 691, D.I. 693). For the following reasons, Plaintiffs' Motion for Partial Summary Judgment and Defendants' Motion for Summary Judgment on Invalidity are DENIED. Defendants' Cross-Motion is GRANTED.

I. BACKGROUND

Plaintiffs Amgen, Inc., Amgen Manufacturing Limited, and Amgen USA Inc. (collectively "Plaintiffs") filed suit against Defendants Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, and Regeneron Pharmaceuticals, Inc. (collectively "Defendants") on October 17, 2014. (D.I. 1). Plaintiffs assert that Defendants' manufacture and sale of Praluent, a drug that treats patients with high levels of low density lipoprotein cholesterol, infringes claims of U.S. Patent Nos. 8,829,165 ("the '165 patent") and 8,859,741 ("the '741 patent") (collectively, the "Amgen patents"). (D.I. 1). The parties stipulated to infringement of certain claims on February 22, 2016. (D.I. 235). During trial, the Court issued two Rule 50(a) rulings. The Court determined that as a matter of law, the patent claims were non-obvious and Plaintiffs had failed to meet the burden of showing that Defendants' infringement was willful. (D.I. 345 at 5:2-3; D.I. 302). The case was submitted to the jury on the remaining issues: written description and enablement of the patent claims. The trial resulted in a judgment for Plaintiffs that the patents are not invalid. (D.I. 304). After trial, Defendants moved for renewed judgment as a matter of law on patent validity and for a new trial. (D.I. 331, 332). Plaintiffs moved for a permanent injunction. (D.I. 336). The Court denied Defendants' post-trial motions and entered final

judgment in favor of Plaintiffs under Rule 54(b) on January 3, 2017. (D.I. 390, 391). The Court granted Plaintiffs' motion for a permanent injunction on January 5, 2017. (D.I. 392).

Defendants appealed. (D.I. 402). The Federal Circuit determined that the Court had erred in precluding post-priority date evidence relevant to written description and enablement, and had improperly instructed the jury on written description. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1371 (Fed. Cir. 2017). The Federal Circuit remanded for a new trial on written description and enablement. *Id.*

The parties now move for summary judgment. Defendants move for summary judgment that the asserted patents are "invalid on written description and enablement grounds." (D.I. 631 at 6; D.I. 630). Plaintiffs move for partial summary judgment to "estop Defendants from arguing that Amgen's selected claims lack written description and enablement." (D.I. 635 at 8; D.I. 634). Defendants cross-move for summary judgment on estoppel. (D.I. 673).

II. LEGAL STANDARD

"The 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." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247–49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

III. DISCUSSION

A. Defendants' Motion for Summary Judgment of Invalidity

Defendants ask the Court for summary judgment of invalidity for lack of written description and no enablement. (D.I. 630). Plaintiffs assert that genuine disputes of material fact preclude summary judgment. (D.I. 678 at 5). I agree with Plaintiffs.

1. Written Description

The written description requirement contained in 35 U.S.C. § 112, ¶ 1 requires that the specification "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc., v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (cleaned up). "In other words, the 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.* The written description inquiry is a question of fact. *See id.* Although it is a question of fact, "[c]ompliance with the written description requirement . . . is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008). "A party must prove invalidity for lack of written description by clear and convincing evidence." *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015).

Defendants assert that no disputes of material fact exist and that the patent is invalid for lack of written description. (D.I. 631 at 14). Plaintiffs argue that there are genuine disputes of material facts under both the common structural features test and representative species test. (D.I. 678 at 6-7). I agree with Plaintiffs that genuine issues of material fact preclude summary judgment on the written description defense.

First, the parties dispute whether the specification discloses a common structural feature of the claimed antibodies. (D.I. 631 at 15-17; D.I. 678 at 9-11). Defendants argue that the Federal Circuit's opinion in *Amgen* stands for the proposition that an antibody cannot be described by its function—binding to an antigen. (D.I. 631 at 16-17). However, in *Amgen*, the Federal Circuit recognized that it is "hotly disputed [whether] knowledge of the chemical

structure of an antigen gives the required kind of structure-identifying information about the corresponding antibodies." 872 F.3d at 1378. The parties' experts continue to dispute whether the function of binding correlates to the structure of the antibody. (D.I. 631 at 16-17; D.I. 678 at 10-11). Additionally, Defendants' expert, Dr. Petsko, has testified that the pattern of hydrophobic and non-hydrophobic residues is a common structural feature of the claimed antibodies. (D.I. 678 at 10).

Second, genuine disputes of material facts exist under the representative species test. While the parties do not dispute the underlying evidence, the parties' experts disagree on the significance of these facts. (D.I. 631 at 18-24; D.I. 678 at 8-9). Plaintiffs' patents "describe at least 32 antibodies by sequence that fall within the claimed genus by binding to the fifteen amino acid sweet spot on PCSK9." (D.I. 678 at 8). Defendants argue that these patent claims do not meet the representative species test because 1) the patents disclose antibodies that bind to no more than eight PCSK9 residues, but claim antibodies binding up to fifteen residues, 2) the patents fail to disclose antibodies that bind to any of the combination of residues to which the competitor antibodies bind, and 3) the patents only disclose four antibodies that share sixty percent or more of its heavy or light chain CDR sequences with any of the competitor antibodies. (D.I. 632 at 20-21). However, Plaintiffs' experts, Dr. Petsko and Dr. Rees, have testified that a person of ordinary skill in the art would understand the exemplary antibodies to be representative of the claimed genus due to common key sequence characteristics with post-priority antibodies. (D.I. 678 at 9).

Taking the evidence under both tests in the light most favorable to the non-moving party, as I am required to do, a reasonable jury could find the disclosed antibodies to be sufficiently

representative of the genus. Therefore, the written description requirement is not amenable to summary judgment. *PowerOasis*, 522 F.3d at 1307.

2. Enablement

The enablement requirement, considered a separate and distinct requirement contained in 35 U.S.C. § 112, ¶ 1, assesses whether "one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Because the enablement inquiry takes into account what is known to one skilled in the art, the Federal Circuit has "repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art." *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004). "Enablement is a legal question based on underlying factual determinations." *Vasudevan*, 782 F.3d at 684. Factors considered in assessing the enablement requirement 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.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). "A party must prove invalidity for lack of enablement by clear and convincing evidence." *Vasudevan*, 782 F.3d at 684.

Defendants assert that no dispute of material fact remains and that they have proven no enablement by clear and convincing evidence. (D.I. 631 at 24-27). Plaintiffs argue that 1) the patent claims are enabled and 2) there are material disputes of fact as to whether the specification's disclosed process is a "trial and error" process and whether Plaintiffs practiced the full scope of the claims. (D.I. 678 at 11-12, 24-25).

I agree with Plaintiffs that genuine disputes of material fact remain as to whether the patent claims are enabled. The parties dispute whether the specification's disclosed process is an "unpredictable, trial and error process" requiring years or decades to make additional embodiments within the claimed genus. (D.I. 631 at 25; D.I. 678 at 25). While the parties do not dispute that repetition is required to make antibodies within the claimed genus, the parties' experts dispute the predictability of this repetition and the amount of time required to make antibodies within the genus from the specification's disclosures. (D.I. 631 at 25; D.I. 678 at 25). The parties also have genuine disputes regarding the post-priority evidence. Specifically, Defendants argue that the post-priority evidence shows that Plaintiffs were attempting to make more antibodies within the claimed genus and were unable to do so. (D.I. 631 at 26). Plaintiffs assert that this post-priority evidence shows their attempts to make novel antibodies with different properties from the claimed genus. (D.I. 678 at 26). Taking the evidence in the light most favorable to the non-moving party, as I am required to do, a reasonable jury could find that the patent claims are enabled. Thus, summary judgment of no enablement is inappropriate.

Therefore, as disputes of material fact remain as to both written description and enablement, summary judgment of invalidity is denied.

B. Plaintiffs' Motion for Partial Summary Judgment of Estoppel

Plaintiffs assert that the doctrines of judicial estoppel and quasi-estoppel should be applied to estop Defendants from making a multitude of arguments in support of their written description and enablement defenses. (D.I. 635 at 7-8). Plaintiffs contend that Defendants have submitted applications and made representations to the United States Patent and Trademark Office (the "PTO") in other proceedings that directly contradict arguments made in this case, justifying estoppel. (D.I. 635 at 7-8). Defendants respond that their patent filings and

representations in the PTO proceedings cited are not inconsistent and do not warrant the application of either judicial estoppel or quasi-estoppel. (D.I. 674 at 6-7).

The doctrine of judicial estoppel bars a party that has previously asserted a legal position from asserting an inconsistent or contrary legal position in a later proceeding. *Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 419 (3d Cir. 1988). This equitable remedy is applied to preserve the integrity of the system. Its focus is on the relationship between the litigant and the judicial system. *Id.* The elements of judicial estoppel in the Third Circuit are: (1) the party to be estopped is taking two irreconcilably inconsistent positions; (2) the party to be estopped has changed his or her position in bad faith; and (3) the use of judicial estoppel is tailored to address the harm identified and no lesser sanction would adequately remedy the damage done. *See Montrose Med. Group Participating Savings Plan v. Bulge*r, 243 F.3d 773, 777-78 (3d Cir. 2001).

Quasi-estoppel is a similar doctrine recognizing the "duty of consistency." *In re Baker Hughes Inc.*, 215 F.3d 1297, 1301-02 (Fed. Cir. 2000). Similar to judicial estoppel, it prevents a litigant "from shifting to a contrary position touching on the same facts or transaction" and "the earlier position was then to the advantage of the [litigant] but that it is now to the [litigant's] advantage to shift his position." *Id.* at 1301 (quoting *Union Carbide Corp. v. United States*, 612 F.2d 558, 566 (Ct. Cl. 1979)). The doctrine "only applies when the earlier position amounts to a misstatement of fact, not of law," and the misstatement must be one on which the government or opposing party "reasonably relied."[1] *Id.* at 1302; *see also Black's Law Dictionary* 669 (10th ed.

[1] Plaintiffs argue that I should apply the quasi-estoppel requirements enumerated in *Cahall v. Carey's Diesel, Inc.*, 2018 WL 2370869 (D. Del. May 24, 2018). However, in that case I was addressing quasi-estoppel in the context of Delaware state law claims and admiralty claims, and as such, applied the state law doctrine on quasi-estoppel. *Id.* Here, the underlying claims are federal claims. Thus, I apply the federal doctrine of quasi-estoppel.

2014) (quasi-estoppel "prevent[s] one from repudiating an act or assertion if it would harm another who reasonably relied on the act or assertion").

Plaintiffs assert Defendants should be estopped from making the following seven arguments:

1. the Representative Species Test requires an example antibody for every binding location on an antigen;
2. the Representative Species Test requires exhaustive exemplification of diversity of amino acid sequence and gene usage;
3. the Representative Species Test requires exemplification of every bond that can occur at every residue between an antibody and an antigen;
4. binning or mutagenesis cannot show where an antibody binds;
5. antibodies that share function lack a common structure/function relationship;
6. Plaintiffs' specification must disclose non-human antibody examples for enablement and written description support; and
7. making additional antibodies within Plaintiffs' claims requires undue experimentation.

(D.I. 635 at 17-26). I disagree. The application of judicial estoppel and quasi-estoppel are not appropriate here.

1. Estoppel No. 1: The Representative Species Test Requires an Example Antibody for Every Binding Location on an Antigen

Judicial estoppel is not appropriate because the representations to the PTO cited by Plaintiffs are not "irreconcilably inconsistent" with the stated position in this case. Plaintiffs point to several of Defendants' own patent filings and issued patents where either an application was filed or a patent was issued claiming a genus of antibodies where the specification did not disclose "an example antibody for every binding location on an antigen." (D.I. 635 at 18-19). However, the applications and patents cited[2] do not address the exact same factual matters that

[2] I will summarize the status of the PTO filings that Plaintiffs cite here. The cited claims of the 15/595,373 application ("the '373 application) were rejected in August 2018. Defendants amended claim 42 to be limited to antibodies with specified amino acid sequences and cancelled claim 59. (D.I. 679, Ex. 6). Defendants amended the 14/801,384 application ("the '384 application") in November 2018. (*Id.*, Ex. 7). Certain claims of U.S. Patent No. 8,501,184 patent ("the '184 patent") were rejected by the PTO and then cancelled by Defendants in 2013; the issued

are at issue in this case. For judicial estoppel to apply, there must be a more direct relationship between the purportedly inconsistent representations. *See MobileMedia Ideas, LLC v. Apple Inc.*, 907 F. Supp. 2d 57, 622-23 (D. Del. 2012) (judicial estoppel precluded position contrary to prosecution of *directly related predecessor* patent), *aff'd in part, rev'd in part*, 780 F.3d 1159 (Fed. Cir. 2015); *see also Endo Pharms. Inc. v. Mylan Pharms., Inc.*, 2014 WL 334178, at *22-24 (D. Del. Jan. 28, 2014) (judicial estoppel inapplicable to statements made to PTO in prosecution of different patent family than that of patent-in-suit). Here, the purported inconsistent representations were made in the context of unrelated patent filings with material differences from the patents at the heart of this suit. Therefore, even if the representations may be facially inconsistent at first glance, Plaintiffs have not demonstrated that the previous representations are so "irreconcilably inconsistent" as to warrant application of judicial estoppel.

The application of quasi-estoppel would also be inappropriate here. The purported inconsistencies cited by Plaintiffs go to a legal conclusion—the requirements of the Representative Species test—rather than a factual issue. Quasi-estoppel, as noted above, "only applies when the earlier position amounts to a misstatement of fact, not of law." *Baker Hughes*, 215 F.3d at 1302. Thus, Defendants will not be estopped from making this argument.

2. Estoppel No. 2: The Representative Species Test Requires Exhaustive Exemplification of Diversity of Amino Acid sequence and Gene Usage

Estopping Defendants from making this argument would be inappropriate for the same rationale explained for Estoppel No. 1.

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claims are for specific antibodies. (*Id.*, Exs. 9, 10, 11). The claims of the 14/697,186 application ("the '186 application") were rejected by the PTO in August 2016 and abandoned in March 2017. (*Id.*, Ex. 8). U.S. Patent Nos. 9,545,451 ("the'451 patent") and 9,809,653 ("the '653 patent") do not claim any antibodies related to PCSK9. (*Id.*, Ex. 12, '451 patent, cl.1, Ex. 13, '653 patent, cl.1).

3. Estoppel No. 3: The Representative Species Test Requires Exemplification of Every Bond that can Occur at Every Residue Between an Antibody and an Antigen

Estopping Defendants from making this argument would be inappropriate for the same rationale explained for Estoppel No. 1.

4. Estoppel No. 4: Binning or Mutagenesis Cannot Show Where an Antibody Binds

The application of judicial estoppel or quasi-estoppel to this position is inappropriate because Plaintiffs have not demonstrated that Defendants' previous positions are "irreconcilably inconsistent." Plaintiffs point specifically to the '373 application and the inclusion of mutagenesis data in that application. (D.I. 635 at 22). However, as Defendants note, the claims of the '373 application are limited to specific amino acid sequences, and therefore the application does not rely on the mutagenesis data to show where an antibody binds. (D.I. 674 at 20). The positions are therefore not inconsistent, and estoppel is not warranted.

5. Estoppel No. 5: Antibodies that Share Function Lack a Common Structure/Function Relationship

Neither judicial estoppel or quasi-estoppel is warranted. First, Plaintiffs have failed to show an inconsistency between the cited PTO filings and the argument they seek to estop. The cited patent application (U.S. SN 14/068,173) sought a patent on antibodies directed at a different protein (ASIC1), not PCSK9. (D.I. 674 at 21). Second, even if the representations made were inconsistent, the PTO rejected the purportedly inconsistent claim. (D.I. 674 at 21-22). Therefore, Plaintiffs have not demonstrated either the necessary adoption of the purported inconsistent position for judicial estoppel or the necessary benefit of the purported inconsistent position for quasi-estoppel.

6. Estoppel No. 6: Plaintiffs' Specification Must Disclose Non-Human Antibody Examples for Enablement and Written Description Support

Plaintiffs have not demonstrated an inconsistency warranting estoppel. Plaintiffs cite only the '373 application as a purported inconsistent position. (D.I. 635 at 24-25). The '373 Application has been expressly limited to particular amino acid sequences of a human PCSK9 antibody (alirocumab) and therefore is not inconsistent with the position Plaintiffs seek to estop. (D.I. 674 at 23). Moreover, Plaintiffs have not shown the necessary adoption of or reliance on the purportedly inconsistent position as the cited claims of the '373 application were rejected by the PTO in August 2018. (D.I. 679, Ex. 6). Therefore, neither judicial estoppel or quasi-estoppel is appropriate.

7. Estoppel No. 7: Making Additional Antibodies Within Plaintiffs' Claims Requires Undue Experimentation

Plaintiffs have failed to show an inconsistency warranting the application of either judicial estoppel or quasi-estoppel. Plaintiffs cite the testimony of Defendants' expert Dr. Ravetch during the March 2016 trial and the prosecution history of the '184 patent. (D.I. 635 at 25-26). However, there is no inconsistency between the assertion that making additional antibodies requires undue experimentation and Dr. Ravetch's previous testimony that the field was well-developed, that generating antibodies was routine, and that alanine scanning was a routine technique used to identify specific residues on PCSK9 to which an antibody binds.

Moreover, to the extent the identified statements may be inconsistent, Plaintiffs have failed to demonstrate both adoption of the position by the PTO or the Court and any benefit resulting to Defendants from the purportedly inconsistent position. The claims of the '184 patent to which Plaintiffs point were rejected and cancelled in 2013. (D.I. 674 at 24). Additionally,

Defendants were unsuccessful on written description at the first trial. Thus, Plaintiffs have not shown that estoppel is warranted.

Plaintiffs have not shown that estoppel is warranted for any of the seven identified positions. Plaintiffs' motion is denied. Defendants' cross-motion is granted.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Partial Summary Judgment is DENIED, Defendants' Cross Motion for Summary Judgment on Estoppel is GRANTED, and Defendants' Motion for Summary Judgment on Invalidity is DENIED.

An accompanying order will be entered.