IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 14-1317-SLR
	)	(Consolidated)
SANOFI, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 18th day of February, 2016, having reviewed the various papers submitted by the parties in connection with their pretrial evidentiary issues;

IT IS ORDERED that:

1. **The UTSW PCSK9 handout** is excluded as being disclosed untimely. In this regard, it would take further discovery to flesh out whether it is prior art, as the facial indicia of such is not sufficient to pass muster. If not prior art, the handout is cumulative and likely to lead to mischief if admitted to demonstrate the state of the art.

2. ***Daubert* motions: standard of review.** A qualified expert may testify in the form of an opinion if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[1] Fed. R. Evid. 702. As summarized by the Third Circuit in *Elcock v. Kmart Corp.*, 233 F.3d 734 (3d Cir.

[1]Of course, an expert must be qualified as well, an issue not in dispute presently.

2000), "Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Id.* at 741. The burden of persuading the judge to allow the expert to testify is on the party tendering the expert, and is by a preponderance of the evidence. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743-45 (3d Cir. 1994). As noted by the Supreme Court, "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumbo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

3. **Cross *Daubert* motions regarding post-priority date evidence.** Both parties have filed *Daubert* motions to exclude post-priority date evidence. Plaintiffs' motion seeks to exclude expert testimony regarding the structure of post-priority date antibodies that were not disclosed in the selected patents. (D.I.191) Defendants' motion seeks to exclude expert testimony that relies on later-developed evidence to demonstrate the structure of the disclosed antibodies. (D.I.185) Although characterized differently, both motions relate to defendants' written description defense.

4. In this case, the patent claims[2] asserted against defendants are directed to genuses of antibodies. Claim 1 of the '165 patent, for example, recites:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238,A239, I369, S372, D374, C375, T377, C378, F379, V380, or S81 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

Defendants argue that such claims as that recited above are invalid for lack of written

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[2]Selected claims of U.S. Patent Nos. 8,829,165 ("the '165 patent"), 8,859,741 ("the '741 patent"), and 8,871,914 ("the '914 patent").

description pursuant to 35 U.S.C. §112, ¶ 1 because: (1) the claimed antibodies are defined by their function, not by their structure; (2) although the patents identify representative examples of the antibodies encompassed by the asserted claims, the examples are identified only by their amino acid sequences, not by their structure; (3) information about their structure is necessary to determine where these antibodies bind to PCSK9; (4) the only structural information provided by plaintiffs is comprised of post-priority date x-ray crystallography analysis. Plaintiffs respond in kind as follows: (1) the claims "clearly recite several structural features;" (2) the structure of the selected antibodies is an "inherent property" of where they bind to PCSK9; (3) "inherently disclosed properties" are deemed present in the specification. (D.I. 202 at 1, 3)

4. To satisfy the written description requirement, "the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (citation omitted); *see also Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011). "[T]he hallmark of written description is disclosure," and "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). A written description of an invention involving a chemical genus "requires a precise definition, such as by structure, formula, [or] chemical name" of the claimed subject matter sufficient to distinguish it

from other materials. *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Support for a genus claim requires either a "representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350; *Regents*, 119 F.3d at 1568. "[A]n applicant can claim an antibody to novel protein X without describing the antibody when (1) the applicant fully discloses the novel protein and (2) generating the claimed antibody is so routine that possessing the proten places the applicant in possession of an antibody." *Centocor*, 636 F.3d at 1351-52. Because "each patented advance has a novel relationship with the state of the art from which it emerges," the written description inquiry "is a question of fact" with the law being "applied to each invention at the time it enters the patent process." *Ariad,* 598 F.3d at 1351. As explained by the Federal Circuit in *Ariad, "*requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention' - that is, conceive of the complete and final invention with all its claimed limitations - and disclose the fruits of that effort to the public." *Id.* at 1353.

5. The case law cited above gives broad leeway to the court in terms of admitting evidence that illuminates the state of the art **at the time of filing** in order to determine whether there is sufficient disclosure of the claimed invention, in this case, a genus. Given the complexity of the technology at issue and the "considerable leeway" I have as a judge to determine whether an expert's knowledge will help the jury understand the evidence and determine issues of fact, I conclude that the clearest,

most consistent result is to grant both motions and preclude the use of any such evidence in connection with the issue of written description.

6. ***Daubert* motions relating to damages.** As per the normal course of events, both plaintiffs and defendants accuse the opposing experts of basing their economic analyses on inappropriate data. Both experts agree that there are no comparable bare license agreements. In order to base their respective opinions on some modicum of real-world data, plaintiffs' expert resorted to using distributor fees as relevant comparables and defendants' expert resorted to using collaboration agreements and cross-license agreements as relevant comparables. With the exception of the Dezima acquisition agreement and the Genentech/Regenron settlement agreement,[3] I am satisfied that the experts have adequately explained in their reports the relevance of their respective data vis a vis the various *Georgia-Pacific* factors.[4] Therefore, defendants' motion as to the reasonable royalty opinions of Dr. Meyer (D.I. 185) is denied, and plaintiffs' motion to exclude the expert testimony of Dr. Stevens (D.I. 187) is granted in part and denied in part.

United States District Judge

[3]Identified by Dr. Stevens. I will preclude these business arrangements as being too far afield from a bare patent license to be relevant comparables.

[4]Including those factors relating to the parties' licensing practices and the fact that plaintiff "does not out-license its patent rights to a competitor where the technology covered by the patent rights is technology that Amgen itself intents to commercialize in the same geographic area and for the same therapeutic use." (D.I. 188, ex. 4, ¶ 146)