IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN MANUFACTURING, LIMITED, and AMGEN USA, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 14-1317-SLR (Consolidated)
SANOFI, SANOFI-AVENTIS U.S., LLC, AVENTISUB LLC, and REGENERON PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 2nd day of March, 2016, having heard argument on the motion for reargument filed by defendants, and having reviewed the papers filed in connection therewith;

IT IS ORDERED that said motion (D.I. 231) is granted to the extent I have entertained further argument on the issues presented, but denied as to its substantive request, for the reasons that follow:

1. I issued a memorandum order on February 18, 2016 that addressed various pretrial evidentiary issues in the above captioned litigation, including whether evidence regarding the structure of antibodies that did not exist at the time of filing (and, therefore, were not disclosed in the patents-in-suit) should be excluded for purposes of defendants' written description defense. I concluded that, because the written

description requirement is tested as of the filing date, such evidence should be excluded. Defendants contend that my decision is contrary to the law, particularly, the Federal Circuit's reasoning in *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc. and Centocor Biologics, LLC*, 759 F.3d 1285 (Fed. Cir. 2014). The Court in *AbbVie* upheld a jury's finding of invalidity of genus claims that were functionally defined based on lack of written description. The Court reasoned that

> [w]hen a patent claims a genus using functional language to define a desired result, "the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented a species sufficient to support a claim to the functionally defined genus." . . . We have held that "a sufficient description of a genus . . . requires the disclosure of 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."

Id. at 1299 (citations omitted). The question presented was whether the patents at issue described representative species to support the entire genus. Without apparent objection, defendant "presented expert testimony that the antibodies described in the patents were structurally similar, but that they differed from [the accused antibody] in many respects." *Id.* at 1293. According to the Federal Circuit,

> the jury heard ample evidence that AbbVie's patents only describe one type of structurally similar antibodies and that those antibodies are not representative of the full variety or scope of the genus . . . . [More specifically, the accused antibody] differs considerably from the Joe-9 antibodies described in AbbVie's patents. . . . Centocor's expert testified that antibodies with 80% sequence similarity to J695 could bind to completely different antigens, . . thus illustrating the significant structural differences between [the accused antibody] and the Joe-9 antibodies and the unpredictability of the field of invention. Centocor also presented evidence of other differences between [the accused antibody] and the Joe-9 antibodies, such as CDR length and epitope binding site.

Id. at 1300. The Court concluded that there was "no evidence to show any described antibody to be structurally similar to, and thus representative of [the accused antibody]. There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as [the accused antibody]." *Id.* at 1301.

2. By giving its imprimatur to the jury's verdict, the Federal Circuit arguably departed from its own precedent, established in *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), that later-developed or later-discovered products should not be used to test compliance with 35 U.S.C. § 112.[1] In this regard, the Court in *Hogan* reasoned that,

> to now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system. . . .
>
> The business of the PTO is patentability, not infringement. . . . The courts have consistently considered subsequently existing states of the art as raising question of infringement, **but never of validity**.

Id. at 607 (emphasis added). *See also United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989); *Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347 (Fed. Cir. 2000); *Amgen, Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313 (Fed. Cir. 2003); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed.

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[1]It is important to keep in mind that the district judge in the *AbbVie* case had consolidated an infringement action filed by AbbVie with an appeal by Centocor from an interference proceeding in which AbbVie's [6,914,128] patent was awarded priority over Centocor's patent application covering the accused antibody. In other words, it may not be surprising that the *AbbVie* record does not contain the kind of evidentiary issues that have arisen instantly, and that the Federal Circuit simply decided the issues presented - on the record presented - without attending to the more significant question of whether it is ever or always appropriate to use post-priority evidence of an embodiment that was not known or even in existence at the time of filing to invalidate a patent based on lack of written description support.

Cir. 1991); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004); *Biogen Idec, Inc. & Genentech, Inc. v. Glaxo Smith Kline LLC*, 713 F.3d 1090 (Fed. Cir. 2013). *See also* Goldstein, Jorge, *"AbbVie Deutschland* and Unknown Embodiments: Has the Written Description Requirement for Anitbodies Gone Too Far?," 9 LSLR 399 (Bloomberg BNA, Apr. 3, 2015). This leaves me between a rock - the written description requirement has always been anchored in the state of the art at the time of filing - and a hard place - *AbbVie* arguably has imposed the "impossible burden"[2] on inventors to "at least describe some species representative of antibodies that are structurally similar to" unknown future embodiments. *AbbVie*, 759 F.3d at 1301.

3. Without a specific recognition by the Court in *AbbVie* that it was so dramatically changing the law on written description, I choose to interpret it narrowly and limit it to its unusual facts and procedural posture. Therefore, while I appreciate the arguments made by defendants, I decline to change my ruling precluding the admission of any post-priority date evidence on written description.[3]

United States District Judge

[2]*Hogan*, 559 F.2d at 606.

[3]I note in closing that this significant issue was not addressed during claim construction or in the context of infringement which, absent the dramatic change in perspective arguably foretold by the *AbbVie* decision, would be the most sensible way of addressing broad genus claims and future embodiments not foretold and described in the specification.