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 10th day of March, 2016, having reviewed the papers filed in connection with various evidentiary issues;

IT IS ORDERED that the relief requested vis a vis **plaintiffs' evidentiary issues 10 and 14** is granted in part and denied in part. Plaintiffs assert that there are no acceptable non-infringing substitutes because the FDA-approved label indications for Repatha® and Praluent® limit the patient population to those on "maximally tolerated statin therapy." According to plaintiffs, "[b]y definition, statins could not be a substitute because these patients were already maxed out on statins and still needed additional LDL-lowering." (D.I. 252) Defendants counter that, consistent with *Slimfold Mfg. Co. v. Kinkead Indus.,* 932 F.2d 1453, 1458 (Fed. Cir. 1991), statins should be considered acceptable non-infringing alternatives, unless plaintiffs can demonstrate that "consumers specifically want a [drug] with [the patented] advantages." Generally the evidence in dispute (whether physicians specifically want to use Repatha® with its

higher dosage) is relevant to the question posed in *Slimfold.* I agree with plaintiffs, however, that evidence of why physicians might not prescribe the higher dosage Repatha® will not include any reference to the FDA's suggested "concerns regarding very low LDL," given that Repatha® has been approved by the FDA as "safe and effective" for all the indications approved for Praluent®. Without knowing the specifics of the anticipated testimony, further discussion may be warranted.

United States District Judge