IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 15-839-RGA
	:	
HOSPIRA, INC.,	:	
	:	
Defendant.	:	

ORDER ON MOTIONS IN LIMINE

Amgen's MIL #1 is DENIED. I think the actual post-hypothetical negotiation facts can be considered by the jury to help it evaluate a reasonable royalty. Hospira's position is that such evidence, among other things, goes to show that the uncertainty it says would have been taken into account in the hypothetical negotiation is not fanciful. The fact that the FDA has not yet approved Hospira's product is also relevant to the safe harbor analysis. The probative value of such evidence, which I think is significant, is not substantially outweighed by any unfair prejudicial value, of which I think there is very little.

Amgen's MIL #2 is GRANTED in principle, which is to say that I will sustain objections to Hospira introducing evidence comparing the accused process to the prior art, to Amgen's commercial process, and to examples in the patent for the purpose of proving that the accused process does not infringe the claims or to show the meaning of "selectively eluting." I say "in principle," because the line between improper comparison and implicit comparison is to some extent unavoidable given the infringement, invalidity and damages issues that are going to be raised. Expert

testimony that examples in the specification and commercial embodiments bear on the plain and ordinary meaning of claim terms will suggest an improper literal infringement standard. *See Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1286 (Fed. Cir. 2002) ("[I]nfringement is to be determined by comparing the asserted claim to the accused device, not by comparing the accused device to the figures of the asserted patent."); *Int'l Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 772 (Fed. Cir. 1993) ("[I]nfringement is determined on the basis of the claims, not on the basis of a comparison with the patentee's commercial embodiment . . . ."). An expert may not argue claim construction to a jury, and the defendant may not establish non-infringement by comparing specification or commercial embodiments to the accused products. Nor are a defendant's experts permitted to support their explanations of plain and ordinary meaning with evidence of the specification and commercial embodiments.

"At trial, parties may introduce evidence as to the plain and ordinary meaning of terms not construed by the Court to one skilled in the art, so long as the evidence does not amount to arguing claim construction to the jury." *MediaTek inc. v. Freescale Semiconductor, Inc.*, 2014 WL 971765, at *4 (N.D. Cal. Mar. 5, 2014) (alterations and emphasis omitted).[1] The question, then, is whether experts' testimony about the plain and ordinary meaning of claim terms supported by reference to specification and commercial embodiments would necessarily constitute impermissible claim construction or suggest an improper literal infringement standard. Testimony that embodiments in a patent specification support an expert's opinions regarding the plain and ordinary

[1] *MediaTek inc.* is the most thoughtful case I have seen dealing with this issue. It is a difficult issue because anything that could be presented to a jury to assist its understanding of the plain and ordinary meaning can also be (and often is) presented to the court at a claim construction hearing.

meaning of claim terms would amount to claim construction and suggest that literal infringement can be established by a comparison between accused products and specification embodiments.[2] *See id.* at *5 (excluding expert testimony as arguing claim construction to the jury where the expert "relie[d] heavily on the prosecution history, specifications, and even provisional applications to explain and expound upon a specific meaning and/or requirements of the terms identified"); *Catalina Lighting, Inc.*, 295 F.3d at 1286. Testimony that commercial embodiments support an expert's opinions regarding the plain and ordinary meaning of claim terms would suggest that literal infringement can be established by a comparison between accused products and commercial embodiments. *See Int'l Visual Corp.*, 991 F.2d at 772; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1339 (Fed. Cir. 2005) (rejecting claim interpretation based on commercial embodiment). Suggesting, incorrectly, that literal infringement can be established by comparing accused products with specification or commercial embodiments would risk unfair prejudice that would substantially outweigh the probative value of testimony regarding the plain and ordinary meaning of claim terms bolstered by reference to specification and commercial embodiments.

Hospira's experts are therefore precluded from testifying that specification and commercial embodiments support their views regarding the plain and ordinary meaning of "selectively eluting."[3] Certainly, Hospira is precluded from arguing a meaning to the

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[2] An expert's testimony that a patent's prosecution history supports his or her understanding of the plain and ordinary meaning of a claim term would likewise amount to arguing claim construction to the jury. *See Apple, Inc. v. Samsung Elecs. Co.*, 2014 WL 660857, at *5 n.3 (N.D. Cal. Feb. 20, 2014) ("Although [the expert's] reliance on the prosecution history to confirm his plain and ordinary meaning opinion is appropriate, the Court will not allow him to testify about that prosecution history because it would confuse the jury and prejudice [the patent owner], and such evidence is not relevant to how a person of ordinary skill in the art reading the specification would understand that term.").

[3] Of course, Amgen's experts also cannot do what Hospira's experts cannot do.

jury through its expert that it could have argued to the Court in the context of claim construction, as that truly would be "arguing claim construction to the jury." Although Hospira's experts are precluded from testifying that specification and commercial embodiments support their views regarding the plain and ordinary meaning of claim terms, they are not precluded from making any reference whatsoever to patent specifications and commercial embodiments. Should Hospira's experts refer to specification or commercial embodiments in the course of their testimony regarding the plain and ordinary meaning of claim terms, the determination whether the testimony amounts to claim construction will have to be made on an objection by objection basis in the context of the trial.

Whether an expert may testify that extrinsic evidence supports his or her testimony regarding the plain and ordinary meaning of claim terms is context dependent. *See MediaTek inc.*, 2014 WL 971765, at *5. Hospira's experts are not *per se* prevented from testifying that their views regarding the plain and ordinary meaning of claim terms are supported by dictionary definitions, textbooks, product guides, prior art references, or the testimony of persons of skill in the art (including inventors of the asserted patents). Upon objection by either party at the appropriate time, such testimony will be excluded if, in context, it amounts to claim construction or compares accused products to embodiments to establish non-infringement.[4]

Amgen's MIL #3 is DENIED. To the extent Amgen opens the door by presenting evidence about historical events, Hospira can bring up patents that were issued, are not

[4] As an example, an inventor's answer to the question "what do you understand 'x' to mean?" is not claim construction. An inventor's answer to the question "what did you mean when you referred to 'x' in the patent?" is claim construction.

the patents-in-suit, and which have now expired. Hospira should understand that it cannot bring up expired patents to argue (or hint at) that Amgen is doing something unethical, immoral, illegal, or predatory, in obtaining and/or asserting later-expiring patents. The jury should understand which inventions the patents-in-suit relate to, and that other patents do not cover the accused products. The probative value of this evidence is not substantially outweighed by any unfair prejudicial value, although I do recognize that the potential for unfair prejudicial value exists. Hospira is advised to tread carefully.

Hospira's MIL #1 is mostly DISMISSED as moot, in view of Amgen's representations that it will not use prior litigation with others for any purpose in front of the jury other than by Dr. Heeb in connection with comparability analysis of the Amgen/Roche settlement. And Hospira seems to agree that such use is appropriate. It seems to me like there is still room for dispute between the parties as to what exactly Dr. Heeb can say. Absent some detailed proffer of Dr. Heeb's testimony submitted as permitted at the pretrial conference, Amgen is prohibited from saying anything about the Amgen/Roche litigation other than the fact that it existed.

Hospira's MIL #2 is DENIED. The probative value of the expert's use of dot-blot test results to prove literal infringement is a question for the jury. *Amgen Inc. v. F. Hoffmann-La Roche Ltd*, 580 F.3d 1340, 1385 (Fed. Cir. 2009). The probative value is not substantially outweighed by any unfair prejudice. Indeed, I do not see any potential for prejudice or confusion.

Hospira's MIL #3 is DENIED. The documents in question were signed off by the CEO of Hospira, while he was CEO and within the scope of his employment relationship.

The documents are statements of a party-opponent. *See* Fed. R. Evid. 801(d)(2)(D). I do not see a basis under Rule 403 to exclude them. If they do not mean what they say, Hospira is welcome to put on evidence addressing that point.

IT IS SO ORDERED this 11 day of September 2017.

Richard G. Andrews
United States District Judge