

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD;)	
ROCHE DIAGNOSTICS GmbH; and)	
HOFFMANN-LA ROCHE INC.,)	
)	
Defendants.)	
_____)	

**DEFENDANTS' OBJECTIONS TO AMGEN'S PROPOSED
PRE-TRIAL JURY INSTRUCTIONS**

Defendants, F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche") hereby object to the pre-trial jury instructions set forth in the Pre-Trial and Post-Trial Jury Instructions Proposed by Amgen Inc. (D.N. 918).¹ Roche has proposed its own pre-trial jury instructions for the Court's consideration (D.N. 947).

The purpose of preliminary instructions is merely to offer the jury an objective and impartial overview of what they will be asked to do in this case. Amgen's proposed preliminary instructions are structured to be extremely argumentative and not at all impartial. Roche fashioned its proposed preliminary instructions from prior instructions this Court gave to other juries in patent cases. Amgen's instructions do not appear to follow this Court's prior instructions. There are several legal misstatements in Amgen's

¹ Roche will object to Amgen's post-trial jury instructions prior to the close of evidence.

proposed preliminary instructions. For example, Amgen would have this Court tell the jury that Lin personally must have committed inequitable conduct (as opposed to any of Amgen's representatives or prosecuting attorneys) (p. 17), that prior art is confined to a narrow set of publicly known documents (p. 14-15), and that Amgen sells its product under the protection of the patents-in-suit, when Amgen well knows that a patent does not give one the right to do anything, rather to preclude others (p. 11). Moreover, Amgen peppers the instructions that it would have the Court give with words such as the patents "describe" this or that, while that is an issue for the jury to decide. *Id.* Several of the legal explanations in Amgen's proposed instruction are inaccurate or omit defenses and theories advanced by Roche. In short, there is no balance or fair representation in Amgen's proposed preliminary instructions, including for the reasons set forth below. Roche respectfully requests that the Court not give Amgen's instructions and rather instruct the jury as indicated in Roche's preliminary instructions (D.N. 947).

1. Objection to Instruction VII (Stating that the Court has Already Determined that Roche Infringes the '422 Patent)

Roche objects to Amgen's request that the Court instruct the jury that the Court has already determined that Roche has infringed the '422 patent.² Amgen's Proposed Instructions, page 11. This statement is both inaccurate and highly prejudicial. In granting summary judgment that Roche infringed Claim 1 of the '422 patent, the Court did not consider (as Amgen did not seek summary judgment on) Roche's safe harbor

² Roche has also moved *in limine* to preclude Amgen from making this statement to the jury (D.N. 927).

defense pursuant to 35 U.S.C. §271(e)(1).³ If the safe harbor exception to infringement applies, because the jury determines that Roche's activities were in furtherance of Roche's efforts to secure FDA approval, Roche will not infringe the '422 patent. Thus, Amgen's proposed statement is wrong as a matter of law.

Moreover, the jury will be irrevocably prejudiced if it is informed that the Court has determined that Roche infringes the '422 patent, as the jury will regard Roche as an "infringer" who has committed an unlawful act, and therefore probably committed additional unlawful acts. Such an instruction is particularly misleading as the validity of this claim is very much still in issue, and one cannot be found to infringe an invalid claim. Indeed, evidence of prior illegal or wrongful acts is recognized as so prejudicial that it is regularly excluded under FRE 404(b), subject to narrow exceptions not present here. In this case, the prejudicial effect will be greatly compounded by the pronouncement of infringement coming directly from the Court itself—to whom the jury will naturally afford great deference as the highest authority in the courtroom—as the jury will believe that the Court has "taken sides" as between the parties.

As numerous cases have recognized, the Court holds great sway and influence with the jury. Any indication by the Court one way or another on a contested issue could inadvertently influence the jury's thinking.⁴ Juries rightly view the Court as neutral

³ Court Order dated August 28, 2007, granting in part [509] Amgen's motion for summary judgment as to infringement of the '422 patent (but not addressing safe harbor issue). Roche reserves the right to object to and/or appeal the Court's ruling.

⁴ *Owens v. United States*, 483 F.3d 48, 67 (1st Cir. 2007), quoting *Quercia v. United States*, 289 U.S.466, 470 (1933) ("The influence of the trial judge on the jury is necessarily and properly of great weight and his lightest word or intimation is received with deference, and may prove controlling."); *Crowe v. Di Manno*, 225 F.2d 652, 655 (1st Cir. 1955), citing *Starr v. U.S.*, 153 U.S. 614, 626 (1894) ("The influence of the trial

between two disagreeing sides and any words or findings by the Court can dramatically influence the jury.⁵

An instruction that the jury must consider infringement of each patent independently and should not be influenced by the Court's prior determination on the '422 patent is plainly inadequate to avoid prejudice to Roche, as they would be insufficient to overcome the jury's perception that the Court regards Roche as an infringer. *See Mendenhall v. Cedarrapids, Inc.*, 5 F.3d 1557, 1573-5 (Fed. Cir. 1993) (affirming trial court's exclusion of prior decisions on infringement and validity as unfairly prejudicial due to jury's tendency to follow those decisions on infringement and validity decision presently before the jury); *United States v. Filani*, 74 F.3d 378, 386 (2d Cir. 1996) (“[T]he presiding judge cannot ... foster the notion that the judge believes one version of an event and not another. Curative instructions to the jury ... do not remove such an impression once it is created.”).

2. Objection to Instruction VII (Providing Overview of Infringement Without Reference to Material Change or Safe Harbor Defenses)

Roche objects to Amgen's proposed pre-trial jury instruction providing an overview of the law of infringement, but without mentioning that the jury must decide whether the safe harbor defense for FDA approval applies, and whether MIRCERA[®] is materially changed prior to its importation into the United States. Amgen's Proposed Instructions, pages 12-13. These are critical issues in this case, and should be addressed

judge on the jury 'is necessarily and properly of great weight' and 'his lightest word or intimation is received with deference, and may prove controlling.'”).

⁵ *Logue v. Dore*, 103 F.3d 1040, 1045 (1st Cir. 1997) (“the judge's participation must be balanced; he cannot become an advocate or otherwise use his judicial powers to advantage or disadvantage a party unfairly”).

in an pre-trial infringement instruction. Roche requests the Court to give Roche's pre-trial instruction on infringement, filed separately herewith, which fully and accurately addresses the issues to be decided by the jury. Roche's Preliminary Instruction No. 5 (D.N. 947).

3. Objection to Instruction VIII (Reiteration of "Presumed Valid" and "Clear and Convincing Evidence" Dozens of Times in Validity Instructions)

Amgen asks the Court to tell the jury that Amgen's patents are "presumed valid" and that Roche must prove invalidity by "clear and convincing evidence" literally dozens of times. Amgen's Proposed Instructions, pages 14-16. Such a repetitious instruction would be highly inappropriate, as it elevates one issue among many to the jury and improperly suggests that the Court that Roche will not be able to meet its burden. Roche's own instruction on validity sets forth the standard accurately and is fair and balanced. Roche requests that the Court give Roche's proposed pre-trial instruction on this issue. Roche's Preliminary Instruction No. 4 (D.N. 947).

4. Objection to Instruction VIII (Inequitable Conduct Must Have Been Committed by Dr. Lin Personally)

Amgen's proposed pre-trial instructions suggest that Dr. Lin himself, or his own personal attorney, must have committed inequitable conduct in order for Roche to prevail on this defense. Amgen's Proposed Instructions, page 17. This is plainly wrong, as inequitable conduct by any of Amgen's representatives or prosecuting attorneys will render the patents-in-suit unenforceable. Amgen's attempt to narrow the scope of inequitable conduct and personalize it to Dr. Lin must be rejected. Roche's proposed pre-trial instruction on inequitable conduct is accurate, and should be adopted. Roche's Preliminary Instruction No. 6 (D.N. 947).

5. Objection to Instructions VII and VIII (Organization of Instructions and Characterization of Roche's Contentions)

Roche objects to Amgen's proposed pre-trial jury instructions to the extent that they are organized according to the contentions of the parties (with Amgen's contentions regarding infringement presented first), rather than according to the issues that the jury is being asked to decide, namely, patent validity, infringement and inequitable conduct (in that order). Amgen's proposed instructions do not accurately set forth the parties' contentions. In addition, Amgen's proposed instructions on Roche's invalidity positions do not accurately reflect the law on these theories. This Amgen proposal as to legal issues is likely to confuse the jury who will be instructed on the law by the Court at the conclusion of the trial. For example, many of Roche's contentions are missing (*e.g.*, safe harbor, material change), inaccurate (*e.g.*, defining prior art too narrowly) or are presented in such a biased and argumentative manner as to be prejudicial (*e.g.*, "Roche also asserts even if it does infringe, it does not matter...."). Amgen's Proposed Instructions, pages 14-16. In any event, it is not necessary for the Court to explain the parties' contentions except in the context of patent validity, infringement and inequitable conduct. Roche's proposed instructions are more appropriate, and should be adopted by the Court.

6. Objection to Instructions V and VI (Parts of a Patent and Significance of Patent Claims)

Finally, Roche objects to the portions of Amgen's proposed pre-trial jury instructions addressing the parts of a patent and the significance of patent claims, as they contain numerous inaccuracies. For example, Amgen's instructions assert (twice) that the cited prior art references were actually "considered" by the patent examiner, which is of course not necessarily the case, especially where, as here, many thousands of pages

were submitted. In addition, Amgen's characterization of "prior art" is much too narrow. Roche's proposed instructions as to the parts of a patent are accurate and consistent with the pre-trial instructions this Court has given in other patent cases, and should be adopted by the Court. Roche's Preliminary Instruction No. 3 (D.N. 947).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court decline to adopt Amgen's proposed pre-trial jury instructions and instead give Roche's proposed pre-trial instructions, filed separately.

Dated: September 3, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH,
and HOFFMANN-LA ROCHE INC.

By their attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non registered participants on September 4, 2007.

/s/ Julia Huston

Julia Huston