

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
)	Civil Action No.: 1:05-CV-12237 WGY
v.)	
)	
F. HOFFMANN-LA ROCHE LTD, a)	
Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LA ROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**AMGEN INC.’S OBJECTIONS TO DEFENDANTS’
[PROPOSED] PRE-TRIAL JURY INSTRUCTIONS**

Plaintiff, Amgen Inc., hereby objects to the pre-trial jury instructions set forth in the Pre-Trial Jury Instructions proposed by Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”).

Amgen generally objects to Roche’s preliminary jury instructions on the following grounds:

1. The instructions are not impartial and objective;
2. The instructions contain misstatements of law;
3. The instructions omit or mischaracterize Amgen contentions;
4. The instructions misstate Roche’s contentions;
5. The instructions omit reference to prior adjudications of this Court that are material to the issues the Jury must resolve; and
6. The instructions do not closely conform to the model instructions that are cited by Roche.

For these reasons and the reasons set out below, Amgen respectfully requests that this Court not give Roche’s preliminary instructions to the Jury. In contrast, Amgen’s Preliminary

Instructions closely follow the Federal Circuit Bar Association Model Jury Instructions and should be given.

I. OBJECTION TO INSTRUCTION 1 (STATING THE PTO MAKES MISTAKES)

Amgen objects to Roche's request that the Court instruct the Jury that the United States Patent Office makes mistakes. Roche's proposed "Overview" instruction states "Sometimes the Patent Office makes a mistake." (p. 3.) This instruction misstates the law in a manner prejudicial to Amgen because it undermines the presumptions enjoyed by the patents-in-suit.

Patents are presumed valid by statute. 35 U.S.C. §282. In addition, when prior art and/or invalidity arguments are considered by the Patent Office a patent enjoys an additional presumption that the examiner has correctly addressed these issues. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Roche's proposed instruction improperly seeks to undermine these presumptions with an instruction given by the Court as a matter of law. This instruction would prejudicially undermine these two presumptions for Amgen's Patents.

II. OBJECTION TO INSTRUCTION 2

Amgen objects to this proposed instructions because it is not impartial and objective. Roche's instruction discusses infringement and explains it's noninfringement arguments in detail. (p. 5.) In contrast, when Roche's instruction discusses invalidity it does not even state that Amgen claims the patents are valid, let alone provide an explanation of Amgen's validity defenses (e.g., the Patent Office judges validity in the first instance). (*Id.*) Similarly, Roche's instruction discusses inequitable conduct, but again does not state that Amgen disagrees, or the reasons for that disagreement. (*Id.*)

III. OBJECTION TO INSTRUCTION 3

Amgen objects to this proposed instruction because it prejudicially and erroneously states the law. These prejudicial and erroneous statements include:

- Claims describe "what the applicant believed was its exact invention." (p. 7.)

Claims are allowed by the Patent Office for inventions it determines are novel, nonobvious, and properly supported by the specification. Roche's instruction to the contrary states that claims cover what an applicant (not the inventor) *believes* is the invention.

- “You have to teach the world how to do what you do. The different parts of the patent go to the teaching of the patent.” (*Id.*)

This instruction over-emphasizes the enablement requirement and fails to state what it is that must be enabled, the presumption of enablement, and the test of enablement. The specification of the patent has to teach *one of skill in the art* how to make and use the *claimed* invention.

- The abstract, drawings and specification show “what the inventors believe they invented.” (*Id.*)

Roche attempts to undermine and down-play the role of the Patent Office by improperly implying that the patent only contains what the inventors *believe* they invented, rather than containing a description that the Patent Office has determined meets the statutory requirements for the claimed inventions. This instruction also directs the Jury to read the abstract to determine what was invented.

IV. OBJECTION TO INSTRUCTION 4

Amgen objects to this proposed instruction because it is arbitrary and subjectively unfair, and it prejudicially and erroneously misstates the law. Compared to Roche Preliminary Instruction 5, this instruction is arbitrary and unfair. Roche's Preliminary Instruction 5 states upfront Amgen's burden of proof on infringement and explains that burden (more likely than not). Roche's Preliminary Instruction 4 does not state its burden of proof until then end (on the second page) and does not describe that burden. (pp. 8-9.) In addition, Roche's Preliminary Instruction does not inform the Jury that Amgen asserts its claims are valid, nor are the reasons for Amgen's assertion of validity described.

Roche's Preliminary Instruction 4 improperly states the law because Roche states that:

- Amgen's claims are obvious because ". . . others were already using things so similar to Amgen's invention . . ."

Roche is prejudicially misleading the Jury by stating their allegation of obviousness as the standard for obviousness.

- Amgen's claims are invalid under 35 U.S.C. §112, first paragraph, because ". . . the claims are overbroad and deficient because they do not adequately describe claimed invention or teach the world how to make the invention . . ."

Again, Roche is misleading the Jury by stating their allegation of invalidity as the standard.

- Roche misnames its obviousness-type double patenting allegation as "double patenting," and the instruction fails to state that the Jury must first determine whether a claim from an earlier issued patent is prior art.

This step is skipped and it is presumed that the claims asserted by Roche are prior art.

V. OBJECTION TO INSTRUCTION 5

Amgen objects to this proposed instruction because it is arbitrary and subjectively unfair, and it prejudicially and erroneously misstates the law. This instruction is arbitrary and unfair when compared with Roche's Preliminary Instructions 4 and 6. This Preliminary Instruction sets out at the beginning, Amgen's burden of proof with an explanation of that burden. (p. 10.) Roche's Preliminary Instructions 4 and 6, do not describe Roche's burden of proof on invalidity or inequitable conduct until the second page of each Preliminary Instruction. (pp. 9, 14.) In addition, Roche's Preliminary Instruction tells the Jury ". . . Roche's product, called MIRCERA®, is approved for sale outside the United States, but is pending approval for sale in the United States." (p. 10.) The sale of MIRCERA® outside of the United States is irrelevant to this lawsuit.

Roche's Preliminary Instruction 5 makes the following misstatements of the law:

- Roche wants this Court to instruct the Jury that MIRCERA® will not infringe if it falls within the safe-harbor of 35 U.S.C. §271(e)(1). Roche asserts this allegation

even as to the already adjudicated finding of infringement on claim 1 of the '422 Patent.

This instruction is improper under the law because this Court has already determined that Sec. 271(e)(1) does not attach to Amgen's declaratory judgment action. Roche is improperly seeking to relitigate this issue in violation of principles of law of the case and *stare decisis*.

- Roche wants this Court to instruct the Jury that MIRCERA® can escape infringement under the Reverse Doctrine of Equivalents. Roche asserts this allegation even as to the already adjudicated finding of infringement on claim 1 of the '422 Patent.

This instruction is improper because Roche cannot relitigate this Court's finding of infringement of claim 1 of the '422 Patent under principles of law of the case, waiver, and *stare decisis*.

- Roche wants this Court to instruct the Jury that MIRCERA® will not infringe if has been materially changed from the claimed subject matter.

Roche's Preliminary Instruction improperly seeks to confuse the Jury into applying the "materially changed" test to Amgen's composition claims. Roche's Preliminary Instruction also is intentionally vague on what is to be compared in the materially changed test. A proper instruction would tell the Jury that it must first determine whether the EPO in MIRCERA® is made by Amgen's patented methods. Second, the instruction would tell the Jury to determine whether that EPO product has been materially changed by the subsequent processes performed by Roche.

VI. OBJECTION TO INSTRUCTION 6

Amgen objects to this proposed instruction because it is arbitrary and subjectively unfair, and it prejudicially and erroneously misstates the law. This instruction is arbitrary and unfair when compared with Roche's Preliminary Instruction 5 for the reasons stated above.

Roche's Preliminary Instruction 5 makes the following misstatements of the law:

- Roche's Preliminary Instruction states "The Examiner has only a limited amount of time and resources available and, therefore, must rely on information provided by applicant with respect to the technical field of the invention and the prior art." (p. 13.)

This statement is objectionable because it improperly undermines the presumption of validity and the presumption and examiner properly does their job when they expressly consider issues of patentability during prosecution. In addition, this portion of the Preliminary Instruction is objectionable because it misleads the Jury regarding the duty of the examiner to search for prior art. The Manual of Patent Examination Procedures requires that examiners conduct searches for prior art. (MPEP 900 et seq.)

- Roche's Preliminary Instruction states ". . . the Patent Examiner cannot . . . confirm scientific data submitted by the applicant." (*Id.*)

This statement is not true for the examiners in the Biotech Art Groups for most have advanced degrees and are capable of assessing scientific evidence placed before them. For example, the examiner who issued each of the patents-in-suit, Senior Level Examiner James Martinell, had a Ph.D.

- Roche's Preliminary Instruction states that "Amgen" is subject to the duty of candor and good faith. (*Id.*)

Only real persons are subject to the duty of candor. *See Bruno Independent Living Aids Inc. v. Acorn Mobility Services Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005). Corporations are not.

- Roche's Preliminary Instruction also states that the "burying" of references can violate the duty of candor and good faith. (*Id.*)

This portion of the Preliminary Instruction is in conflict with Federal Circuit authority. The Federal Circuit rejected this exact allegation when references are submitted to the PTO on form 1449, and the examiner initials those references. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).

VII. CONCLUSION

For the reasons stated above, Amgen respectfully requests that the Court give Amgen's preliminary jury instructions that are set forth in Amgen's Pre-Trial and Post-Trial Jury Instructions (D.N. 918).

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

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/s/ Michael R. Gottfried

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