

**IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF MASSACHUSETTS**

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

**AMGEN’S BENCH MEMORANDUM IN SUPPORT OF PROPOSED JURY
INSTRUCTION FOR INEQUITABLE CONDUCT**

Amgen requests the Court provide the jury with the attached jury instruction on inequitable conduct, as set forth in Exhibit A hereto. This instruction is in accord with the applicable law on inequitable conduct.¹

In order to prove that a patent is unenforceable due to inequitable conduct, a party must show that the applicant (or his legal representative), with intent to mislead or deceive the Patent Office, failed to disclose to the Patent Office material, non-cumulative information known to the applicant (or his legal representatives) to be material, or submitted materially false information to the Patent Office in arguing for the patentability of a claim.² The party asserting inequitable conduct must prove threshold levels of both materiality and intent by clear and convincing

¹ By submitting this instruction, Amgen does not waive its long-standing objection to the issue of inequitable conduct being considered by the jury. Inequitable conduct is an equitable matter to be decided by the Court, and Amgen maintains its objection to the jury hearing this issue (as well as its position that in this case Roche is not entitled to jury trial on the issues of validity or infringement either). See Amgen’s Motion and Supporting Memorandum Requesting This Court Try Roche’s Inequitable Conduct Defenses.

² *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330-31 (Fed. Cir. 2004); 37 C.F.R. § 1.56.

evidence,³ keeping in mind that an otherwise material reference is not material for the purposes of inequitable conduct if it is merely cumulative of information already before the Patent Office.⁴

Further, intent to deceive cannot be inferred solely from the fact that information was not disclosed—there must be a factual basis for a finding of deceptive intent.⁵ Nor can intent to deceive be inferred from materiality, which is “a separate and essential component of inequitable conduct.”⁶ If the Court determines that both the threshold levels of materiality and intent were achieved, then the Court must balance materiality and intent, “with a greater showing of one factor allowing a lesser showing of the other.”⁷

The mere submission of references to the PTO satisfies the duty of disclosure and is not considered impermissible “burying.”⁸ Where the duty of disclosure is deemed satisfied, no inquiry into intent is necessary.⁹ A prior art disclosure which places a reference before the PTO at an opportunity for submission is not inequitable conduct; instead, it suggests a *lack* of intent to deceive the PTO.¹⁰ The applicable case law makes clear that, as long as the reference at issue is before the examiner, even if submitted without explanation and with a number of other references, the duty of disclosure is not violated except where the reference is being submitted to correct a past misstatement (which is not the case here and thus no instruction on this point is

³ *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984).

⁴ *Molins PLC*, 48 F.3d at 1179 (citing *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991)).

⁵ *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996) (quoting *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988)).

⁶ *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir.1990); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 439 F.3d 1335, 1340-41 (Fed. Cir. 2006).

⁷ *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001).

⁸ See *Fiskars*, 221 F.3d at 1327.

⁹ *Id.* at 1326.

¹⁰ *Id.* at 1327.

necessary).¹¹

Amgen's duty of candor is satisfied by the disclosure of prior art to the PTO. In *Molins v. Textron*, which is the primary authority discussing "burying" in the context of inequitable conduct, the patentee discovered and submitted a long listing of relevant prior art *after* a patent issued, but had not pointed out why that prior art was relevant. The challengers argued that this conduct amounted to "burying," and therefore showed intent to deceive the PTO.¹² But the court held that the method of disclosure was not inequitable conduct: "when a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it cannot be deemed to have been withheld from the examiner."¹³ The reference was disclosed, so the court refused to infer intent to deceive the PTO.

Five years later, in *Fiskars v. Hunt*, prior art was cited in an initial submission but a challenger claiming inequitable conduct argued that a particularly relevant reference should have been highlighted for an examiner who did not consider it.¹⁴ The Federal Circuit dismissed that argument and reiterated that:

When a reference was cited to the patent examiner it cannot be deemed to have been withheld [from the examiner]... An applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner...An applicant is not required to tell the PTO twice about the same prior art, on pain of loss of the patent for inequitable conduct.¹⁵

¹¹ See, e.g., *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1567 (Fed. Cir. 1983) ("the pertinent inquiry is whether the Examiner received complete and accurate information during prosecution within sufficient time to act upon it before he allowed the claims"); see also *eSpeed Inc. v. BrokerTec USA LLC*, 417 F. Supp. 2d. 580, 598 (D. Del. 2006) *aff'd* on other grounds, 480 F.3d 1129 (Fed. Cir. 2007).

¹² *Molins PLC*, 48 F.3d at 1184.

¹³ *Id.*

¹⁴ *Fiskars*, 221 F.3d at 1326-1327.

¹⁵ *Id.* (citing *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (finding that inequitable conduct could not be based on an applicant's failure to cite a prior art reference when the examiner independently cited the same reference)).

Roche's "burying" argument could not support Roche's claim of inequitable conduct since the Federal Circuit has made it clear that providing a reference to the examiner, even among other references, cannot support a claim of inequitable conduct. To satisfy the duty of disclosure, the applicant need not explain to the examiner the relevance of a particular piece of prior art, or otherwise take steps to ensure that the examiner actually considers those references that have been submitted. Roche's references to "burying" prior art during the inequitable conduct phase will confuse the jury and unfairly prejudice Amgen.¹⁶

Finally, legal arguments to the Patent Office cannot form the basis of an inequitable conduct claim.¹⁷ In *Akzo* the defendants claimed that the applicant committed inequitable conduct by arguing that his invention was not anticipated by two prior art references.¹⁸ The Federal Circuit rejected defendants' inequitable conduct claim, ruling that:

We uphold the Commission's findings and conclusion that Du Pont's affidavit or *arguments before the examiner did not constitute material misrepresentations*. As Akzo concedes, the examiner had both the Morgan '645 patent and the Kwolek '542 patents before him throughout the examination process. It was on the basis of these two patents that Du Pont's first three applications were rejected. *The mere fact that Du Pont attempted to distinguish the Blades process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the Blades process based on the art in front of him.*¹⁹

For the above reasons, the Court should provide the submitted jury instruction attached hereto at attachment A and referenced in Amgen's revised jury instructions, submitted herewith.

¹⁶ See, e.g., *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1567 (Fed. Cir. 1983); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

¹⁷ *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1481 (Fed. Cir. 1986); *Environ Prods., Inc. v. Total Containment, Inc.*, 951 F. Supp. 57, 61 (E.D. Pa. 1996); see also *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F.Supp.2d 362, 393 (S.D.N.Y. 2000).

¹⁸ *Akzo*, 808 F.2d at 1482. See also, *Environ Prods.*, 951 F. Supp. at 61 ("There is no policy reason which would support the unprecedented expansion of the interpretation of 'material information' to include legal arguments.").

¹⁹ *Id.*

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (ECF) system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Michael R. Gottfried

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