

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

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE, Ltd, ROCHE
DIAGNOSTICS GmbH and HOFFMANN-LA
ROCHE INC.,

Defendants.

Civil Action No. 05-12237 WGY

U.S. District Judge Young

**OPPOSITION TO AMGEN'S BENCH MEMORANDUM IN SUPPORT OF
PROPOSED JURY INSTRUCTION FOR INEQUITABLE CONDUCT (D.I. 1323)**

I. INTRODUCTION

Amgen's explanation of the legal standards regarding inequitable conduct is hopelessly incomplete and invites reversible error. Indeed, Amgen again ignores precedential case law and the sections of the Manual of Patent Examination Procedure (M.P.E.P.) directly on point, instead, cherry-picking cases that are inapplicable to the facts here. Indeed, the arguments now raised by Amgen (D.I. 1323) in support of its proposed jury instruction (D.I. 1323-2) is a rehash of the same failed arguments set forth in Amgen's summary judgment briefing. There, this Court properly rejected Amgen's contention that the applicable law could not support a finding of materiality or intent. Here, Amgen seeks a highly prejudicial jury instruction that effectively removes Roche's inequitable conduct defense from the finder of fact and circumvents this Court's previous ruling that, as a matter of law, there are facts to support both a finding of materiality and intent.

II. ARGUMENT

Amgen incorrectly asserts that inequitable conduct can only be proven by failure to disclose material information or by submission of materially false information to the Patent Office in arguing for the patentability of the claim. (D.I. 1323 at 1). This statement is erroneous for a number of reasons.

First, a violation of the duty of disclosure, candor and/or good faith-- which leads to inequitable conduct -- is not negated by mere submission of information to the Patent Office. Recently -- *i.e.* after the cases relied upon by Amgen -- the Federal Circuit made clear that mere submission of information is not a defense against inequitable conduct where an applicant buries material information or presents the information in a manner so that the examiner would be likely to ignore it and permit the application to issue as a patent *eSpeed Inc. v. BrokerTec USA LLC*, 480 F.3d 1129, 1138 (Fed. Cir. 2007). Amgen argues, however, this case stands merely for the proposition that “burying” can only occur if the “reference is being submitted to correct a past misstatement.” (D.I. 1323 at 2). This is wrong. In *eSpeed*, the Federal Circuit upheld the district court’s finding of inequitable conduct because, despite submitting the relevant material information to the examiner, “the ‘blizzard of paper’ submitted to the PTO... left the examiner with the impression that the examiner did not need to conduct any further ... investigation.” *eSpeed*, 480 F.3d at 1137. *See also Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co. Inc.*, 24 USPQ2d 1801 (N.D. Ind. 1992) *aff’d*, 11 F.3d 1072 (Fed.Cir. 1993) (“it is likewise a violation of the duty of candor and fair dealing with the Patent Office for an applicant or its attorney to disclose a pertinent prior art patent reference to the examiner in such a way as to ‘bury’ it ... so that the examiner would be likely to ignore the entire list and permit the application to issue.”).

This latest reminder by the Federal Circuit of the relevant law is completely consistent with the long-standing provisions of the M.P.E.P. regarding the duty of disclosure. The M.P.E.P. specifically instructs patent attorneys not to bury references because that behavior may lead to charges of inequitable conduct. *See* MPEP § 2002.03 (5th ed. Rev. 3, May 1986) (“non-identification of an especially relevant passage buried in an otherwise less or non-relevant text could result in a holding of ‘violation of duty of disclosure’”).

Second, Amgen’s argument that art submitted to the Patent Office cannot be “buried” not only ignores the relevant case law cited above, it also presupposes that the relevant art was “before the examiner.” (D.I. 1323 at 2-3)¹. Amgen, however, ignores those parts of Roche’s inequitable conduct argument that, in some instances, Amgen may have submitted information to one branch of the PTO, but not to the Examining Corp which is charged with issuing the patents-in-suit. Pursuant to the Code of Federal Regulations, an applicant must disclose material information directly to the examiner to discharge the duty of good faith and candor and the duty of disclosure. *See* 37 CFR 1.4(b) (“Since each file must be complete in itself, a separate copy of every paper to be filed in a patent application, patent file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical.”); 37 CFR 1.4(c) (“Since different matters may be considered by different branches or sections of the United States Patent and Trademark Office, each distinct subject, inquiry or order must be contained in a separate paper to avoid confusion and delay in answering papers dealing with different subjects.”). It is not enough that the applicant submit relevant information to another, separate branch of the PTO (such as the Board of Patent Appeals

¹ *Citing Fiskars, Inc. v. Hunt Mfg.*, 221 F.3d 1318, 1326-1327 (Fed. Cir. 2000) and *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

and Interferences), yet not disclose the same material information to the examiner charged with potentially issuing the application as a patent. *See, e.g., Gen. Elec. Co. v. United States*, 206 USPQ 260, 280 (Ct. Cl. 1979); *A.B. Dick Co. v. Burroughs Corp.*, 617 F. Supp. 1382, 1397 (N.D. Ill. 1985), *aff'd* 798 F.2d 1392 (Fed. Cir. 1986); *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1377-81 (Fed. Cir. 2000).

Amgen erroneously contends that as a matter of law attorney argument cannot constitute inequitable conduct. (D.I. 1323 at 4). However, the case law is clear: legal arguments made by an attorney that are knowingly false breaches the duty of candor afforded the Patent Office. *See Semiconductor Energy Lab., Co. v. Samsung Elecs. Co.*, 24 F. Supp.2d 537, 542 (E.D. Va. 1998) (“where, as here, material misrepresentations are made in a position advocated to the PTO with intent to mislead, inequitable conduct does exist”), *aff'd* 204 F.3d 1368 (Fed. Cir. 2000); *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1379 (Fed. Cir. 2000) (patentee’s repeated arguments to Examiner that claims were entitled to benefit of earlier filing dates constituted “affirmative misrepresentation”); *A.B. Dick Co. v. Burroughs Corp.*, 617 F. Supp. 1382, 1393 (N.D. Ill. 1985) (counsel’s argument regarding relevance was “affirmatively misleading representation” cutting in favor of a finding of inequitable conduct), *aff'd* 798 F.2d 1392 (Fed. Cir. 1986). Furthermore, “[a]n applicant should know information is material when the examiner repeatedly raises an issue to which the information relates.” *Cargill Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007). In addition, by submitting a Petition to Make Special -- which Amgen successfully accomplished in prosecuting at least the ‘868 patent -- Amgen induced the examiner’s reliance on its arguments and representations. *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994).

With respect to Amgen's arguments regarding intent (D.I. 1323 at 2), the Federal Circuit has reiterated time and again that "[t]here is no requirement that intent to deceive be proven by direct evidence; in fact, it is rarely proven by such evidence." *eSpeed Inc. v. BrokerTec USA LLC*, 480 F.3d 1129, 1138 (Fed. Cir. 2007). Mere denials of intent to mislead may not be sufficient to overcome circumstantial evidence of intent to deceive. *LaBounty Mfg., Inc. v. United States Int'l Trade Comm.*, 958 F.2d 1066, 1076, 22 USPQ2d 1025, 1033 (Fed.Cir.1992). Thus, as a matter of law, the jury is entitled to infer intent from various factors, including:

- the materiality of a reference. See *Cargill Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359,1367 (Fed. Cir. 2007) ("We have never held that materiality is irrelevant to the question of intent"); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs.*, 394 F.3d 1348 (Fed. Cir. 2005) ("intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information");
- evidence that applicant could not have made the same patentability arguments had information been disclosed. See *LaBounty Mfg. v. United States ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992); *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379(Fed. Cir. 2006); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001);
- evidence that the patentee submitted material information to other entities, such as FDA. See *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989);
- burying material information. See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995)("Burying a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."); *eSpeed Inc. v. BrokerTec USA LLC*, 417 F. Supp. 2d 580, 598 (D. Del. 2006) (the "blizzard of paper is therefore more consistent with an intent to hide than to disclose");

Furthermore, "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997); *see also, e.g., Cargill Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007); *Ferring B.V. v. Barr*

Laboratories Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006); *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 2007 WL 1452731 (Fed. Cir. May 18, 2007).

III. CONCLUSION

For the foregoing reasons, Roche respectfully requests that this Court reject Amgen's proposed jury instruction XV (D.I. 1323-2), which is attached as Exhibit A to Amgen's bench memorandum.

DATED: October 10, 2007

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CERTIFICATE OF SERVICE

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