

INEQUITABLE CONDUCT

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INEQUITABLE CONDUCT

I. ABSOLUTE PLAGUE

The Federal Circuit has stated that "... the habit of charging inequitable conduct in almost every major patent case has become an absolute plague ..." (Kangaroos U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1576 (Fed. Cir. 1985)) and that inequitable conduct is not "a magic incantation [that should be] asserted against every patentee." FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).

"'Inequitable conduct' should not be, a magic incantation asserted against every patentee. Nor is that allegation established upon a mere showing that art or information having some degree of materiality was not disclosed. To be guilty of inequitable conduct, one must have intended to act inequitably. Thus, one who alleges a 'failure to disclose' form of inequitable conduct must offer clear and convincing proof of: (1) prior art or information that is material; (2) knowledge chargeable to applicant of that prior art or information and of its materiality; and (3) failure of the applicant to disclose the art or information resulting from an intent to mislead the [Patent and Trademark Office]."

FMC Corp., 835 F.2d at 1415. Inequitable conduct can be found where, with an intent to deceive, a patentee fails to disclose to the USPTO information material to patentability. *See, e.g.,* Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998); Molins PLC v. Textron, Inc., 48 F.3d 1172 at 1178 (Fed. Cir. 1995). When a defendant alleges that the patentee has withheld such material information, "there must be clear and convincing evidence that the applicant made a deliberate decision to withhold [the information]." Baxter Int'l, 149 F.3d at 1329 (citing Molins PLC, 48 F.3d at 1181).

II. LAW GOVERNING INEQUITABLE CONDUCT GENERALLY

Inequitable conduct renders issued patents unenforceable. *See, Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988), *cert denied*, 490 U.S. 1067 (1989). *See, Novo Nrodisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2005). To make this showing, the asserting party must show that the patent applicant intentionally misled or deceived the Patent Office on an issue that was material to patentability, Id. If the party asserting inequitable conduct makes a threshold

showing of both materiality and intent, the Court must then balance the level of materiality against the level of intent to determine if inequitable conduct occurred. *See, Purdue Pharma L.P.*, 438 F.3d 1123, 1128-29 (Fed. Cir. 2006).

III. LEGAL STANDARDS

The patent applicant and attorneys practicing before the Patent Office owe a duty to prosecute applications and to argue for patentability with candor, honesty, and in good faith, *Elk Corp. of Dallas v. GAF Building Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999); 37 C.F.R. § 1.56 (c) (2004). Failure to abide by this duty constitutes inequitable conduct, which can render a patent unenforceable, *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Inequitable conduct can result from a failure to disclose material information with an intent to mislead or deceive the Patent Examiner, *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998). Both materiality and intent are questions of fact that must be proven by the party charging inequitable conduct by clear and convincing evidence, *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1379 (Fed. Cir. 2002), that is, with a "firm belief or conviction that the matter sought to be established is highly probable and free from serious doubt," *Transclean Corp. v. Bridgewood Servs., Inc.*, 77 F. Supp.2d 1045, 1070 (D. Minn. 1999) (quoting *Maxwell v. K-Mart Corp.*, 880 F. Supp. 1323, 1329 (D. Minn. 1995)), *aff'd in part, vacated in part on other grounds*, 290 F.3d 1364 (Fed. Cir. 2002); *3M Innovative Properties Company v. Dupont Dow Elastomers LLC*, 361 F. Supp. 2d 958, 973-982 (D. Minn. 2005).

The Patent Office has established the following standard for materiality for applications filed after March 16, 1992:

"Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of unpatentability."

37 C.F.R. § 1.56 (b) (2004). The Federal Circuit has recently held that materiality should be evaluated under this amended rule for applications pending after the effective date of this amendment, Bruno Independent Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1352 (Fed. Cir. 2005).

The factual question of intent "rarely include[s] direct evidence of admitted deceitful conduct," GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001). Intent is instead more often proven by showing acts the natural consequence of which are presumed to be intended by the actor, Molins, 48 F.3d at 1180. In addition, assessment of the evidence of intent can operate on a sliding scale relative to materiality. In other words, the greater the showing of materiality, the more likely that intent can be presumed, Lifetechs, Inc. v. CloneTech Lab., Inc., 224 F.3d 1320, 1324 (Fed. Cir. 2000) ("the court must conduct a balancing test between the levels of materiality and intent, with the greater showing of one factor allowing a lesser showing of the other."); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1455 (Fed. Cir. 1984) ("a greater showing of materiality of withheld information would necessarily create an inference that its non-disclosure was wrongful."). Yet the mere withholding of material references is not enough to presume intent, Transclean Corp., 77 F. Supp.2d at 1090 (citing Hebert v. Lisle, 99 F.3d 1109, 1116 (Fed. Cir. 1996)). Rather, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive," Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988); *see also*, Id. at 873 (conduct must be "sufficient to require a finding of deceitful intent in light of all the circumstances"). Finally, it bears noting that the intent in question is an intent to deceive the Patent Office into issuing the patent, not merely the intent to do what was done in prosecution, Therma-Tru Corp. v. Peachtree Doors, Inc., 44 F.3d 988, 995 (Fed. Cir. 1995) ("intent ... does not mean that the inventor intended to do what he did in patent prosecution; it means that the inventor intended to deceive or mislead the examiner into granting the patent.").

Once the requisite showings of materiality and intent are made, the Court weighs those elements in light of the circumstances to determine whether the conduct is so culpable that the patent is unenforceable, GFI, Inc., 265 F.3d at 1273.

A. Materiality

An alleged infringer may contend that the materiality of withheld references is low because such references do not disclose a critical element of the patent(s). This distinction is not enough by itself to assign low materiality since the patentability of the claims over a withheld reference is not the standard. *See*, Molins, 48 F.3d at 1179; Gardco Mfg., Inc. v. Herst Lighting Co., 820 F.2d 1209, 1214 (Fed. Cir. 1987); AB. Dick Co. v. Burroughs Corp., 798 F.2d 1392, 1397 (Fed. Cir. 1986) ("the test for materiality is not whether there is anticipation or obviousness").¹

Such omitted references may be material because they refute or are inconsistent with arguments made by an applicant during prosecution. *See*, Bruno Independent Living Aids, Inc., 394 F.3d at 1352 (citing 37 C.F.R. § 1.56 (2004)).

A reasonable fact finder might find by clear and convincing evidence arguments made to overcome the claim rejections were material. *See*, Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003) ("whether [withheld] reference meets the threshold level of materiality would require a detailed factual analysis of the relevance of the teachings of that reference both with respect to the claims of the patents-in-suit and with respect to the other prior art references that were before the examiner.").

¹ These cases were decided under the former Rule 1.56 standard for materiality. However, the new rule "was not intended to constitute a significant substantive break in the previous standard [.]," Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1366 n.2 (Fed. Cir. 2003).

A difference in a single element in a withheld reference, however important that element may be to the patented invention, is not automatically dispositive of materiality ... References lacking different elements are often combined to reject an application under 35 U.S.C. § 103 ... In other words, materiality is not analyzed in a vacuum. It is not dependent upon a single element viewed in isolation. Rather, it is judged based on the overall degree of similarity between the omitted reference and the claimed invention in light of the other prior art before the examiner, Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1328 (Fed. Cir. 1998).

An accused infringer might argue that the withheld prior art is immaterial because it was cumulative of other art before the Office. A cumulative reference is, by definition, not material, 37 C.F.R. § 1.56 (b) (2004).

B. Intent

The Federal Circuit requires an applicant to err on the side of disclosure, particularly in close cases, Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997) (close cases should be resolved by disclosure); LaBounty Mfg. v. United States ITC, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("Close cases should be resolved by disclosure, not unilaterally by applicant."). Intent may be found where an applicant distinguished the prior art cited by the Examiner by noting the absence of an element that is found in the withheld references. A reasonable fact finder could find the requisite intent by clear and convincing evidence because the Examiner accepted "an argument for patentability that could not have been made had the art been disclosed," GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001) [difficult to establish subjective good faith where applicant knew of high degree of materiality]; Kemin Foods L.C. v. Pigmentos Vegetales Del Centro S.A., 2004 U.S. Dist. LEXIS 17737 at *36-39 (S.D. Iowa, Sept. 2, 2004) (denying motion for summary judgment on intent element where inventors knew of withheld reference and made unilateral decision to withhold it from Patent Office).

An applicant may argue that intent to deceive cannot be found even if the withheld references are material if an applicant's reasons for withholding the references are "plausible." *See*, Dayco Prods., 329 F.3d at 1367. Assessing the plausibility of an applicant's decisions, however, would require the Court to accept the accuracy of his/her materiality judgment based on post-issuance events, rather than on the arguments made to secure the patent. While plausibility may be indicative of good faith, like credibility, this is an element that should be weighed by the fact finder.

Summary judgment may be granted on the intent element. *See*, Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp.2d 69, 139-47 (D. Del. 2001), *aff'd*, 314 F.3d 1313, 1358 (Fed. Cir. 2003) (court-tried case in which each alleged piece of material information was disclosed to the Patent Office at some point in the prosecution. *See*, Id.

at 139 (Goldwasser study disclosed in interference action, and evidence established that examiner responsible for patent prosecution reviewed interference record); Id., at 142, 146 ("the Egrie Input was disclosed and considered" by the PTO; "Amgen disclosed the '293 experiments"); Id., at 146-47 ("Amgen directly informed" the PTO of the litigation)); Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1328, 1330-31 (Fed. Cir. 2004) (no showing of intent to deceive where prior art reference, which patentee mischaracterized to Patent Office, was before the Examiner throughout the prosecution); Abbott Labs v. Torpharm, Inc., 300 F.3d 1367, 1380 (Fed. Cir. 2002) (no dispute that "the record fails to show that the mystery crystal was produced by any process similar to that disclosed in the patent"); Matsushita Elec. Ind. Co., Ltd. v. Cinram Int'l, Inc., 299 F. Supp.2d 348, 360-61 (D.Del. 2004) ("no evidence of record that [the inventor] knew of the withheld references"); Alfa Leisure, Inc. v. King of the Road, 314 F. Supp.2d 1010, 1016 (CD. Cal. 2004) (no evidence of an intent to deceive, "such as circumstantial evidence showing that Alfa engaged in a pattern of nondisclosure").

Inequitable conduct is a claim tried to the court. *See*, Cabinet Vision v. Cabnetware, 129 F.3d 595, 600 n.4 (Fed. Cir. 1997).

IV. LAW GOVERNING PATENT ATTORNEYS' STATEMENTS REGARDING PRIOR ART

When particular prior art is before an Examiner, attorney "[s]tatements ... which consists of ... an interpretation of what the prior art discloses [do not] constitute affirmative misrepresentations of material fact." Young v. Lumenis, Inc., 492 F.3d 1336 (Fed. Cir. 2007); *see also*, Fiskars, Inc. v. Hunt Manufacturing Co., 221 F.3d 1318, 1327 (Fed. Cir. 2000) (an applicant cannot be guilty of inequitable conduct if the reference was cited to the Examiner); Chip-Mender, Inc. v. The Sherwin Williams Co., No. 05-3465 (PJH) 2006 WL 13058 (finding no fraud "solely based on an alleged failure to bring every detail of the disclosed reference to the Examiner's attention"); Innogenetics N.V. v. Abbott Laboratories, 2006 U.S. Dist. LEXIS 49422, 82 USPQ2d 1009 (W.D. Wis. 2006) [granted summary judgment against defendant who alleged inequitable conduct]; 2006 U.S. Dist. LEXIS 62310 (W.D. Wis. 2006) [awarded attorneys' fees to plaintiff]. Even intellectual dishonest arguments, in the absence of probative evidence, do not amount to

affirmative misrepresentation before a Patent Examiner. *See, Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998).

In Young, the accused infringer argued that the asserted patent was invalid due to inequitable conduct, Id. at 9. During prosecution, the patent applicant in Young had overcome a prior art rejection by convincing the Examiner that the reference at issue did not disclose key aspects of the claimed invention, Id. When the accused infringer later argued that the applicant's arguments regarding the cited reference constituted affirmative misrepresentations of material fact, the Federal Circuit was quick to disagree:

"Young argued against the [Fossum] rejection, and the examiner was free to reach his own conclusions and accept or reject Young's arguments. We therefore fail to see how the statements in the October 2005 Response [to an Office Action], which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact." Id.

Accord, Akzo v. N.V. v. U.S. Int'l Trade Comm., 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("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.").

In some cases, an attorney argument can cross the line into intentional misrepresentation that constitutes inequitable conduct: Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003); Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co., Ltd., 4 F. Supp.2d 477 (E.D. Va. 1998); and Ronald A. Katz Tech. Licensing, L.P. v. Verizon Commc'ns., Inc., 2002 WL 1565483 (E.D. Pa.). Each of these cases, however, highlights the compelling evidence required for a finding of inequitable conduct. In Hoffman-La Roche, for example, the patent holder had affirmatively misrepresented both its performance and the results of experiments that were material to the patent during prosecution, Hoffman, 323 F.3d at 1363-72. In Semiconductor Energy, the patent applicant had engaged in "a clear pattern and practice of initial nondisclosure, followed by incremental disclosure only when compelled ... to do so, followed, at times,

by mischaracterization," Semiconductor Energy, 4 F. Supp.2d at 496. In Katz, the Court of Federal Claims declined to strike defendant's inequitable conduct defense in the early stages of litigation, because the record was insufficiently developed to determine, to a clear and convincing standard, whether the patent holder's statements during prosecution were "mere advocacy" or "clear misrepresentation," Katz, 2002 WL 1565483 at *4.

Each of these cases underscores that, to prove inequitable conduct, an alleged infringer must show that applicant knowingly presented clearly erroneous arguments about the reference.

V. AN UNPUBLISHED DOCUMENT MAY NOT BE PRIOR ART AND, THEREFORE, WOULD NOT BE MATERIAL IN ANY EVENT

Non-disclosure of a document cannot serve as the basis of inequitable conduct claims if it is not prior art. A written reference describing an invention is "prior art" when it is a "printed publication," i.e., that has been disseminated and is accessible to the public, 35 U.S.C. § 102; *see also*, In re Klopfenstein, 380 F.3d 1345, 1348 (Fed. Cir. 2004). A written reference that is treated as confidential, or is otherwise inaccessible to the public, might not be a "publication" within the meaning of § 102. *See*, e.g., Northern Telecom Inc. v. Datapoint Corp., 908 F.2d 931, 936-37 (Fed. Cir. 1990) (holding four unclassified government reports circulated to approximately 50 individuals and organizations were not "printed publications"). When a document has been classified as secret by the government, or has been circulated only among a restricted group of individuals or entities, the document might be characterized as confidential and unpublished. *See*, e.g., Lockheed Aircraft Corp. v. United States, 553 F.2d 69, 78 (Ct. Cl. 1977) (government-classified reports are not prior art); Ex parte Suozzi, 125 USPQ 445 (Pat. Off Bd. App., 1959) (circulating 25 copies of an unclassified research report to multiple governmental agencies and individuals is not "publication"); Aluminum Co. of America v. Reynolds Metals Co., 14 USPQ2d 1170 (N.D. Ill. 1989) (reports circulated to 33 different governmental agencies and private companies were publicly inaccessible and unpublished).

VI. REFERENCES CUMULATIVE TO THE REFERENCES BEFORE THE EXAMINER

"[E]ven where an applicant fails to disclose an otherwise material prior art reference, that failure will not support a finding of inequitable conduct if the reference is 'simply cumulative to other references.' i.e., if the references teach no more than what a reasonable Examiner would consider to be taught by the prior art already before the PTO," The Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1574-75 (Fed. Cir. 1997); *see also*, Rolls-Royce Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1107 (Fed. Cir. 1986) (nothing in law or logic requires an applicant to submit non-material, merely cumulative references for USPTO review).

VII. HYPOTHETICAL: SUPPLEMENTAL IDS & NON-PAYMENT OF \$180 ADMINISTRATIVE FEE

Applicant's attorney filed a 3-page Supplemental Information Disclosure Statement (the Supp. IDS) with a Form PTO-1499 (IDS) that listed six U.S. Patent Documents. Alleged infringer argues that the filing of this Supp. IDS constituted inequitable conduct because (1) the attorney signed a letter stating that the references were not known to applicant three months earlier and (2) applicant's attorney did not pay a \$180 administrative fee required if material references had indeed been known for more than three months.

Alleged infringer argues that applicant's attorney used a Supplemental Information Disclosure Statement to update the USPTO on newly-issued patent numbers and publications numbers for co-pending applications that were references in the application for the patent without paying a \$180 administrative fee.

In support of its argument that patent counsel's actions of filing the Supp. IDS constituted inequitable conduct, the alleged infringer points to case law holding that affirmative misrepresentations, such as a misstatement in a petition to make special, can constitute inequitable conduct. In Ulead Systems, Inc. v. Lex Computer & Management Corp., 351 F.3 1139, 1150 (Fed. Cir. 2003), the Federal Circuit reversed a holding of inequitable conduct based on a mistake in the written record where the patentee incorrectly claimed small entity status because there was no evidence of an intent to

deceive the USPTO. *See also, Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 744-745 (Fed. Cir. 2002) (holding of inequitable conduct reversed because record did not support materiality or intent behind misleading affidavits). The issue is not whether every statement on the form was literally true; the issue is whether patent counsel made a false statement that was material to patentability with an intent to deceive the USPTO.

In an attempt to support a finding of intent to deceive the USPTO, the alleged infringer cites Paragon Podiatry, 984 F.2d 1182 at 1189 (Fed. Cir. 1993) for the proposition that smoking gun evidence is not required to establish an intent to deceive. The Federal Circuit itself later clarified its smoking gun statement:

"Paragon does not hold that there need be no evidence of culpable intent. In Paragon the affiants with 'deliberate artfulness' swore that they were 'not employed' by Paragon whereas they were owners or paid consultants of Paragon; this evidence was found to establish culpable intent. The court did not hold in Paragon that intent could be found without any factual basis. *See, e.g., Goodyear Tire & Rubber Co. v. Hercules Tire & Rubber Co.*, 162 F.3d 1113, 1122 (Fed. Cir. 1998) ('Both materiality and culpable intent are essential factual predicates of inequitable conduct, and each must be proved by clear and convincing evidence. '); B.F. Goodrich Co. v. Aircraft Braking Systems Corp., 72 F.3d 1577, 1584, 37 U.S.P.Q.2D (BNA) 1314, 1319 (Fed. Cir. 1996) ('One alleging inequitable conduct must prove the threshold elements of materiality and intent by clear and convincing evidence.')

Fiskars, Inc. v. Hunt Manufacturing Co., 221 F.3d 1318, 1327-28 (Fed. Cir. 2000). The alleged infringer must offer evidence of materiality or intent beyond the Supp. IDS submission itself. "Conjecture alone is not sufficient to show an intent to deceive to support the defense of inequitable conduct," In re Hayes Microcomputer Products, Inc. v. Ven-Tel, Inc., 982 F.2d 1527, 1546 (Fed. Cir. 1992).

The alleged infringer further contends that applicant committed inequitable conduct by not paying the \$180 administrative fee that would be due if applicant was indeed aware of (material) references on the Supp. IDS more than three months before its filing. Would applicant's patent counsel deliberately misstate applicant's initial knowledge of the listed items with deceptive intent, thereby jeopardizing patent rights possibly valued in the millions of dollars just to save \$180.00? Common sense strongly

suggests otherwise. The submission of any deficiency fee payment, when accepted by the USPTO, is effective to correct a patentee's error, if any, Ulead Systems, Inc., 351 F.3d 1139, 1150 (Fed. Cir. 2003). Other than as it relates to payment of the fee, nothing in the Supp. IDS affected the prosecution or standing of the patent substantively at all.²

Applicant must show that false statements material to patentability were made with the intent to deceive the USPTO. The statements concerning the listed applications are irrelevant to patentability (a) because all were either already disclosed or were filed after the relevant priority date; and (b) the only consequence to applicant would have been an additional \$180 fee, which has been paid and accepted, as even the MPEP guidelines themselves contemplate. MPEP § 609.05(a).

In hindsight, applicant's counsel could have provided the updated patent and publication number information to the Examiner in a separate communication and still not have been required to pay the \$180 fee. Adding additional update information to the form designed primarily for prior art disclosure is at worst a minor procedural irregularity.³ To infer both materiality and intent to deceive from it is outrageous and offensive.

² Even in Ulead Systems, where summary judgment of inequitable conduct was reversed due to fact issues relative to intent, the alleged misrepresentation had a demonstrable effect on the patent. There, the alleged misrepresentation was that the applicant's patent lawyer had a good faith belief that his client was a small entity. Because of the misrepresentation, the USPTO accepted smaller maintenance fees, thereby extending the survival of the patent. There is no provision of patent law which makes issuance of a patent dependent on payment or non-payment of the \$180 fee associated with CFR § 1.97.

³ Because the IDS was reviewed and considered by the USPTO, it must be deemed in compliance with the Patent Rules (37 CFR) and MPEP guidelines. MPEP § 609 and its sub-parts deal with the Examiner's treatment of Information Disclosure Statements. MPEP § 609.01 delineates the Examiner's obligations with respect to a submitted IDS, including reviewing it for compliance with, *inter alia*, 37 CFR §§ 1.97 and 1.98. MPEP § 609.05(a) requires the Examiner to review an IDS for compliance with 37 CFR § 1.97, including the requirements for fees and/or statement under 37 CFR § 1.97(e). If, after such compliance review, the Examiner finds the IDS in order and after he has taken each reference into consideration, he is to initial each item listed to reflect that it has been considered. MPEP § 609.06(b). Moreover, if the Examiner determines that an IDS is not in compliance, including with 37 CFR §§ 1.97 and 1.98, the Examiner is directed to inform the applicant of the reasons that the IDS, or any citation on the IDS was not considered. MPEP § 609.01. The applicant is then given an opportunity to correct the non-

VIII. ALLEGED UNENFORCEABILITY BASED ON FAILURE TO DISCLOSE LITIGATION TO THE USPTO

The existence of patent lawsuits are generally made known to the USPTO by the Court.

An alleged infringer may argue that: (1) applicant (separate from the Court) should have disclosed the existence of existing litigation to the USPTO; and (2) applicant should have disclosed alleged infringer's allegations made during the litigation to the USPTO.

A. Analysis of Materiality

An alleged infringer might assume that MPEP § 2001.06(c) dictates that pending litigation involving the parent application must constitute "material" information and that even an unknowing failure to comply with MPEP § 2001.06(c) automatically constitutes inequitable conduct. The MPEP, however, only sets forth USPTO procedures; it is not a statement of the law, Regents Of University Of New Mexico v. Knight, 321 F.3d 1111, 1121 (Fed. Cir. 2003). The MPEP is used by patent examiners and practitioners for guidance on procedural matters, Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1439 (Fed. Cir. 1984); Molins PLC, 48 F.3d at 1180 n.10.⁴ The law (not the MPEP) dictates no such requirement to provide notice of pending litigation under all circumstances. Rather, notice to the USPTO of litigation related information like all

compliance. MPEP § 609.05(a). Here, the Supp. IDS was accepted and the listed references considered by the Examiner.

⁴ See also, the Foreword of the MPEP itself:

"This Manual is published to provide U.S. Patent and Trademark Office (USPTO) patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the USPTO. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. **The Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.**" (emphasis added.)

information -- is only required when it falls under the applicant's Duty to Disclose Information Material to Patentability under 37 CFR § 1.56.⁵

37 CFR § 1.56(b) provides the standard for material information that should be submitted to the USPTO. This section provides that:

"information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) [i]t establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) [i]t refutes, or is inconsistent with, a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the Office, or (ii) [a]sserting an argument of patentability."

In addition to not itself being a standard for materiality, MPEP § 2001.06(c) does not provide that all litigation information is material, nor does it by its own terms turn a failure to disclose pending litigation into a duty of disclosure with intent to deceive, Kothmann Enters., Inc. v. Trinity Indus., Inc., No. H-01-2668, 2006 U.S. Dist. LEXIS 3755, at *41 (S.D. Tex. Jan. 13, 2006). Instead, the relationship between a patent involved in litigation and a patent prosecuted before the USPTO should be analyzed to determine whether the applicant failed to disclose information that was material under Rule 1.56 and, if so, the degree of materiality.⁶ That requires first an analysis to determine whether the undisclosed information was even material to patentability under

⁵ In the case of reissue and reexamination proceedings, by contrast, explicit requirements for providing notice of pending litigations involving or relating to the same patent are contained in the CFR. 37 CFR §§ 1.565 and 1.985 (reexamination); 37 CFR § 1.178(b) (reissue). These provisions require that an applicant must inform the Office of any prior or concurrent proceedings in which the patent is or was involved, such as ... litigations and the results of such proceedings. (Emphasis added.) The fact that explicit provisions exist in the Patent Rules indicates an intent on the part of the statutes to provide for such notice in cases, such as reissue and reexamination, where it is deemed important. There is no such notice provision relative to normal application prosecution. Moreover, in the case of *inter partes* reexamination, 37 CFR § 1.985(b) further states that such notification must be limited to merely providing notice of the other proceeding without discussion of issues of the current *inter partes* reexamination proceeding. Any paper not so limited will be returned to the sender.

⁶ An approach that required patent-holders to transmit to the USPTO every allegation of invalidity or unenforceability made by an accused infringer would permit infringers in litigation to disrupt pending continuation applications through a back door by filing unsubstantiated allegations involving the parent application.

37 CFR § 1.56(b) and, only then, an analysis of the extent to which the pending litigation affected the patentability of the invention claimed in the pending application. The degree of materiality, in turn, informs the analysis of whether the failure to disclose was accompanied by deceptive intent, Id. at *42. The correct approach should specifically analyze the claim terms at issue in both the litigation and the patent prosecution to see whether and how the litigation affected the patentability of the invention claimed in the application. Thereafter, a balancing test should be undertaken to determine whether inequitable conduct has occurred. Such approach is consistent with Rule 1.56 and the relationship of that rule with § 2001.06 of the MPEP, Id. at *43.

B. Evidence of Intent to Deceive

An alleged infringer's *ipso facto* argument may assume intent from the alleged failure to disclose the information that it argues was material. As stated in FMC Corp. v. Manitowoc Co., 835 F.2d 1411 at 1415 (Fed. Cir. 1987), inequitable conduct is not established upon a mere showing that art or information having some degree of materiality was not disclosed. To be guilty of inequitable conduct, one must have *intended* to act inequitably, Hoffmann-La Roche, Inc. v. Promega Corporation, 323 F.3d 1354, 1359 (Fed. Cir. 2003) ("A party seeking to have a patent declared unenforceable has a heavy burden to meet. Inequitable conduct requires misrepresentation or omission of a material fact, together with an intent to deceive the USPTO. Both of these distinct elements must be shown by clear and convincing evidence.").

In Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp.2d 69, 146-147 (D. MA 2001), defendant alleged that two patents should be held unenforceable because plaintiff had not advised the USPTO that they had been added to the litigation through amendment. The Court rejected the inequitable conduct allegations, noting that the defendant had not even begun to demonstrate any intent to deceive the USPTO, Amgen, 126 F. Supp.2d at 147. The Federal Circuit affirmed, Amgen, Inc. v. Hoechst Marion Roessel, Inc., 314 F.3d at 1358, reasoning that "there must be some threshold showing of intent to be balanced; ... [the court] will not find inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the USPTO."

Applicant may offer a plausible explanation for the failure to disclose the pending litigation, Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993) (The affiant must at least state facts supporting a plausible justification or excuse for the misrepresentation.). Perhaps applicant and its attorney was simply not aware of MPEP § 2001.06(c). Perhaps applicant's attorney believed that any obligation to supplement the Court-generated notice to the USPTO would only arise upon some decision of the Court that would in fact impact patentability of the continuation. Perhaps applicant's attorney's (at worst) inadvertent noncompliance with an MPEP guideline is insufficient to constitute an intent to deceive. Conduct far more culpable has been held less than inequitable: The B.F. Goodrich Co. v. Aircraft Braking Systems Corp., 72 F.3d 1577 (Fed. Cir. 1996) ("carelessness does not demonstrate an intent to deceive"); Brasseler, U.S.A. I, L.P v. Stryker Sales Corp., 267 F.3d 1370, 1382 (Fed. Cir. 2001) (a finding of deceptive intent may not be based solely on gross negligence by attorneys).

An alleged infringer may rely on Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253 (1997) as supporting an inference of a finding of inequitable conduct. Critikon was an appeal after trial on the merits and no evidence was ever submitted in Critikon as to why the litigation was never reported; and intent was inferred from the complete absence of a good faith explanation, Id. at 1257.

An alleged infringer may cite Brasseler, U.S.A. I, L.P v. Stryker Sales Corp., 267 F.3d 1370, 1384-85 (Fed. Cir. 2001), for the proposition that ignorance of the law is no excuse. This is a misstatement of Brasseler where, as in Critikon, no evidence of good faith was ever produced, Id. Moreover, the attorneys in Brasseler knowingly failed to disclose and disregarded numerous warnings that material information or prior art existed and there was conflicting testimony regarding the reasons for refusing to investigate the facts leading to the failure to disclose, Id. at 1383-85.

IX. PRECEDENT FOR BIFURCATION OF INEQUITABLE CONDUCT ISSUES

Inequitable conduct is an issue for the Court, not the jury, Afga Corp. v. Creo Products Inc., 451 F.3d 1366, 1375 (Fed. Cir. 2006) ("a judge retains the discretion to conduct a bench trial on the inequitable issue of unenforceability in the same case where invalidity is to be tried to a jury"); Akron Polymer Container Corp. v. Exxel Container,

Inc., 148 F.3d 1380, 1383 (Fed. Cir. 1998) ("in balancing the degrees of materiality and intent, the district court, in the sound exercise of its equitable discretion, decides whether inequitable conduct has occurred").

In Digital Control, Inc. v. Charles Machine Works, Inc., 437 F.3d 1309, 1314, 1317, 1319-21 (Fed. Cir. 2006), the trial court dealt with inequitable conduct allegations by deciding materiality on summary judgment and holding an evidentiary hearing on the intent issue. The decision on materiality was reversed as to one of the prior art references involved, but the Federal Circuit did not criticize the procedure adopted.

In McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 47 F.3d 897, 908 (Fed. Cir. 2007), the District Court bifurcated the trial into two phases. The first phase was a bench trial on the inequitable conduct, and the second a jury trial on the remainder of the claims, counterclaims and affirmative defenses. After a four day bench trial of the first phase, the Court found inequitable conduct had occurred. The Federal Circuit affirmed.

In AFGA Corp. v. Creo Products, Inc., 451 F.3d 1366, 1372-73 (Fed. Cir. 2006), the Federal Circuit held that a district court's decision to hold a bench trial on the defendants' inequitable defense before conducting a jury trial on the plaintiff's infringement claims did not preclude the trial court from later conducting a jury trial on plaintiff's claims and, thus, did not deprive the plaintiff of its Seventh Amendment right to a jury trial. The AFGA case involved inequitable conduct and validity. Although the issues overlapped to some degree, the Court concluded that they were not common issues and, therefore, did not preclude the district court from conducting a separate bench trial before convening a jury to determine AFGA's infringement claim. *See also*, Gardco Mfg., Inc. v. Herst Lighting Co., 820 F.2d 1209, 1213 (Fed. Cir. 1987); Yanni v. City of Seattle, 2005 U.S. Dist. LEXIS 32428 (W.D. WA 2005) (granting a motion in limine to bifurcate malicious prosecution claims from claims involving unlawful detention, false arrest and excessive force).

X. INEQUITABLE CONDUCT CLAIMS MAY BE DISTINCT AND WITHOUT COMMONALITY TO THE OTHER ISSUES

The materiality issues might not require some kind of determination of patent invalidity (e.g., anticipation, obviousness, etc.). A patent may be valid and yet be rendered unenforceable for inequitable conduct. The "conduct-of-the-applicant-in-the-PTO" issue raised in a non-jury trial and the separated infringement/validity issues may be distinct and without commonality, either as claims or in relation to the underlying fact issues, Gardco Mfg. Inc. v. Herst Lighting Co., 820 F.2d 1209, 1213 (Fed. Cir. 1987) [tried inequitable claim in a bench trial prior to a jury trial on the validity and infringement issues]. The trial court in Gardco "explicitly refused to make any findings relating to the patentability of the claimed invention, in view of the undisclosed art or otherwise, and made no finding on infringement." Accordingly, the rule set forth in Beacon Theatres, Inc. v. Westovec, 359 U.S. 500, 79 S.Ct. 948, 3 L.Ed.2d 988 (1959) did not apply, Id. See also, Shum v. Intel Corporation, 2007 U.S. App. LEXIS 20184 (Fed. Cir. 2007) [distinguishing the Beacon Theatres rule and Cabinet Vision v. Cabinetware, 129 F.3d 595, 600 (Fed. Cir. 1997) from Gardco, supra., and Agfa Corp. v. Creo Products, 451 F.3d 1366 (Fed. Cir. 2006)].

In Agfa, supra., 451 F.3d at 1372-1373, the district court separated the inequitable conduct issue for a bench trial and postponed a jury trial on infringement and invalidity. The Federal Circuit stated in Agfa that while inequitable conduct and validity questions "overlap in the consideration of some aspects of the same relevant evidence, they do not involve a common issue," Id. The Federal Circuit reaffirmed its prior holding in Gardco (453 F.3d at 1373):

"Because the materiality of prior art is distinct from validity issues (without even considering the additional intent requirement for inequitable conduct), this court's earlier reasoning in Gardco remains sound. Materiality, therefore, does not present common issues with validity. Because the issues are not 'common,' the Beacon Theatres rule does not apply to protect Agfa's jury trial request."

The Agfa Court found it unnecessary to impanel a jury after the bench trial on inequitable conduct, finding that the patent was unenforceable, Id.

It may be reasonable to address the inequitable conduct claims first before the difficult and arduous task of undertaking a trial on the merits of the infringement and validity claims. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 65 S. Ct. 993, 89 L.Ed. 1381 (1945).

Other courts have bifurcated inequitable conduct issues for a bench trial prior to a jury trial on infringement and invalidity, if necessary, Armament Systems and Procedures, Inc. v. IQ Hong Kong, Ltd., 2007 U.S. Dist. LEXIS 2051 (E.D. WI 2007) [granted defendant's motion for immediate bench trial on the inequitable conduct issue prior to jury trial]; Agfa Corp. v. Creo Products, 451 F.3d 1366 (Fed. Cir. 2006); Daimlerchrysler AG v. Feuling Advanced Technologies, Inc., 276 F. Supp.2d 1054, 1056 (S.D. CA. 2003); Refac International, Ltd. v. Lotus Development Corporation, 81 F.3d 1576, 1579 (Fed. Cir. 1996) [separate bench trial on inequitable conduct]; Elkhart Brass Manufacturing Company, Inc. v. Task Force Tips, Inc., 867 F. Supp. 782 (N.D. IN. 1994) [granted the plaintiff's Rule 42(b) motion, holding that inequitable conduct be bifurcated and tried to the bench prior to the jury trial]; Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993) [no right to a jury trial respecting the factual element of culpable intent as part of the defense of inequitable conduct]; Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Company, Inc., 837 F. Supp. 1444, 1447 (N.D. IN 1992) [granting defendant's motion to try separately the issue of inequitable conduct before the Patent Office]; Gardco Mfg. Inc. v. Herst Lighting Co., 820 F.2d 1209, 1213 (Fed. Cir. 1987).