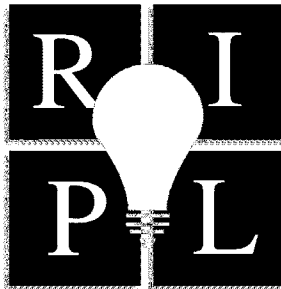


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DUTY TO DISCLOSE: *DAYCO PRODUCTS v. TOTAL CONTAINMENT*

TOM BRODY

ABSTRACT

The duty to disclose, as set forth by 37 C.F.R. § 1.56 and case law from the Federal Circuit, should be followed during the prosecution of all patent applications. This duty requires that inventors and their attorneys provide the United States Patent and Trademark Office with a list identifying relevant publications, patent applications, patents, legal proceedings, written rejections from patent examiners, and sales, both public and confidential. “Relevant” means relevant to the claims. The consequences of failing in this duty can be severe, namely, a holding of inequitable conduct. Inequitable conduct, in the patenting context, requires two prongs—materiality of the publication and intent to deceive the Patent Office. Patent practitioners are confronted by many gray areas, e.g., the boundaries of the duty, whether disclosing an Abstract can satisfy the duty of disclosing the corresponding full length publication, how to remedy situations where an inventor failed to timely disclose the publication, and how to assess deceptive intent.

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DUTY TO DISCLOSE: *DAYCO PRODUCTS V. TOTAL CONTAINMENT*

TOM BRODY*

“We leave for another day a final disposition of this issue”¹

INTRODUCTION

The duty to disclose information to the United States Patent and Trademark Office (“USPTO”) is a major issue for the patent practitioner. Failure to disclose can have severe consequences, for example, invalidation of your patent and all related patents in the patent family. Guidance for this duty comes from 37 C.F.R. § 1.56 (“Rule 56”), as well as from relevant cases from the United States Court of Appeals for the Federal Circuit (“Federal Circuit”). In March 1992, 37 C.F.R. § 1.56 was amended, resulting in a standard that was narrower and more clearly defined. The pre-March 1992 standard encompassed any information that a reasonable examiner might find important in evaluating a patent application, while the post-March 1992 standard more narrowly encompassed only information relevant to patentability of the claims.

In general, the Federal Circuit has continued to follow the broad standard, that is, the standard articulated in established case law and by the pre-March 1992 administrative law. However, in a few opinions, the Federal Circuit and the U.S. district courts have opted to follow the narrower administrative standard. The result is a periodic but continuing inconsistency in the application of the duty to disclose.

Another inconsistency, which confronts the patent attorney on a day-to-day basis, is that the narrower administrative law (37 C.F.R. § 1.56) directly governs the information (publications; evidence of sale or public use) that must be provided with every patent application, while the attorney must also take into account the broader Federal Circuit standard that might be applied by the court in a downstream litigation. The problem here is that by the time litigation is initiated, it is too late for the patent attorney to disclose information that should have been submitted during the prosecution phase of the patent.

In 2003, the Federal Circuit in *Dayco Products, Inc. v. Total Containment, Inc.*² confronted the problem of the two different standards for the duty to disclose, but chose not to resolve the issue at the time, writing, “we leave for another day a final disposition of this issue.”³ The thirteen years of uncertainty, regarding the application of these two standards, seemed to have been brought to an end with two

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¹ *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003).

² *Id.*

³ *Id.*

decisions from 2005. Both of these decisions, *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*⁴ and *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*,⁵ held that the federal courts should give deference to the USPTO's formulation of the standard of materiality at the time an application is being prosecuted.⁶ For example, the court in *Purdue Pharma* (emphasis added) wrote, "[i]n evaluating materiality, this court has consistently referred to the standard set forth in PTO Rule 56 . . . [b]ecause all of the patent applications at issue in this case were pending on or filed *after* March 16, 1996 [the post-March 1992 standard], we look to the current version of Rule 56."⁷ On the other hand, later in the year 2006, the Federal Circuit revived the era of uncertainty by holding that both standards were valid, and that it was acceptable for the court to apply the broad standard, the narrow standard, or both standards (*Digital Control, Inc. v. Charles Machine Works*,⁸ *Agfa Corp. v. Creo Products, Inc.*,⁹ and *Ferring B.V. v. Barr Laboratories, Inc.*¹⁰).

This essay discloses the two different standards for the duty to disclose, documents the continuing inconsistency in the courts in applying the pre-March 1992 and post-March 1992 standards for the duty to disclose, and discloses doctrines that apply uniquely to the duty to disclose, such as the Doctrine of Infectious Unenforceability. This essay details an array of techniques for convincing a court to render a holding of inequitable conduct, thereby resulting in the unenforceability of a patent. By disclosing these techniques, this essay inherently provides guidance on how better to satisfy the duty to disclose.

The patent applicant has a duty to disclose certain forms of information to the USPTO by way of an information disclosure statement ("IDS"), where the IDS is accompanied by a list identifying the documents, as well as copies of the actual documents. The IDS, the list, and clean copies of publications and any other documents need to be submitted in a *parent* patent application, whereas in *daughter* or *child* patent applications, the applicant need only submit the IDS and the list, but not the copies. A reissue application is not considered to be a daughter patent application because the reissue application is not co-pending with the parent, and here the IDS, the list, and clean copies, all need to be re-submitted.

Failure to disclose information by way of an IDS can be particularly severe, resulting in a holding of inequitable conduct as to the inventor's alleged deceptive behavior in prosecuting one or more claims in the pending patent application or the issued patent. Where inequitable conduct is found, the court will render unenforceable *all of the claims* in the patent or patent application.¹¹ The court may even render unenforceable *all related patents and patent applications*, that is, the parent, sibling, and daughter patents, by way of a doctrine called infectious

⁴ 394 F.3d 1348 (Fed. Cir. 2005).

⁵ 410 F.3d 690 (Fed. Cir. 2005), *reh'g granted*, 438 F.3d 1123 (Fed. Cir. 2006).

⁶ *Bruno Indep. Living Aids*, 349 F.3d at 1353; *Purdue Pharma*, 410 F.3d at 696.

⁷ *Purdue Pharma*, 438 F.3d at 1129.

⁸ 437 F.3d 1309, 1316 (Fed. Cir. 2006) (employing the "reasonable examiner" standard of review, and noting that the PTO's adoption of Rule 56 does not supplant this earlier standard).

⁹ 451 F.3d 1366, 1373 (Fed. Cir. 2006).

¹⁰ 437 F.3d 1181, 1187 n.6 (Fed. Cir. 2006).

¹¹ *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984).

unenforceability.¹² The duty to disclose, as it applies to disclosing publications, public uses, and sales, has been reviewed.¹³

I. LANGUAGE IN AN INFORMATION DISCLOSURE STATEMENT

Publications, documentation of sales and public uses, and confidential documents such as laboratory data, can be submitted to the USPTO by way of an IDS, where the IDS is accompanied by copies of the documents. The IDS is the gold standard for determining whether a reference has been properly disclosed to the USPTO. An important characteristic of this gold standard is that it identifies the references in a neutral manner, and refrains from characterizing any cited publications as “prior art.” Where an applicant or inventor characterizes a publication as “prior art,” the result is that the patent examiner will have a stronger case in arguing that the claims should be invalidated under 35 U.S.C. § 102 or § 103, based on that publication.

The IDS generally contains a stock statement regarding the references cited on the accompanying list. The statement can take the following form:

Citation of these documents should not be construed as a representation that the documents are in fact material or are in fact prior art with respect to the instant invention. The examiner should not make any inference relating to the relative pertinence of cited references based upon the order in which the art is presented. Citation of these documents should not be construed as a representation that an exhaustive search has been made or that more pertinent art may not be in existence.¹⁴

This neutral manner is consistent with the language of 37 C.F.R. § 1.97(h), a rule that became effective on March 16, 1992.¹⁵ The phrase implies that the applicant is not aware of any references that are of greater materiality than those cited. In contrast, a stock phrase in an IDS, taking a different form than that quoted

¹² *Baxter Int'l v. McGaw, Inc.*, 958 F. Supp. 1313, 1315–16 (N.D. Ill. 1997), *aff'd in part, rev'd in part*, 149 F.3d 1321 (Fed. Cir. 1998) (reversing the district court decision and holding patents unenforceable due to inequitable conduct).

¹³ Kenneth R. Adamo, *Recent Developments in Inequitable Conduct: The (Statutory) Duty of Disclosure? “Fraud” On the P.T.O.*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 110, 120 (1991); Kenneth R. Adamo & Robert P. Ducatman, *The Status of the Rules of Prohibited Conduct Before the Office: “Violation of the Duty of Disclosure” out of “Inequitable Conduct” by “Fraud.”* 68 J. PAT. & TRADEMARK OFF. SOC'Y 193, 194 (1986); Irving Kayton et al., *Fraud in Patent Procurement: Genuine and Sham Charges*, 43 GEO. WASH. L. REV 1, 32–33 (1974); John F. Lynch, *Evolution and Future of New Rule 56 and the Duty of Candor: New Rule 56: The Second Time Around*, 20 AIPLA Q.J. 144, 158 (1992); Harry F. Manbeck, Jr., *Evolution and Future of New Rule 56 and the Duty of Candor: The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 140–41 (1992); R. Carl Moy, *The Effect of New Rule 56 on the Law of Inequitable Conduct*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 257, 257–58 (1992); Harold C. Wegner, *Inequitable Conduct and the Proper Roles of Patent Attorney and Examiner in an Era of Internal Patent Harmonization*, 16 AIPLA Q.J. 38, 50–64 (1988).

¹⁴ See Content of Information Disclosure Statement, 37 C.F.R. § 1.98 (2006).

¹⁵ Duty of Disclosure, 57 Fed. Reg. 2021 (Jan. 17, 1992) (to be codified at 37 C.F.R. pts. 1, 10) [hereinafter Duty of Disclosure].

above, raised the issue of whether a cited reference was prior art. The following phrase is from *Riverwood International Corp. v. R.A. Jones & Co.*¹⁶: “The prior art references listed constitute the closest art of which the Applicant is aware relating to the invention of the above identified application. The applicant discloses and claims an invention over this prior art.”¹⁷

Because of the nature of this particular stock phrase, it was argued that the submitted IDS identified one of the references (the '806 patent), and transformed it into prior art by admission. The defendant asserted that patentee's IDS transformed the '806 patent into prior art. In making this assertion, the defendant's goal was to shift the burden to the patentee to argue why the reference was not prior art. Therefore, it is best for the language in the IDS to set forth the references disclosed therein in neutral terms. Prior art by admission was an issue in other cases, for example in *In re Fout*¹⁸ and *In re Nomiya*.¹⁹ Admitting that a reference is prior art can trigger the duty to disclose the prior art reference.

II. MATERIALITY AND INTENT ARE USED TO DETERMINE INEQUITABLE CONDUCT

As first set forth by the Federal Circuit in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*,²⁰ a finding of inequitable conduct, due to a failure to disclose involves a balancing of materiality and intent.²¹ For example, if there is only a slight hint or indication of intent to deceive the USPTO, there can still be a finding of inequitable conduct, where the non-disclosed reference is *highly material*.²² But if the reference is only somewhat material or slightly material, there can still be a finding of inequitable conduct, where there exists direct “smoking gun” evidence of deceptive scheming to conceal the reference.²³ As set forth in *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*,²⁴ and other cases,²⁵ the Federal Circuit has described this sliding scale as follows: “When balanced against high materiality, the showing of intent can be proportionally less.”²⁶ Where it is not possible to detect any intent to deceive, it is improper to arrive at a holding of inequitable conduct. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*²⁷ held that the sliding scale must be used, and that “[t]here still must be a factual basis . . . for a finding of intent . . . when the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.”²⁸

¹⁶ 324 F.3d 1346 (Fed. Cir. 2003).

¹⁷ *Id.* at 1351.

¹⁸ 675 F.2d 297, 301 (C.C.P.A. 1982).

¹⁹ 509 F.2d 566, 571 (C.C.P.A. 1975).

²⁰ 725 F.2d 1350 (Fed. Cir. 1984).

²¹ *Id.* at 1364.

²² *Airwick Indus., Inc. v. Sterling Drug, Inc.*, 720 F. Supp. 409, 414 (D.N.J. 1989); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997).

²³ *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818 (1945).

²⁴ 267 F.3d 1370 (Fed. Cir. 2001).

²⁵ *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003).

²⁶ *Brasseler*, 267 F.3d at 1380.

²⁷ 439 F.3d 1335 (Fed. Cir. 2006).

²⁸ *Id.* at 1341.

It is proper for a court to infer intent to deceive where there is no smoking gun. In fact, the available case law demonstrates that, where there has been a holding of inequitable conduct, intent to deceive was almost always inferred. The available case law demonstrates that intent is usually inferred, and seldom direct. *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*,²⁹ in a limited en banc hearing, held that some actual evidence for intent, that is, evidence beyond mere negligence must be shown.³⁰ The en banc hearing held that gross negligence alone cannot justify an inference of intent to deceive.³¹

Inequitable conduct's use of this balancing act is to be contrasted with findings of fraud. For a finding of fraud, a balancing act is not used, and here there must be independent findings of high materiality and of direct evidence of scheming and intent to deceive, as set forth in *Nobelpharma AB v. Implant Innovations, Inc.*,³² and other cases.³³

The following clarifies what is prior art that is highly material versus prior art that is slightly material. A prior art publication that is highly material can be one that discloses the entire claim of an inventor's patent, that is, one that discloses each and every one of the elements of the claim. This type of publication would be suitable for a rejection under 35 U.S.C. § 102 (anticipation). Another type of publication that is highly material is a publication by the inventor named on the patent, where the publication discloses that the claimed invention does not work. In contrast, a publication that discloses all of the elements of a claim except for one element can be characterized as only somewhat material. This type of publication may be suitable for a rejection under 35 U.S.C. § 103 (obviousness).

III. THREE STANDARDS OF MATERIALITY

Materiality of a reference has been defined by three standards. The first standard is whether a reasonable examiner would consider the information important in deciding to allow the application to issue as a patent (37 C.F.R. § 1.56(a) (1991); the pre-March 1992 standard; reasonable examiner standard). The second standard is whether the reference establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim (37 C.F.R. § 1.56(b)(1) (1992); the post-March 1992 standard; prima facie unpatentability standard). The third standard is whether it would have conclusively established unpatentability, that is, after the following three events—articulation of a prima facie case of unpatentability by the examiner, rebuttal by the applicant, and reconsideration by the examiner.

The post-March 1992 Rule 56 contains a clause that distinguishes this rule from the third standard: "A prima facie case of unpatentability is established . . . before any consideration is given to evidence which may be submitted in an attempt to

²⁹ 863 F.2d 867 (Fed. Cir. 1988).

³⁰ *Id.* at 873.

³¹ *Id.* at 876.

³² 141 F.3d 1059, 1070–71 (Fed. Cir. 1998).

³³ *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346–47 (Fed. Cir. 2007); *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1144 (Fed. Cir. 2003); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

establish a contrary conclusion of patentability”³⁴ This third standard, which is not properly used when assessing materiality of a reference, is essentially the same as the “but for” standard. The “but for” standard has been alluded to in only a handful of cases, for example, *N.V. Akzo v. E.I. Dupont de Nemours & Co.*³⁵ and *Argus Chemical Corp. v. Fibre Glass-Evercoat Co.*³⁶ To repeat, the third standard is not an appropriate standard in patent law.

The pre-March 1992 standard is described in *A.B. Dick Co. v. Burroughs Corp.*³⁷ and *Li Second Family L.P. v. Toshiba Corp.*,³⁸ where the Federal Circuit wrote that the test for materiality is whether a reasonable examiner would have considered the information important.³⁹ In other words, the pre-March 1992 standard was *not* whether the reference would likely serve as a basis for a finding of prima facie unpatentability, for example, under where the patent examiner imposes a rejection under 35 U.S.C. § 102 or § 103. Discussions of material information usually concern references of a type that could be used in a rejection under 35 U.S.C. §§ 101, 102, 103, or 112, that is, references of a sort that are properly disclosed in an IDS.

Failure to disclose a reference that could lead to a rejection for double patenting can also be an issue in determining inequitable conduct. Double patenting rejections occur where one inventor (or assignee) owns two patents, and where the two patents contain claims that are either identical to each other, or similar to each other.⁴⁰ Where two patent applications are being considered by the same examiner, the inventor should ensure that the examiner is aware of both applications. Also, where the two patent applications are being considered by different examiners, the inventor should ensure that both examiners are aware of both applications. Where double patenting is an issue or potential issue, failure to disclose can lead to a finding of inequitable conduct and a rendering of unenforceability of the relevant patents.⁴¹

An IDS is most often used to submit publications, as well as grant applications, brochures, advertisements, information on sales and public uses, confidential pages from laboratory notebooks, and information disclosing collaborations between various inventors. Generally, the IDS is used to list and disclose publications and patents. However, failure to disclose other forms of information can be used in determining inequitable conduct due to failure to disclose a material reference. Small entity status, which has essentially no relationship to the patentability of claims, is normally disclosed on the *transmittal form*.⁴² Deceptive information relating to small entity status can influence the court’s thoughts on whether failure to submit a publication was with deceptive intent. Inventorship is disclosed by the *oath*.⁴³ Priority is disclosed in the *first paragraph of the patent’s specification*.⁴⁴ Sources of

³⁴ 37 C.F.R. § 1.56(b)(2)(ii) (2006).

³⁵ 810 F.2d 1148, 1152 (Fed. Cir. 1987).

³⁶ 759 F.2d 10, 14 (Fed. Cir. 1985).

³⁷ 798 F.2d 1392 (Fed. Cir. 1986).

³⁸ 231 F.3d 1373 (Fed. Cir. 2000).

³⁹ *A.B. Dick*, 798 F.2d at 1397; *Li Second Family*, 231 F.3d at 1379.

⁴⁰ See 3 DONALD S. CHISUM, CHISUM ON PATENTS § 9.01 (2007).

⁴¹ See, e.g., *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 925 (Fed. Cir. 2007); *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382–84 (Fed. Cir. 1998).

⁴² See 37 C.F.R. § 1.27(c) (2006).

⁴³ *Id.* § 1.63(a)(2).

⁴⁴ *Id.* § 1.78(a).

federal funding are disclosed on the *first page of the specification*.⁴⁵ Ownership is disclosed on the *assignment*.⁴⁶ These types of information are properly disclosed by formats other than an IDS. But if the information is withheld or incorrect, the oversight can provoke a court to find inequitable conduct for failure to disclose a typical publication.

A. Relative to Each Other, the Pre-March 1992 Standard Is Anti-Patent Holder, While the Post-March 1992 Standard Is Pro-Patent Holder.

Relative to each other, the earlier standard is anti-patent holder, while the later standard is pro-patent holder. The pro-patent holder and anti-patent holder nature of these two standards is demonstrated by the fact that, in many opinions, the plaintiff (patent holder) had argued to apply the post-March 1992 standard, while the defendant (accused infringer) had argued to apply the earlier standard. Moreover, some published opinions have actually stated that the post-March 1992 standard is the narrower standard or the more stringent standard.⁴⁷

One telling scenario showing a patentee's preference for the narrow post-March 1992 standard is found in *Upjohn Co. v. Mova Pharmaceutical Corp.*⁴⁸ The patent owner, with the goal of influencing the court to apply the narrow post-March 1992 standard, repeatedly used the term *patentability* in its arguments regarding materiality.⁴⁹ The term *patentability* invokes the narrower and more stringent post-March 1992 standard, not the earlier more-encompassing standard.

B. Inconsistent Application of the Pre-March 1992 and Post-March 1992 Standards

The courts have not been consistent in following the March 16, 1992 change in Rule 56. Generally, for patents prosecuted before March 1992, the courts have followed the broader pre-March 1992 standard. But for patents filed and prosecuted entirely after March 1992, some of the cases have cited (or cited and applied) the pre-March 1992 standard, while other cases have cited (or cited and applied) the post-

⁴⁵ U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 310 (8th ed., 5th rev. 2006) [hereinafter MPEP]; *see also* 35 C.F.R. § 202(c) (2006).

⁴⁶ 37 C.F.R. § 3.1.

⁴⁷ *Purdue Pharma v. Endo Pharms., Inc.*, 70 U.S.P.Q.2d 1185, at 1203 (S.D.N.Y. 2004), *aff'd*, 410 F.3d 690 (Fed. Cir. 2005), *reh'g granted, aff'd in part, vacated in part*, 438 F.3d 1123 (Fed. Cir. 2006) (vacating the inequitable judgment); *Mentor Graphics Corp. v. Quickturn Design Sys.*, No. C 00-1030 SI, C 99-5464 SI, C 00-3291 SI, C 02-1426 SI, 2003 U.S. Dist. LEXIS 16197, at *26-27 (N.D. Cal. July 30, 2003); *Jack Schwartz Shoes, Inc. v. Sketchers U.S.A., Inc.*, 233 F. Supp. 2d 512, 514 (S.D.N.Y. 2002); *Monsanto Co. v. Bayer Bioscience N.V.*, 264 F. Supp. 2d 852, 859 (E.D. Mo. 2002), *rev'd*, 363 F.3d 1235 (Fed. Cir. 2004), *remanded to 2007 U.S. Dist. LEXIS 27156* (E.D. Mo. Apr. 12, 2007), *aff'd*, 2008 U.S. App. LEXIS 1409 (Fed. Cir. Jan. 28, 2008) (affirming the finding that the patent is unenforceable due to inequitable conduct); *E. Am. Trio Prods. v. Tang Elec. Corp.*, 97 F. Supp. 2d 395, 403 (S.D.N.Y. 2000); *see* *Boehringer Ingelheim Vetmedica v. Schering-Plough Corp.*, 106 F. Supp. 2d 667 (D.N.J. 2000), *aff'd*, 320 F.3d 1339 (Fed. Cir. 2003).

⁴⁸ 225 F.3d 1306, 1313-15 (Fed. Cir. 2000).

⁴⁹ *Id.* at 1314.

March 1992 standard. The court in *Monsanto Co. v. Bayer Bioscience, N.V.*⁵⁰ observed that after the USPTO changed its standard, the Federal Circuit had not followed suit.⁵¹ Inconsistencies in the application of the two standards are detailed at the end of this essay.

Two cases from 2005, *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services*,⁵² and *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*,⁵³ appeared to have brought an end to this particular uncertainty of which standard would be applied in the courts. As both opinions stated, the courts should give deference to the USPTO's formulation of the standard of materiality at the time an application is being prosecuted. However, the result was short-lived. Three cases from 2006, *Digital Control Inc. v. Charles Machine Works*,⁵⁴ *Agfa Corp. v. Creo Products*,⁵⁵ and *Ferring B.V. v. Barr Laboratories, Inc.*,⁵⁶ held that the USPTO's adoption of the narrower standard of materiality did not replace the reasonable examiner standard found in the Federal Circuit's established case law, and that the narrower standard of the post-March 1992 Rule 56 merely provides an additional test of materiality.⁵⁷

C. Which Date Controls Choice of Law, the Date of the Deceptive Act or the Filing Date of the Patent Application?

Does choice of administrative law that is applied, the pre-March 1992 Rule 56 or the post-March 1992 Rule 56, depend on the *filing date of the patent application*, or does it depend on the actual *date of the alleged inequitable conduct*?

A number of cases have found that the controlling date is the date of the event of inequitable conduct.⁵⁸ *CFMT, Inc. v. Yieldup International Corp.*⁵⁹ referred the lower court's opinion of the correct standard (and did not confirm or dispute this opinion), where the lower court "applied the pre-1992 standard for materiality, because the relevant acts took place before 1992."⁶⁰

D. A Third Standard of Materiality, the "But For" Standard.

⁵⁰ 264 F. Supp. 2d 852.

⁵¹ *Id.* at 859 n.33.

⁵² 394 F.3d 1348, 1353 (Fed. Cir. 2005).

⁵³ 438 F.3d 1123, 1129 (Fed. Cir. 2006).

⁵⁴ 437 F.3d 1309 (Fed. Cir. 2006).

⁵⁵ 451 F.3d 1366 (Fed. Cir. 2006).

⁵⁶ 437 F.3d 1181 (Fed. Cir. 2006).

⁵⁷ *Digital Control*, 437 F.3d at 1316; *Agfa Corp.*, 451 F.3d at 1373; *Ferring B.V.*, 437 F.3d at 1187 n.6.

⁵⁸ See, e.g., *In re Harita*, 847 F.2d 801, 809 (Fed. Cir. 1988); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1551 (Fed. Cir. 1983); *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1340 (Fed. Cir. 2003).

⁵⁹ 349 F.3d 1333.

⁶⁰ *Id.*

A third standard, the “but for” standard, was articulated and properly rejected in *Cordis Corp. v. Medtronic AVE, Inc.*,⁶¹ where the court held that the test for materiality was *not* whether the information would *conclusively decide the issue of patentability*.⁶² The “but for” standard was also rejected in *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*,⁶³ which characterized the “but for” standard as information a jury found to be invalidating.⁶⁴ The U.S. district court hearing *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*⁶⁵ characterized the third standard by writing that the patent would have issued “but for” the misrepresentation or omission.⁶⁶ The third standard is not part of Rule 56.⁶⁷ This lack of application of the “but for” standard was noted by Harry F. Manbeck, Jr. in *Evolution and Future of New Rule 56 and the Duty of Candor: The Evolution and Issue of New Rule 56*.⁶⁸

E. Examples of References That Are Material Under the Pre-March 1992 Standard but Are Not Material Under the Post-March 1992 Standard.

Guidance as to the difference between the more encompassing pre-March 1992 standard of materiality, and the narrower post-March 1992 standard, is provided by the following cases. From the available cases, it is apparent that the degree of guidance is somewhat sparse. The relative lack of guidance has inspired the routine submission of huge IDSs, of up to 100 or more publications, where the goal of the patent attorney is to ensure satisfaction of the broader standard of disclosure.

*Argus Chemical Corp. v. Fibre Glass-Evercoat Co.*⁶⁹ provides a practical definition of a reference that is likely material under the broad standard, but not material under the narrow standard, stating that this type of reference is one that is so close to the claimed invention that it induces the attorney handling the application to amend the claims, before initial examination, to avoid reading directly on the products.⁷⁰ Ordinarily, one might view the reference as lacking in materiality, because the reference is not material to the claims under review. However, the fact that the reference was directly material to the claims as originally submitted renders the reference material under the broader standard even after the amendment.

⁶¹ 194 F. Supp. 2d 323 (D. Del. 2002), *rev'd on other grounds*, 339 F.3d 1352 (Fed. Cir. 2003) (reversing infringement based on doctrine of equivalents and not addressing materiality of reference to a U.S. application).

⁶² *Id.* at 366.

⁶³ 92 F. Supp. 2d 857 (E.D. Wis. 2000), *aff'd in part, rev'd in part*, 31 F. App'x 727 (Fed. Cir. 2002) (affirming the lower court's finding of no inequitable conduct but reversing and remanding the issue of infringement).

⁶⁴ *Id.* at 873.

⁶⁵ 90 F. Supp. 2d 540 (D.N.J. 2000), *aff'd in part, vacated in part*, 246 F.3d 1368 (Fed. Cir. 2001), *remanded to* 90 F. Supp. 2d 522 (D.N.J. 2000) (denying defendant's summary judgment motion for inequitable conduct based on nondisclosure of prior art, misconduct in prosecution, and misrepresentations or omissions, and granting summary judgment for unresponsive statements to the USPTO).

⁶⁶ *Id.* at 548.

⁶⁷ Manbeck, Jr., *supra* note 13, at 141.

⁶⁸ *Id.* at 139–41.

⁶⁹ 759 F.2d 10 (Fed. Cir. 1985).

⁷⁰ *Id.* at 14.

Additional guidance as to what might be material under the broad standard, but not material under the narrow standard, comes from *Rhenalu v. Alcoa, Inc.*⁷¹ Alcoa, owner of U.S. Patent No. 5,213,639,⁷² failed to disclose Alcoa's "417 Process," a process that improved damage tolerance of bare plate products.⁷³ The 417 Process consists of a preheat step and a reheat step.⁷⁴ The court pointed out that these steps are *contrary* to the teachings of the U.S. Patent No. 5,213,639, and held that the 417 Process cannot be considered material because it contains features that contradict the claimed invention.⁷⁵ By suggesting that the process was contrary to the claims, the court did not mean that the non-disclosed information (the 417 Process) rendered the claimed invention doubtful; it meant that the non-disclosed information was so strikingly different from the claimed invention as to be irrelevant to the claims.

*Bayer AG v. Sony Electronics, Inc.*⁷⁶ provides additional guidance of a reference that might be material under the broad standard but not under the narrow standard.⁷⁷ The court wrote that this reference could be one that discloses "the path that leads an inventor to the invention."⁷⁸ The opinion wrote that this type of reference could have some degree of materiality, though not a high degree of materiality.⁷⁹

*Merck & Co. v. Teva Pharmaceuticals USA, Inc.*⁸⁰ appears to identify a reference (July 1996 Lunar News) that is material under the broad standard, but not material under the narrow standard.⁸¹ The court held that this document "has some degree of materiality because it has relevance to the claimed invention, specifically the recommended once-weekly dosage level . . . [but it] does not render the claimed invention invalid as either obvious or anticipated."⁸²

*Specialty Composites v. Cabot Corp.*⁸³ also seems to identify a reference (Gardner Italian patent) that is material under the broad standard, but not under the narrow standard.⁸⁴ That this reference was found to have some degree of materiality was based, at least in part, on the fact that it was not disclosed during the prosecution of the original patent, but was disclosed later on during a reissue proceeding.⁸⁵ The court noted that the lower court found that this, and other, references "were material, but apparently did not find them to be particularly material."⁸⁶

⁷¹ 224 F. Supp. 2d 773, 805 (D. Del. 2000).

⁷² U.S. Patent No. 5,213,639 (filed Mar. 6, 1992).

⁷³ *Rhenalu*, 224 F. Supp. 2d at 791.

⁷⁴ *Id.* at 798.

⁷⁵ *Id.* at 807.

⁷⁶ 229 F. Supp. 2d 332 (D. Del. 2002), *aff'd*, 2003 U.S. App. LEXIS 25581 (Fed. Cir. Dec. 5, 2003).

⁷⁷ *Id.* at 362.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ 288 F. Supp. 2d 601 (D. Del. 2003), *rev'd*, 395 F.3d 1364 (Fed. Cir. 2005).

⁸¹ *Id.* at 633.

⁸² *Id.* at 632.

⁸³ 845 F.2d 981 (Fed. Cir. 1988).

⁸⁴ *Id.* at 992.

⁸⁵ *Id.*

⁸⁶ *Id.*

F. MATERIAL INFORMATION

Material information generally includes research publications, patents and published patent applications, both U.S. and foreign, published abstracts and proceedings from a conference, theses catalogued in a library, and grant applications that are publicly available. Material information also includes documentation of a sale or public use. These types of information are properly disclosed by way of an IDS.

Other forms of information can be relevant to determining relevance of a non-disclosed publication, for example, small entity status, ownership, inventorship, and sources of federal funding. Although these forms of information are properly submitted by other formats, for example, by the patent transmission form or by the inventor's oath, the deceptive disclosure of small entity status or inventorship can persuade the court to believe that non-disclosure of a publication also involved deceit. Inventorship is only occasionally an issue in the Federal Circuit.⁸⁷

Dicta from *Ulead Systems, Inc. v. Lex Computer & Management Corp.*⁸⁸ provides an interesting guideline regarding materiality. This case found that materiality of omitted or concealed information is increased where the USPTO has no way of securing information on its own.⁸⁹

1. Materiality Shown by Citation in a Foreign Counterpart Application or a Related U.S. Application

a. Foreign Counterpart Application

When a patent application is submitted to the USPTO, most applicants also submit an identical international application ("PCT application").⁹⁰ The PCT application serves as a place-holder for a period of time that subsequently branches off into regional applications or into applications into individual nations.⁹¹ Shortly after the PCT application is filed, but before the application branches off into the individual nations, an International Search Report is issued and mailed to the inventor.⁹² For each reference, the Report indicates whether it is highly material or merely provides background technical information.

In a number of cases from the Federal Circuit, materiality of a reference to a U.S. application has been determined by its citation in the International Search Report during prosecution of its counterpart foreign application.⁹³ Conversely, where

⁸⁷ See, e.g., *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000); *Fla. State Bd. of Educ. v. Am. Biosciences, Inc.*, 333 F.3d 1330 (Fed. Cir. 2003).

⁸⁸ 130 F. Supp. 2d 1137 (C.D. Cal. 2001), *vacated*, 351 F.3d 1139 (Fed. Cir. 2003).

⁸⁹ *Id.* at 1144.

⁹⁰ See 37 C.F.R. § 1.431 (2006).

⁹¹ *Id.* § 1.496.

⁹² *Id.* § 1.413(c)(5).

⁹³ *Cordis Corp. v. Medtronic AVE, Inc.*, 194 F. Supp. 2d 323 (D. Del. 2002), *rev'd on other grounds*, 339 F.3d 1352 (Fed. Cir. 2003) (reversing the lower court's finding of infringement based on the doctrine of equivalents but not addressing the issue of materiality regarding a reference);

the International Search Report classifies a publication as merely disclosing technical background, the Report can establish that the reference is non-material.⁹⁴

In addition to the Search Report, the PCT issues a written opinion as to the patentability of the claims. Similarly, the patent offices in individual foreign countries also issue written opinions on patentability. However, foreign legal opinions that directly assess patentability are not likely to be material to any U.S. application. The Federal Circuit in *Molins PLC v. Textron, Inc.*⁹⁵ and *ATD Corp. v. Lydall, Inc.*⁹⁶ has cautioned that standards of patentability differ between foreign patent offices and the USPTO⁹⁷ and that details of foreign prosecution, such as the legal basis for rejection, are *not* an additional category of material information.⁹⁸

b. Where the Related Applications Are Both U.S. Basic Patent Applications

*D.O.C.C. Inc. v. Spintech Inc.*⁹⁹ illustrates a situation where a reference (Knight patent) was cited in a rejection of a first patent application, but where the applicant failed to disclose the same reference to the examiner of a related second patent application.¹⁰⁰ The two patent applications were co-pending. The examiner (examiner Snay) cited the Knight patent against the first application, resulting in the applicant's abandonment of that application.¹⁰¹ However, the applicant failed to disclose the Knight patent to the examiner (examiner Yuen) of the second patent application. The second application was allowed and it issued. The court rendered this allowed patent unenforceable because of failure to disclose Knight.¹⁰²

c. Re-Examination Proceeding

Re-examination is a special procedure available to all patentees.¹⁰³ The re-examination proceeding can be initiated by a patentee interested in confirming the strength of his or her patent. In a word, the issued patent is reviewed by a patent examiner, where the examiner has the challenge of imposing rejections against the patent, in view of the prior art. Where the patent survives the re-examination, the patentee can expect to have a stronger patent that can survive scrutiny during any possible litigation. A question that arises is whether a re-examination proceeding can be used to disclose a prior art reference that had previously been concealed and

Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); AEA Tech. v. Thomas & Betts Corp., 167 F. Supp. 2d 993 (N.D. Ill. 2001); Emerson Elec. Co. v. Spartan Tool, L.L.C., 223 F. Supp. 2d 856 (N.D. Ohio 2002); ATD Corp. v. Lydall, Inc., 159 F.3d 534 (Fed. Cir. 1998).

⁹⁴ TAP Pharm. Prods v. Owl Pharms., 419 F.3d 1346, 1352 (Fed. Cir. 2005).

⁹⁵ 48 F.3d 1172 (Fed. Cir. 1995).

⁹⁶ 159 F.3d 534.

⁹⁷ *Molins PLC*, 48 F.3d at 1180.

⁹⁸ *ATD Corp.*, 159 F.3d at 547.

⁹⁹ 36 U.S.P.Q.2d 1145 (S.D.N.Y. 1994).

¹⁰⁰ *Id.* at 1147.

¹⁰¹ *Id.* at 1154.

¹⁰² *Id.* at 1149.

¹⁰³ See 35 U.S.C. § 302 (2006).

non-disclosed by the inventor during the prosecution of the original patent application? The available case law indicates that the answer is no.

Where an issued patent is later subjected to a re-examination proceeding in the USPTO, the patent examiner may cite references against the patent that had not been disclosed during the prosecution of the original patent application. This situation is evidence of materiality, especially if the rejection cannot be rebutted or where the rejection is not withdrawn. For example, in *Applera Corp. MDS v. Micromass UK Ltd.*,¹⁰⁴ a reference (French) not disclosed during the original prosecution of the patent was disclosed during a later re-examination proceeding of the same patent.¹⁰⁵ Although the court refrained from holding that there was intent to deceive, the early non-disclosure coupled with the later disclosure raised the issue of deceptive intent.¹⁰⁶

In *Molins PLC v. Textron, Inc.*,¹⁰⁷ a material reference (Wagenseil) was withheld with intent to deceive during the prosecution of a parent application, but was timely submitted during a subsequent re-examination proceeding.¹⁰⁸ Citation of the reference during the re-examination did not cure the earlier intent to deceive.¹⁰⁹ The court found the manner in which the applicants had disclosed the reference during re-examination—it had been disclosed in a buried form—was tantamount to not disclosing it at all.¹¹⁰

d. Reissue Application

A reissue application is a format available to the patentee for changing the scope of the claims of an issued patent.¹¹¹ As with a re-examination proceeding, a reissue patent application cannot be used to cure the earlier deceptive non-disclosure of a material reference. The available case law reveals the following regarding reissue applications.

Where the examiner of the reissue application finds the reference *not* material, then the reference would also not be material to the prosecution of the original patent, providing that claims of the same claim scope, as was held in *Gen-Probe, Inc. v. Vysis, Inc.*¹¹² In short, while a reissue application cannot cure any previous intent to deceive, where the examiner of the reissue application finds the reference in question to be immaterial, this finding renders moot any question of the deceptive non-disclosure during the prosecution of the original patent application.¹¹³

¹⁰⁴ 204 F. Supp. 2d 724 (D. Del. 2002).

¹⁰⁵ *Id.* at 759.

¹⁰⁶ *Id.* at 758.

¹⁰⁷ 48 F.3d 1172 (Fed. Cir. 1995).

¹⁰⁸ *Id.* at 1190.

¹⁰⁹ *Id.* at 1179.

¹¹⁰ *Id.* at 1183.

¹¹¹ See 35 U.S.C. §§ 251, 252 (2006).

¹¹² NO. 99-CV-2668 H (AJB), 2002 U.S. Dist. LEXIS 25020 (S.D. Cal. Aug. 2, 2002), *vacated*, 359 F.3d 1376 (Fed. Cir. 2004).

¹¹³ *Id.* at *108.

2. *Non-Disclosure of a Sale or Public Use*

Failure to disclose a sale or public use is a frequent issue arising during patent litigation.¹¹⁴ *Dippin' Dots, Inc. v. Mosey*¹¹⁵ provides a dramatic example where inequitable conduct was found, rendering a patent unenforceable.¹¹⁶ The non-disclosed sale had a high degree of materiality, because it was an invalidating sale. Intent was inferred by the fact that the inventor had “enthusiastically touted sales made after the critical date [the 1-year bar date].”¹¹⁷ The strong materiality of the non-disclosed information, coupled with the weak evidence for intent, satisfied both of the prongs needed for finding inequitable conduct.¹¹⁸

*For Your Ease Only, Inc. v. Calgon Carbon Corp.*¹¹⁹ illustrates an improper disclosure of a sale of the invention.¹²⁰ The sale of the invention (activated carbon cloth; (“ACC”)) was disclosed to the USPTO, but the disclosure was improper. The disclosure took the form of commentary in the patent’s specification, which read: “A commercial jewelry box (purchased from K-Mart Corporation) fitted with FM1-250 ACC (available from Calgon Carbon Corporation, Pittsburgh, Pa.)”¹²¹ But the sale was not additionally disclosed by way of an IDS, as it should have, and the patent was rendered unenforceable.¹²²

The applicant has a duty to disclose any sales occurring one year before the priority date or filing date.¹²³ This statutory one year period is sometimes called a one-year “grace period.”¹²⁴ However, for any sale occurring before the one-year grace period, it can be asked if the sale was truly material or not.¹²⁵ *Reactive Metals & Alloys Corp. v. ESM, Inc.*¹²⁶ held that the inventor has no duty to disclose sales *that the inventor believes to be non-barring* because the *examiner is not in a position to*

¹¹⁴ *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001); *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253 (Fed. Cir. 2001); *Jack Frost Labs., Inc. v. Physicians & Nurses Mfg. Corp.*, Nos. 96-1114, 96-1430, 96-1543, 1997 U.S. App. LEXIS 26138 (Fed. Cir. Sept. 23, 1997); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570 (Fed. Cir. 1995); *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066 (Fed. Cir. 1992); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990); *Allen Organ Co. v. Kimball Int’l, Inc.*, 839 F.2d 1556 (Fed. Cir. 1989); *Reactive Metals & Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578 (Fed. Cir. 1985); *Argus Chem. Corp. v. Fibre Glass-Evercoat Co, Inc.*, 759 F.2d 10 (Fed. Cir. 1985); *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529 (Fed. Cir. 1984); *Mentor Graphics v. Quickturn Design Sys.*, Nos. C 00-1030 SI, C 99-5464 SI, C 00-3291 SI, C 02-1426 SI, 2003 U.S. Dist. LEXIS 16197 (N.D. Cal. July 30, 2003); *Creo Prods., Inc. v. Presstek, Inc.*, No. 99-525-GMS, 2001 U.S. Dist. LEXIS 6226 (D. Del. May 11, 2001).

¹¹⁵ 476 F.3d 1337 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 375 (2007), *and* 128 S. Ct. 391 (2007).

¹¹⁶ *Id.* at 1346.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ No. 02 C 7345, 2003 U.S. Dist. LEXIS 7131 (N.D. Ill. Apr. 24, 2003).

¹²⁰ *Id.* at *16.

¹²¹ U.S. Patent No. 6,412,628 col.4 (filed Mar. 22, 2000); *For Your Ease Only, Inc.*, 2003 U.S. Dist. LEXIS 7131, at *16 n.1.

¹²² *For Your Ease Only, Inc.*, 2003 U.S. Dist. LEXIS 7131, at *16–17.

¹²³ *Reactive Metals & Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578, 1583 (Fed. Cir. 1985).

¹²⁴ *Gemmy Indus. Corp. v. Chrisha Creations, Ltd.*, 452 F.3d 1353, 1358 (Fed. Cir. 2006) (“The Patent Statute, 35 U.S.C. § 102(b) permits a one-year grace period after the invention is first sold or placed on sale, before the entitlement to a patent is barred.”).

¹²⁵ *Reactive Metals & Alloys Corp.*, 769 F.2d at 1583.

¹²⁶ *Id.*

effectively challenge such an assertion.¹²⁷ Similarly, in *Allied Colloids, Inc. v. American Cyanamid Co.*,¹²⁸ the court held that failure to tell the examiner about a sale cannot be deemed material because it is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material.¹²⁹ The sale in *Allied Colloids* was considered a close call by the court because the sale had occurred only one week before the critical bar date.¹³⁰ *Reactive Materials* and *Allied Colloids* contrast with the holdings of *Argus Chemical Corp. v. Fibre Glass-Evercoat Co., Inc.*¹³¹ and *LifeScan, Inc. v. Home Diagnostics, Inc.*¹³²

The *Argus Chemical Corp.* opinion observed that a sale had been made, where the sale constituted a statutory bar under 35 U.S.C. § 102, but that the attorney had submitted an amendment before initial examination, where the goal was to prevent the item, as described in the claims, from being the same as the sold item.¹³³ In other words, the elements in the device as sold matched, on a one-to-one basis, the elements in the original claim. However, after the amendment, the components or elements of the device as sold, no longer matched, on a one-to-one basis, the elements in the claim. The court disapproved of the non-disclosure of the sale, writing that if the applicant had considered the claims sufficiently narrow to be clear of the prior art reference (the sale), then it was *the responsibility of the examiner, not the applicant*, to decide if the original claims had been amended sufficiently to be patentable over the reference.¹³⁴

LifeScan concerned a patent having a priority date of August 13, 1986.¹³⁵ The opinion focused its attention on the non-disclosure of a newspaper article dated February 1987, and a device (NovoCheck meter) displayed at a trade show in September 1987.¹³⁶ Despite the fact that these non-disclosed reference were dated *after* the start of the one-year grace period (Aug. 13, 1985), and also *after* the patent's priority date (Aug. 13, 1986), the court proceeded to review materiality and to assess intent, citing *Mobil Oil Corp. v. Advanced Environmental Recycling Technologies, Inc.*,¹³⁷ for the rule that a reference does not have to be "prior art" to be material.¹³⁸

To conclude, the application should disclose sales or public uses, especially where the sale or public use took place at a time that was close to the critical bar date. In view of the lack of bright line rules regarding whether or not an examiner is in a position to evaluate a sale or public use, the applicant should consider disclosure to be on the safe side.

¹²⁷ *Id.*

¹²⁸ 64 F.3d 1570 (Fed. Cir. 1995).

¹²⁹ *Id.* at 1577.

¹³⁰ *Id.* at 1573.

¹³¹ 759 F.2d 10 (Fed. Cir. 1985).

¹³² 103 F. Supp. 2d 379 (D. Del. 2000), *aff'd without opinion*, 13 F. App'x 940 (2001).

¹³³ *Argus Chem. Corp.*, 759 F.2d at 12.

¹³⁴ *Id.* at 13.

¹³⁵ *Lifescan*, 103 F. Supp. 2d at 382 n.2.

¹³⁶ *Id.* at 381.

¹³⁷ 869 F. Supp. 251, 255 (D. Del. 1994), *aff'd in part without opinion, vacated in part without opinion*, 92 F.3d 1203 (Fed. Cir. 1996).

¹³⁸ *Lifescan*, 103 F. Supp. 2d at 383.

3. Non-Disclosure of Publications or Laboratory Data That Establish Non-Enablement of the Claimed Invention

Most researchers might consider relevant publications to include only those that might serve as a basis for rejection for anticipation (35 U.S.C. § 102) or obviousness (35 U.S.C. § 103). However, publications and confidential laboratory data that call into question the enablement of the claimed invention are also relevant, and must be disclosed. Where a claim is rejected for non-enablement, the rejection is under 35 U.S.C. § 112.

*Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*¹³⁹ provides a dramatic example of a non-disclosed reference that questioned enablement of the claims. A non-disclosed reference (JACS article) was found to be material because the reference proved that a claim was non-enabled.¹⁴⁰ The non-disclosed reference was a publication, reporting the inventor's results and had been published on August 17, 1988.¹⁴¹ The U.S. patent application was filed shortly thereafter, on April 3, 1989. Thus the JACS reference fell within the one-year grace period, and *was not prior art* to the U.S. application.

The JACS reference disclosed that methoxymethyl ("MOM") and trimethylsilyl ("TMS") did not work as protecting groups. The court found that the JACS article was material, found inequitable conduct, and rendered the patent unenforceable.¹⁴²

To review the time line, the inventor generated lab data showing that MOM and TMS did not work, and then the inventor submitted a manuscript for publication in JACS where the manuscript disclosed that MOM and TMS did not work. Later, the applicant filed a patent application claiming use of MOM and TMS (things that the inventor knew did not work), and then the JACS article was published. To conclude, the case law demonstrates that the consequences of failing to disclose an after-arising reference can be severe.

Non-disclosure of references relating to non-enablement was also an issue in *Bayer AG v. Housey Pharmaceuticals, Inc.*¹⁴³ The inventor had failed to disclose the Hsiao and Uehara references, references that raised questions of enablement of the claimed invention. The court held that the Hsiao reference and the Uehara reference were material.¹⁴⁴ Although this non-disclosure, in itself, was held not enough to establish intent to deceive the USPTO, the court invoked the applicant's general pattern of non-credibility and rendered the inventor's patent unenforceable.¹⁴⁵

*Monsanto Co. v. Bayer Bioscience, N.V.*¹⁴⁶ illustrates the situation where laboratory data relating to enablement was held to be highly material.¹⁴⁷ The

¹³⁹ 326 F.3d 1226 (Fed. Cir. 2003).

¹⁴⁰ *Id.* at 1239.

¹⁴¹ *Id.* at 1231.

¹⁴² *Id.* at 1238 (explaining that no expert testified that a person of ordinary skill would know how to make either TMS or MOM work as a protecting group).

¹⁴³ 128 F. App'x 767, 768 (Fed. Cir. 2005).

¹⁴⁴ *Id.* at 770 (holding that Housley did not knowingly withhold the material prior art references).

¹⁴⁵ *Bayer AG v. Housey Pharms., Inc.*, 386 F. Supp. 2d 578, 582 (D. Del. 2005), *aff'd*, 189 F. App'x 959 (Fed. Cir. 2006).

¹⁴⁶ 264 F. Supp. 2d 852 (E.D. Mo. 2002), *rev'd*, 363 F.3d 1235 (Fed. Cir. 2004), *remanded to* 2007 U.S. Dist. LEXIS 27156 (E.D. Mo. Apr. 12, 2007), *aff'd*, 2008 U.S. App. LEXIS 1409 (Fed. Cir. Jan. 28, 2008) (affirming the finding that the patent is unenforceable due to inequitable conduct).

relevant patents claimed a biotechnology product used as an insecticide, where the insecticide was claimed to be active with any plant and with all plants, e.g., tobacco, cabbage, cotton, corn, and potatoes. Unfortunately, some time during the pendency of the patent application, the inventor generated laboratory data demonstrating that *the claimed product did not work with cabbage or cotton*. Even worse, the inventor submitted a Declaration to the USPTO stating, “[t]he test results shown . . . demonstrate that [the invention] . . . can generally be used to provide an insect controlling amount . . . in generally any plant . . . I know of no test results which are contrary to or inconsistent with the test results set forth above.”¹⁴⁸ The court found the non-disclosed test results with cabbage and cotton to be highly material, that intent to deceive was established by the false nature of the declaration, and held the patents unenforceable for inequitable conduct.¹⁴⁹ The take home lesson is that where laboratory data that contradicts the claims are generated, the inventor has a duty to disclose the contradictory data to the USPTO. From this opinion, it can also be seen that any declarations submitted during the prosecution of a patent application can act as lightning rods that can attract allegations of deceptive intent.¹⁵⁰

In commentary in the Federal Register, the USPTO suggested that results from invalid tests and failed experiments should be disclosed, writing that it is the patent examiner who should make the determination after considering all the facts involved in the particular case.¹⁵¹ According to *CFMT Inc. v. Yieldup International Corp.*,¹⁵² test results that go somewhat beyond establishing enablement of a prototype are generally not material and need not be disclosed, that is, test results demonstrating that an embodiment fails to meet a certain commercially desired specification, or an industry-wide standard, are *not* likely to be material.¹⁵³

4. Non-Disclosure of Patents, Patent Applications, and Office Actions (Examiner’s Rejections)

*Molins PLC v. Textron, Inc.*¹⁵⁴ and the Manual of Patent Examining Procedure (“MPEP”) establish that where an applicant or assignee has filed two different patent applications with similar or identical claims, the first application is material to the second application.¹⁵⁵ The patent applications are relevant to each other because of the prohibition against double patenting, that is, the situation where an inventor or assignee owns two patents having identical claims, or two patents with different

¹⁴⁷ *Id.* at 861.

¹⁴⁸ *Id.* at 856.

¹⁴⁹ *Id.* at 862.

¹⁵⁰ See *Jack Frost Labs. Inc. v. Physicians & Nurses Mfg. Corp.*, No. 92-CV-9264, 1997 U.S. Dist. LEXIS 26138, at *10, *19 (Fed. Cir. Sept. 23, 1997) (concerning the issue of non-disclosed data from the inventor’s own laboratory, where the data established non-enablement of the claims).

¹⁵¹ Duty of Disclosure, *supra* note 15, at 2025–26.

¹⁵² 349 F.3d 1333 (Fed. Cir. 2003).

¹⁵³ *Id.* at 1342.

¹⁵⁴ 48 F.3d 1172 (Fed. Cir. 1995).

¹⁵⁵ *Id.* at 1185; MPEP, *supra* note 45, § 2001.06(b); see also *id.* § 804 (stating “a claim in the patent compared to a claim in the application” in an obvious-type double patenting).

expiration dates having claims that are obvious in view of each other.¹⁵⁶ Where two patent applications have the same owner or assignee, the two applications are relevant to each other and must be disclosed to the examiners reviewing the two cases, even if it is merely *conceivable* that there could be a rejection for double patenting.¹⁵⁷ To satisfy the duty to disclose where there is the potential for a double patenting rejection, it is important that the existence (identification by serial number) of the co-pending applications be disclosed, more important that any Office Actions (claim rejections) in the co-pending applications be disclosed, and most important that any *allowed claims* in the co-pending applications be disclosed.¹⁵⁸

Office actions from patent applications having identical claims, or claims of similar scope, are material and must be disclosed. According to *Dayco Products, Inc. v. Total Containment, Inc.*,¹⁵⁹ an office action containing rejections against a claim in a first patent application is material to a second patent application that contains a similar claim.¹⁶⁰ The applicant needs to use an IDS to submit the office action to the examiner reviewing the second application. The *Dayco* holding was applied in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,¹⁶¹ and the disputed patent was rendered unenforceable for inequitable conduct.¹⁶² An inventor had filed two patent applications with similar claims, where the first application was reviewed by a first examiner (Examiner Trafton) and the second application was reviewed by a second examiner (Examiner Lev).¹⁶³ Examiner Lev rejected the claims in the second patent in view of a Baker reference.¹⁶⁴ However, the inventor failed to disclose the Baker reference to the first examiner, and also failed to disclose the office action (Examiner Lev's rejection) to the first examiner.¹⁶⁵ Moreover, a week or so after Examiner Lev imposed the rejection in view of Baker, the inventor informed Examiner Trafton, in writing, that there was no relevant prior art.¹⁶⁶ The Federal Circuit held that the inventor intended to deceive the USPTO.¹⁶⁷ The *Dayco* rule for disclosing office actions should be followed, where double patenting is a potential issue. *Dayco* must also be followed where the cancellation or amendment of any claims had removed the potential for a double patenting rejection.

The above commentary concerns patents of overlapping claim scope that have the same assignee. But what about patents of overlapping or identical claim scope having different owners? Law firms are likely to encounter this situation, though it is generally prevented by doing a conflict of interest analysis prior to accepting new clients. This type of conflict can be prevented by conflict of interest checks, as

¹⁵⁶ MPEP, *supra* note 45, § 804.

¹⁵⁷ *See* *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 912, 919, 923–26 (Fed. Cir. 2007).

¹⁵⁸ *See id.*

¹⁵⁹ 329 F.3d 1358 (Fed. Cir. 2003).

¹⁶⁰ *Id.* at 1365.

¹⁶¹ 487 F.3d 897.

¹⁶² *Id.* at 913–26.

¹⁶³ *Id.* at 903–04.

¹⁶⁴ *Id.* at 906.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 909.

reviewed by Lisa Dolak.¹⁶⁸ The *Molins* opinion refrained from commenting on this type of fact pattern. However, in the *Molins* dissent, Judge Newman wrote that with regard to the patent application that an entirely unrelated client happened to entrust to the same lawyer an attorney's ethical obligations to each client are not erased when possible conflict occurs.¹⁶⁹ In other words, Judge Newman believed that there is not any duty to disclose a first patent application to an examiner of a second patent application, where the first application and second application have entirely different inventors.

5. *Curing Non-Disclosure by Disclosure to an Examiner in a Related Patent Application*

Inventors often file multiple patent applications, where each patent application has its own IDS. A problem that can arise, especially with a lengthy submission of many publications, is submission of one particular publication in one IDS, but inadvertent omission of that publication from the other IDS.

*Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*¹⁷⁰ discloses the following holding. The court held that the non-disclosed reference (abstract of Collins and Benfield) was *not material* to the prosecution of a first patent, where the same reference had been disclosed during the prosecution of a second, related patent, and where the examiner of the second patent had considered the reference, but refrained from using the reference in a rejection of the second patent application.¹⁷¹

In *Allen Organ Co. v. Kimball International, Inc.*,¹⁷² two patent applications were filed on the same day (October 30, 1969), where a material reference (Pearson) had been disclosed in the first application but not in the second application.¹⁷³ A successful argument for *lack of materiality* was based on the fact that the *same examiner* (Stanley Witkowski) had examined both applications,¹⁷⁴ thus indicating the examiner's awareness of the non-disclosed reference when reviewing the second application.¹⁷⁵ A similar successful argument is found in *Kimberly-Clark Corp. v. Johnson & Johnson*,¹⁷⁶ where the court wrote that the examiner was in charge of both patent applications and had a duty of knowing their contents.¹⁷⁷ This type of argument was also successfully used in *Schnadig Corp. v. Collezione Europa U.S.A.*¹⁷⁸

¹⁶⁸ See generally Lisa A. Dolak, *Conflict of Interest: Guidance for the Intellectual Property Practitioner*, 39 IDEA 267, 267 (1999) (discussing "conflicts issues confronted by practitioners representing clients in the procurement and enforcement of intellectual property rights . . .").

¹⁶⁹ *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1192–93 (Fed. Cir. 1995).

¹⁷⁰ 106 F. Supp. 2d 667 (D.N.J. 2000), *aff'd*, 320 F.3d 1339 (Fed. Cir. 2003).

¹⁷¹ *Id.* at 679–80.

¹⁷² 839 F.2d 1556 (Fed. Cir. 1989).

¹⁷³ *Id.* at 1568.

¹⁷⁴ Compare U.S. Patent No. 3,610,799 (filed Oct. 30, 1969) with U.S. Patent No. 3,610,806 (filed Oct. 30, 1969).

¹⁷⁵ *Allen Organ*, 839 F.2d at 1568.

¹⁷⁶ 745 F.2d 1437 (Fed. Cir. 1984).

¹⁷⁷ *Id.* at 1457.

¹⁷⁸ No. 01-C-1697, 2002 U.S. Dist. LEXIS 19083, at *23 (N.D. Ill. Oct. 2, 2002) (stating that this argument by Schanadig raised a genuine issue of material fact and precluded the defendant's

A similar fact pattern for establishing non-materiality, or at least attempting to establish non-materiality, occurred in *J.P. Stevens & Co. v. Lex Tex Ltd.*¹⁷⁹ In the *J.P. Stevens* opinion, it was argued that a reference was cumulative and thus non-material because the examiner had once viewed the reference during the course the prosecution of a *non-related patent*.¹⁸⁰ Lex Tex had failed to disclose a reference (Weiss) to the examiner, during the prosecution of U.S. Patent No. 3,091,912.¹⁸¹ Lex Tex argued that Weiss was not material because Weiss had already been before the examiner during the same examiner's prosecution of the Weiss patent. Unfortunately for Lex Tex, the court was not persuaded, and the court wrote that it was only *possible* that the examiner had remembered the Weiss reference.¹⁸² The court held that the disclosure in the non-related patent did not relieve the materiality of the Weiss reference.¹⁸³

The following situation is similar to that where an application is being reviewed by a first examiner, but the reference is disclosed only to a second examiner. If an applicant fails to cite a reference to the examiner but does cite the reference to another office within the USPTO, for example, to the Interference Branch of the USPTO, the USPTO will not likely accept this as satisfying the duty to disclose. On this question, the court in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*¹⁸⁴ wrote that the USPTO is not the equivalent of a small law firm office, in which notice to one person may fairly be deemed notice to all.¹⁸⁵

6. Materiality Shown by Licensing Agreements and Submissions to Regulatory Agencies

Materiality of a reference to a patent application can be shown, in the situation where the reference in question is a patent, and where the applicant had acquired a license to use the patent. In *J.P. Stevens*, the applicant had acquired a license to a patent (Weiss patent) but had failed to disclose the Weiss patent during the prosecution of its own application, where its own application led to U.S. Patent No. 3,091,912.¹⁸⁶ The court held that *the license agreement was conclusive evidence that the applicant should have known of the materiality of Weiss*, and rendered U.S. Patent No. 3,091,912 unenforceable.¹⁸⁷ Thus, it is critical that patent attorneys and licensing attorneys keep each other informed as to their patenting and licensing activities. Similarly, materiality of a non-disclosed reference can be shown where the

motion for summary judgment on whether Schanadig's patent was unenforceable due to inequitable conduct).

¹⁷⁹ 747 F.2d 1553, 1563–64 (Fed. Cir. 1984).

¹⁸⁰ *Id.* at 1560.

¹⁸¹ U.S. Patent No. 3,091,912 (filed Apr. 19, 1957).

¹⁸² *J.P. Stevens*, 747 F.2d at 1563.

¹⁸³ *Id.* at 1567.

¹⁸⁴ 126 F. Supp. 2d 69 (D. Mass. 2001), *aff'd in part, vacated in part*, 314 F.3d 1313 (Fed. Cir. 2003).

¹⁸⁵ *Id.* at 139 (quoting *A.B. Dick Co. v. Burroughs Co.*, 798 F.2d 1392, 1399 n.7 (Fed. Cir. 1986)).

¹⁸⁶ *J.P. Stevens*, 747 F.2d at 1555–56.

¹⁸⁷ *Id.*

same reference had been submitted to a government regulatory agency, for example, to the Food and Drug Administration (“FDA”). In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,¹⁸⁸ materiality of a non-disclosed reference (Baker) was found because the inventor had identified Baker in an FDA submission.¹⁸⁹ Again, it might be useful, in any company, for regulatory affairs personnel to keep their patent department informed of references cited in FDA submissions.

7. Information on Related Interference Proceedings, Appeals, and Litigations Is Material

The applicant is required to notify the USPTO if an application is involved in a litigation or in an interference.¹⁹⁰ Failure to disclose a related interference, an appeal before the Board of Patent Appeals and Interferences, or a related litigation, is a frequent issue in lawsuits.¹⁹¹ *Marlow Industries, Inc. v. Igloo Products, Corp.*,¹⁹² concerned a patent owner’s attempt to broaden a claim to encompass a picnic box, where the picnic box was capable only of heating or that was capable only of cooling.¹⁹³ The patent owner attempted to broaden the claims in this way, even though a court, in a related litigation, held that the claim could cover only a picnic box that had the ability to do both things (heating when it contained hot dogs and cooling when it contained soda).¹⁹⁴ The inventor failed to disclose the related litigation and, because of this failure to disclose, the court rendered the patent

¹⁸⁸ 487 F.3d 897 (Fed. Cir. 2007).

¹⁸⁹ *See id.* at 916.

¹⁹⁰ 35 U.S.C. § 135 (2006); 37 C.F.R. § 1.178 (2006).

¹⁹¹ *See, e.g.,* *Marlow Indus., Inc. v. Igloo Prods. Corp.*, 65 F. App’x 313, 318 (Fed. Cir. 2003) (emphasizing a district court’s claim construction of patent may be material information); *Newell Window Furnishings, Inc. v. Springs Window Fashions Div., Inc.*, 15 F. App’x 836 (Fed. Cir. 2001) (determining whether litigation involving a design patent that claimed the designs in the patents at issue was material); *Li Second Family L.P. v. Toshiba Corp.*, 231 F.3d 1373, 1378 (Fed. Cir. 2000) (involving a patentee’s failure to include interference proceedings of another patent application to the patent at issue); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1071 (1998) (deciding whether prior litigation involving a patent was material in prosecuting a reissue of that patent); *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.* 707 F.2d 1376, 1383 (Fed. Cir. 1983) (regarding whether prior art references discovered in previous litigation the patentee was involved in should have been disclosed); *DaimlerChrysler AG v. Feuling Advanced Techs., Inc.* 276 F. Supp. 2d 1054, 1061 (S.D. Cal. 2003) (stating the plaintiff’s failure to divulge prior litigation involving the subject matter for a patent is material to the PTO); *Senior Indus. v. Thomas & Betts Corp.*, No 98-C-5842, 2002 U.S. Dist. LEXIS 18995, at *45–46 (N.D. Ill. Sept. 30, 2002) (involving whether articles used in an interference that invalidated plaintiff’s claims in another patent application was material); *Affymetrix Inc. v. PE Corp.*, 219 F. Supp. 2d 390 (S.D.N.Y. 2002) (concerning the issue whether disclosure of prior art in an interference proceeding requires the Primary Examiner to consider such art); *Jeneric/Pentron, Inc. v. Dillon Co.*, 171 F. Supp. 2d 49 (D. Conn. 2001) (concerning the materiality of not disclosing a witness’ testimony from a related patent); *Amgen*, 126 F. Supp. 2d at 139 (arguing a clinical study disclosed in interference proceedings does not satisfy the duty of disclosure in *ex parte* prosecution); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 12 F. Supp. 2d 69 (D. Mass. 1998), *aff’d*, 225 F.3d 1315 (Fed. Cir. 2000).

¹⁹² 65 F. App’x 313.

¹⁹³ *Id.* at 315.

¹⁹⁴ *Id.*

unenforceable.¹⁹⁵ Moreover, the court held that submitting litigation documents without providing the examiner with any roadmapping was like burying or hiding the critical information.¹⁹⁶

Failure to disclose a related litigation or interference proceeding can be cured by *an examiner's independent discovery of the litigation*. For example, in *Amgen, Inc. v. Hoecht Marion Roussel, Inc.*,¹⁹⁷ the examiner had jotted down a note on the file wrapper of the application that he had reviewed the interference file.¹⁹⁸

To conclude, to properly ensure that the litigation had been considered by the examiner, the applicant should disclose the litigation by way of an IDS, preferably with roadmapping of the litigation.

8. Are Rumors or Incomplete Information Material? Duty To Investigate

According to *Life Technologies, Inc. v. Clontech Laboratories, Inc.*¹⁹⁹ an applicant having incomplete information, such as hearsay information or rumors regarding prior use or prior invention by another party, need not disclose this incomplete information to the examiner.²⁰⁰ The opinion disclosed that the inventors had heard from colleagues that a competing researcher (Goff) had presented results similar to theirs, but the record did not show that the inventors had learned any additional details regarding Goff's work.²⁰¹ The court held that because the inventors lacked crucial information, the incomplete knowledge that they did have was not material and did not need to be disclosed.²⁰²

In *Eolas Technologies, Inc. v. Microsoft Corp.*,²⁰³ an inventor (Dr. Doyle) was aware that a competitor's device (ViolaWWW) possessed "a similar, if not identical, capability" as the Doyle device.²⁰⁴ However, the court held that the applicant had possessed only incomplete information, that is, incomplete to the extent that one could not compare the elements of the competitor's device with the elements in the claims.²⁰⁵ Although the court realized that one should not be able to cultivate ignorance, citing *Newell Window Furnishings, Inc. v. Springs Window Fashions*

¹⁹⁵ *Id.* at 320.

¹⁹⁶ *Id.* at 315.

¹⁹⁷ 126 F. Supp. 2d 69 (D. Mass. 2001).

¹⁹⁸ *Id.* at 139.

¹⁹⁹ 224 F.3d 1320 (Fed. Cir. 2000).

²⁰⁰ *Id.* at 1327.

²⁰¹ *Id.* at 1322–23.

²⁰² *Id.* at 1327.

²⁰³ No. 99-C-0626, 2002 U.S. Dist. LEXIS 20285 (N.D. Ill. Oct. 18, 2002), *aff'd in part, vacated in part*, 399 F.3d 1325 (Fed. Cir. 2005).

²⁰⁴ *Id.* at *18–20.

²⁰⁵ *Id.* at *22–24 (stating there was an issue of genuine fact if patentee had complete information, and summary judgment could not be granted for the defendant).

Divisions, Inc.,²⁰⁶ and *FMC Corp. v. Hennessy Industries, Inc.*,²⁰⁷ the court refrained from holding that Dr. Doyle had possessed material information.²⁰⁸

Similarly, in *Harness International, Inc. v. Simplimatic Engineering Co.*,²⁰⁹ the inventor had heard of a prior art bottling machine with “corner mounting,” but had failed to disclose this bottling machine to the USPTO.²¹⁰ Although the inventor’s own device did use “corner mounting,” the court held there was no duty to disclose because of the following facts.²¹¹ First, “corner mounting” was only one of several features of the inventor’s claimed device, second the inventor had never seen the “corner mounting” of the prior art device, and third, the inventor did not know the name of the manufacturer of the prior art device.²¹²

In contrast, in *Brasseler, U.S.A.I., L.P. v. Stryker Sales Co.*,²¹³ the court held that the applicant has a duty to investigate suggestions of prior art (a sale by the inventor), and the court rendered the patent unenforceable for inequitable conduct.²¹⁴ The *Brasseler* opinion concerned a sale by the inventor occurring two weeks before the critical bar date (before the start of the one-year grace period). The inventors were aware of the sale and of the importance of the sale as an act that could invalidate the claims. The inventors instructed the attorney to do a rushed filing. In arriving at the holding of inequitable conduct, the court wrote that “inventors cannot ‘empty-head’ their own patent counsel of the sale.”²¹⁵ Regarding the behavior of the attorneys, the court found that they had *notice* that specific information existed (the sale) and that their “studied refusal to timely investigate and disclose information . . . established that [the attorneys] . . . acted with deceptive intent.”²¹⁶

Similarly, in *DaimlerChrysler AG v. Feuling Advanced Technologies, Inc.*,²¹⁷ the court held that there was a duty to investigate, even though the patent owner argued that the information initially available to him (a photocopy) was too unreliable to trigger a duty to disclose anything to the USPTO.²¹⁸

The consensus from the above cases is that rumors and incomplete information may or may not trigger a duty to investigate. The duty to investigate hinges on the degree of notice, or specificity of notice, at hand to the inventors and attorneys.

9. Non-Disclosure of a Priority Date

²⁰⁶ No. 98-C-5003, 1999 U.S. Dist. LEXIS 17273, at *109 (N.D. Ill. Oct. 7, 1999), *aff’d in part, rev’d in part, vacated in part* 15 Fed. App’x. 836 (Fed. Cir. 2001) (reversing the lower court’s decision of inequitable conduct, stating that the patentee did not intentionally scheme the PTO).

²⁰⁷ 836 F.2d 521, 526 (Fed. Cir. 1987).

²⁰⁸ *Eolas Techs.*, 2002 U.S. Dist. LEXIS 20285, at *24.

²⁰⁹ 819 F.2d 1100 (Fed. Cir. 1987).

²¹⁰ *Id.* at 1107.

²¹¹ *Id.*

²¹² *Id.*

²¹³ 267 F.3d 1370 (Fed. Cir. 2001).

²¹⁴ *Id.* at 1382–83.

²¹⁵ *Id.* at 1378 (citing *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.* 93 F. Supp. 2d 1255, 1264 (S.D. Ga. 1999), *aff’d*, 267 F.3d 1370 (Fed. Cir. 2001)).

²¹⁶ *Id.* at 1383 (citing *Brasseler*, 93 F. Supp. 2d at 1263–64).

²¹⁷ 276 F. Supp. 2d 1054 (S.D. Cal. 2003).

²¹⁸ *Id.* at 1066.

Patent applications always have a filing date, and sometimes have, in addition, an earlier priority date. Priority is generally based on a U.S. Provisional patent application.²¹⁹ When submitting a patent application, priority is properly disclosed in the first paragraph of the specification, or by way of an amendment to the first paragraph. Priority is directly related to patentability under both the pre-March 1992 and post-March 1992 standards of materiality.

Failure to disclose the correct priority date was an issue in *Li Second Family L.P. v. Toshiba Corp.*,²²⁰ a case involving a family of related patent applications. For example, in this family, U.S. Patent No. 4,916,513²²¹ claimed a *structure*, while U.S. Patent No. 4,946,800²²² claimed *methods* for using that structure.²²³ During the prosecution of the structure patent, the examiner and the Board held that the claims could *not* claim priority to earlier members in the patent family (earlier patents filed in 1965 and 1968).²²⁴

Nevertheless, during the prosecution of the *methods* patent, the applicant again claimed priority to the patents filed in 1965 and 1968.²²⁵ The court rendered the *methods* patent unenforceable because the inventor (Li) repeatedly argued that the claims were entitled to the benefit of the earlier filing dates.²²⁶

A publication, advertisement, or brochure, suggesting the existence of prior art patents with an earlier priority date can be material. *Frazier v. Roessel Cine Photo Tech, Inc.*²²⁷ concerned a failure to disclose an advertisement that put the applicant on notice of a competing patent application. The court held that the inventor had a duty to disclose the competitor's ad, and not to determine unilaterally that the ad was not prior art.²²⁸ Note that the ad itself was not prior art, as it had had been published *after* the inventor's filing date.

10. Non-Disclosure of After-Arising Publications, Sales, and Public Use

Publications, sales, and public uses, arising *after* a patent's priority date can be material, and therefore must be disclosed, even though after-arising references are not properly classified "prior art."²²⁹ In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*,²³⁰ the non-disclosed reference was a scientific article published by the inventor after the patent's priority date, disclosing that the same invention as

²¹⁹ See 35 U.S.C. § 119(e)(1) (2006).

²²⁰ 231 F.3d 1373, 1380 (Fed. Cir. 2000).

²²¹ U.S. Patent No. 4,916,513 (filed Oct. 3, 1977).

²²² U.S. Patent No. 4,946,800 (filed Aug. 6, 1973).

²²³ *Li Second Family*, 231 F.3d at 1376.

²²⁴ *Id.*

²²⁵ *Id.* at 1377.

²²⁶ *Id.* at 1378.

²²⁷ No. CV 99-10425-GAF, 2003 U.S. Dist. LEXIS 19607, at *62-63 (C.D. Cal. Apr. 10, 2003), *aff'd in part, rev'd in part*, 417 F.3d 1230 (Fed. Cir. 2005) (reversing the district court's inequitable conduct determination based upon the failure to disclose the advertisement).

²²⁸ *Id.* at *98-99.

²²⁹ *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001).

²³⁰ 326 F.3d 1226 (Fed. Cir. 2003).

claimed in the patent was inoperative.²³¹ Because of the failure to disclose this publication, the court held for inequitable conduct, and rendered the patent unenforceable.²³² In *GFI, Inc. v. Franklin Corp.*,²³³ the non-disclosed material included a viewing by the inventor of a model of a competitor's device (the Durling sofa).²³⁴ The inventor saw the sofa about two months before the inventor's filing date.²³⁵ Thus, the sofa was not prior art, since it fell within the one-year grace period.²³⁶ However, the court rendered the inventor's patent unenforceable for inequitable conduct, writing:

GFI argues that Durling cannot be material because it is not prior art. That is not the law The district court made no finding as to priority and we will not make that determination in the first instance on appeal. In any case, it was incumbent on GFI to disclose the potential priority conflict to the examiner and not to unilaterally make a determination that Durling was not prior art. . . . *It is axiomatic that "close cases should be resolved by disclosure, not unilaterally by applicant."*²³⁷

11. Sources of Federal Funding

Where an applicant's invention was conceived with support from the U.S. government, or where an already-conceived invention was further developed with government support, the applicant is required to include a *federal support clause* in the specification.²³⁸ The federal support clause takes this form, for example, "STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT. This invention was made, in part, with U.S. government support under National Institutes of Health grant no. ABCDEFG1234567. The government may have certain rights in the invention."

In addition to disclosing the above information to the USPTO, the applicant needs to conform with certain reporting requirements. These reporting requirements, as it applies to the National Institutes of Health ("NIH"),²³⁹ are outlined below. *Campbell Plastics Engineering & Manufacturing, Inc. v. Brownlee*²⁴⁰

²³¹ *Id.* at 1231.

²³² *Id.* at 1238–39.

²³³ 265 F.3d 1268.

²³⁴ *Id.* at 1272.

²³⁵ *Id.*

²³⁶ *Id.* at 1274.

²³⁷ *Id.* (emphasis added) (quoting *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992)).

²³⁸ 35 U.S.C. § 202(c)(6) (2006).

²³⁹ A "20-20" *View of Invention Reporting to the National Institutes of Health, NIH Guide for Grants and Contracts in NIH*, NIH GUIDE, vol. 24, No. 33, September 22, 1995, <http://grants2.nih.gov/grants/guide/notice-files/not95-003.html> (last visited Feb. 2, 2008) [hereinafter NIH]; see also 37 C.F.R. § 401.14(f)(4) (stating the following must be included in the application, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.").

²⁴⁰ 389 F.3d 1243 (Fed. Cir. 2004).

dramatically shows the consequences of failing to adhere to the reporting requirements.²⁴¹

The NIH provides funding via the Small Business Innovation Research (“SBIR”) and Small Business Technology Transfer (“STTR”) programs. Inventions made with this funding need to be reported to the NIH.²⁴² Where an invention was conceived under non-government funding, but is later reduced to practice under government funding, the invention also needs to be reported to the U.S. government.²⁴³

NIH must be notified within two months of the inventor’s initial report to the organization that had received the NIH grant.²⁴⁴ Notification to the NIH needs to be sent to the Extramural Invention Reporting and Technology Resources Branch, Office of Policy for Extramural Research Administration (“OPERA”), in Bethesda, Maryland.²⁴⁵ If the inventor fails to adhere to these requirements the U.S. government may obtain title to the invention.²⁴⁶

In *Campbell Plastics Engineering & Manufacturing*, Campbell Plastics had developed, for the U.S. Army, a protective mask.²⁴⁷ After the invention of this mask, Campbell submitted a patent application to the USPTO, now U.S. Patent No. 5,895,537.²⁴⁸ Although Campbell had disclosed all technical aspects of the invention to the Army during the development phase, Campbell had failed to point out that the disclosure contained something new, i.e., that an invention was present.²⁴⁹ Moreover, in filling out the required form (DD Form 882), Campbell had indicated “no invention” and “none.”²⁵⁰ The result was that Campbell lost its patent to the U.S. Government.²⁵¹ Failure to disclose a source of federal funding was also an issue in *Trinity Industries, Inc. v. Road Systems, Inc.*²⁵²

12. Cumulative References

Where a reference is held to be a cumulative reference, the reference is a non-material reference, and need not be disclosed.²⁵³ A reference *is material* when it discloses more claim elements than other documents already disclosed. But the reference is merely cumulative and *not material* if it does not disclose any additional

²⁴¹ *Id.* at 1249.

²⁴² *See* NIH, *supra* note 239.

²⁴³ *Rutgers v. United States*, 41 Fed. Cl. 764, 773 (Fed. Cl. 1998).

²⁴⁴ NIH, *supra* note 239.

²⁴⁵ *Id.*

²⁴⁶ *Id.*

²⁴⁷ *Campbell Plastics Eng’g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243, 1244 (Fed. Cir. 2004).

²⁴⁸ *Id.* at 1246.

²⁴⁹ *Id.* at 1244–45.

²⁵⁰ *Id.*

²⁵¹ *Id.* at 1246, 1249–50.

²⁵² 235 F. Supp. 2d 536, 540 (E.D. Tex. 2002).

²⁵³ *See* *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1179 (Fed. Cir. 1995); *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm.*, 958 F.2d 1066, 1075–76 (Fed. Cir. 1992); *Eaton Corp. v. Rockwell Int’l Corp.*, No. 97-421-JJF, 2001 U.S. Dist. LEXIS 11422, at *10 (D. Del. Feb. 9, 2001), *aff’d in part, rev’d in part*, 323 F.3d 1332 (Fed. Cir. 2003) (reversing the district court’s judgment of infringement due to improper claim construction).

claim elements. In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,²⁵⁴ a prior art reference (Baker) was held to be material, and *not* cumulative, because it was more explicit and clear than other references that were before the examiner.²⁵⁵ In detail, the Baker reference provided over eleven columns of writing relevant to the claims, whereas another reference (Pejas) contained only two columns of relevant writing.

*Eaton Corp. v. Rockwell International Corp.*²⁵⁶ concerned the failure to disclose a patent (Vukovich patent) to the USPTO. The court pointed out that while the Vukovich patent disclosed four of the ten features found in the applicant's patent, the Shulze patent, which had been disclosed to the USPTO, discloses these same four features, but that Shulze also discloses a fifth feature in common with the applicant's claim.²⁵⁷ The court held that Vukovich *was* cumulative, and that Shulze was *not* cumulative.²⁵⁸ Further commentary on what distinguishes non-cumulative references from cumulative references is available from *LifeScan, Inc. v. Home Diagnostics, Inc.*²⁵⁹ This case held that a non-disclosed reference (NovoCheck meter device) was not material, because a patent that had been properly submitted, disclosed "the same thing" as the NovoCheck meter,²⁶⁰ and that another non-disclosed reference (newspaper article) was not material, because it merely concerned "financial and investment aspects"²⁶¹ of a prior art device.

G. INTENT TO DECEIVE

While materiality is the first prong for a finding of inequitable conduct, intent is the second prong. Intent to deceive can be shown as direct evidence of deliberate planning (i.e., a smoking gun), but more usually, intent to deceive is inferred from a pattern of non-disclosures.

1. Intent Shown by Direct Evidence of Deception

*Ashland Products, Inc. v. Truth Hardware Corp.*²⁶² provides a situation where there was direct evidence of intent to deceive the USPTO, and where there was no need to infer intent.²⁶³ Truth Hardware filed a patent application and provided its attorney with a "window operator." The inventor possessed a window operator made by a competitor (Roto Frank/Interlock Operator), where the window operator

²⁵⁴ 487 F.3d 897 (Fed. Cir. 2007), *aff'g* No. S-02-2669 FCD KJM, 2006 U.S. Dist. LEXIS 76517 (E.D. Cal. June 13, 2006).

²⁵⁵ *Id.* at 909.

²⁵⁶ 2001 U.S. Dist. LEXIS 11422.

²⁵⁷ *Id.* at *50–51.

²⁵⁸ *Id.* at *53.

²⁵⁹ 103 F. Supp. 2d 379, 384 (D. Del. 2000), *aff'd*, 13 F. App'x 940 (Fed. Cir. 2001).

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² No. 99-C-5786, 2003 U.S. Dist. LEXIS 11362 (N.D. Ill. July 1, 2003) *dismissed*, 85 F. App'x 195 (Fed. Cir. 2003).

²⁶³ *Id.* at *28.

contained all of the elements of Truth Hardware's submitted claim. This meant that Truth's claim was likely rendered invalid by the competitor's device. However, Truth supplied its attorney with the Roto Frank/Interlock Operator but removed part of the operator (plastic packer), resulting in a device of less relevance to the submitted claims. Because Truth was not truthful to its attorney or to the USPTO, the court rendered its patent unenforceable.²⁶⁴

Another more or less direct showing of intent to deceive comes from *For Your Ease Only, Inc. v. Calgon Carbon Corp.*²⁶⁵ The non-disclosed reference was a brochure (CCI Brochure), and intent to deceive the USPTO was demonstrated as follows. The inventor knew that the CCI Brochure was material information. In preparing the patent application, the inventor had copied information almost verbatim from a confidential document (Tromposch report). This report referred repeatedly to the CCI Brochure. However, in drafting the patent application, the inventor had selectively deleted any mention of the CCI Brochure.²⁶⁶

2. Intent to Deceive Shown by Repeated Exposures to a Non-Disclosed Reference

Repeated exposure to a non-disclosed material reference, or other facts and circumstances surrounding the applicant's conduct, can be used to show intent to deceive the USPTO. *Kansas Jack, Inc. v. Kuhn*²⁶⁷ held that indirect evidence for intent should be accepted by the courts because the "duty of candor owed the PTO being uncompromising, it would deal a *deathblow* to that duty if direct proof of wrongful intent were required."²⁶⁸

*Elk Corp. v. GAF Building Materials Corp.*²⁶⁹ illustrates the situation where repeated exposure was shown to establish intent to deceive the USPTO.²⁷⁰ Repeated exposure took a number of forms, for example, a letter and a memo. The court also observed that it was the standard practice of the patent attorney to disclose all of the prior art cited in a search report.²⁷¹ However, the attorney failed to disclose two references (Bettoli and Giles patents) in the search report. The letter revealed that the applicants knew that the claimed invention was very similar to the Bettoli patent shingle. The memo revealed that the Giles patent was of "special interest." The court inferred intent to deceive and the patent was rendered unenforceable.²⁷²

*National Diamond Syndicate, Inc. v. Flanders Diamond U.S.A., Inc.*²⁷³ also shows the fact-pattern where there was no explicit evidence of scheming, but where documentation of a repeated exposure was used to infer intent.²⁷⁴ The repeated exposures to the non-disclosed prior art took the form of testimony, a publication

²⁶⁴ *Id.* at *29.

²⁶⁵ No. 02-C-7345, 2003 U.S. Dist. LEXIS 21901, at *11-12 (N.D. Ill. Dec. 4, 2003).

²⁶⁶ *Id.* at *20.

²⁶⁷ 719 F.2d 1144 (Fed. Cir. 1983).

²⁶⁸ *Id.* at 1151 (emphasis added).

²⁶⁹ 168 F.3d 28 (Fed. Cir. 1999).

²⁷⁰ *Id.* at 29.

²⁷¹ *Id.* at 32.

²⁷² *Id.*

²⁷³ 67 U.S.P.Q.2d 1671 (N.D. Ill. 2003).

²⁷⁴ *Id.* at 1675.

authored by the inventor, and two letters. Because the evidence demonstrated that the inventor had repeated exposures to the prior art (gems with the Petar Cut design), the court held that the non-disclosure was with deceptive intent.²⁷⁵

*Harris Corp. v. Ericsson, Inc.*²⁷⁶ illustrates a situation where documentation of a face-to-face meeting between an inventor and the author (Van Uffelen) of a non-disclosed reference (1975 Van Uffelen article) was used to help establish intent of the inventor to deceive the USPTO.²⁷⁷

*Evident Corp. v. Church & Dwight*²⁷⁸ illustrates the fact-pattern where documentation of repeated awareness of a non-disclosed reference (Stolar patent) supported a finding of intent.²⁷⁹ This documentation took several forms, for example, a memo from the in-house legal department stating that Stolar was dangerous prior art, a letter from former counsel recommending that Stolar be disclosed to the USPTO. Deceptive intent was also inferred by the fact that the inventor had changed legal counsel, and hired new counsel that was unfamiliar with the Stolar prior art. Changing of legal counsel was also used to support a finding of deceptive intent in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*²⁸⁰ In short, the Federal Circuit believed that the inventor had hired new counsel because the new counsel was unaware of the importance of the non-disclosed reference.²⁸¹

In *Molins PLC v. Textron, Inc.*,²⁸² deceptive intent was inferred because the inventor had repeatedly disclosed a reference (Wagenseil) over the course of thirteen years to the foreign patent office, but failed to disclose the reference to the USPTO.²⁸³ In *Baxter International, Inc. v. McGaw, Inc.*,²⁸⁴ deceptive intent was also inferred by repeated exposure of the inventor to a non-disclosed reference (Borla device), where the repeated exposure took the form of a company memo and by documentation of a visit by the inventor to the manufacturer of the Borla device.²⁸⁵

In *Nobelpharma AB v. Implant Innovations, Inc.*,²⁸⁶ intent to deceive was inferred because a material reference (1997 book on implants) was described or cited in a draft of the patent application, but was subsequently deleted from the patent application as actually filed with the USPTO.²⁸⁷ A similar situation is disclosed in *Bayer AG v. Sony Electronics, Inc.*,²⁸⁸ albeit with a different result.²⁸⁹

²⁷⁵ *Id.* at 1673.

²⁷⁶ 194 F. Supp. 2d 533 (N.D. Tex. 2002), *rev'd in part on other grounds*, 417 F.3d 1241 (Fed. Cir. 2003) (reversing the district court's judgment of infringement due to improper claim construction).

²⁷⁷ *Id.* at 548.

²⁷⁸ Nos. 97-3275 (MLC), 98-4376 (MLC), 2002 U.S. Dist. LEXIS 22600 (D.N.J. Sept. 17, 2002), *aff'd*, 78 F. App'x 113 (Fed. Cir. 2003).

²⁷⁹ *Id.* at *29.

²⁸⁰ No. 95-C-8833 (RPP), 2002 U.S. Dist. LEXIS 13706, at *11-12 (S.D.N.Y. July 25, 2002).

²⁸¹ *Id.* at *12.

²⁸² 48 F.3d 1172 (Fed. Cir. 1995).

²⁸³ *Id.* at 1181-82.

²⁸⁴ 149 F.3d 1321 (Fed. Cir. 1998).

²⁸⁵ *Id.* at 1330.

²⁸⁶ 141 F.3d 1059 (Fed. Cir. 1998).

²⁸⁷ *Id.* at 1072.

²⁸⁸ 229 F. Supp. 2d 332 (D. Del. 2002), *aff'd*, 83 F. App'x 334 (Fed. Cir. 2003).

²⁸⁹ *Id.* at 364 (concluding that the deletion of references contained in the draft was not persuasive that there was an intent to deceive).

In *IDEC Pharmaceuticals v. Corixa Corp.*²⁹⁰ intent to deceive was based on several suspicious acts, namely on the fact that the relevant non-disclosed references (five abstracts) were authored by the applicants, by listing a relevant citation in the text of the patent but burying it in a list of ninety-four references (and not including it in the IDS), and by redacting the title of one of the cited articles (a title that revealed the publication's contents).²⁹¹ The consequence was that the court rendered the patents unenforceable.²⁹²

In another case, *In re Jerabek*,²⁹³ evidence of repeated exposure to a non-disclosed reference took the form of a letter to a foreign counsel regarding prosecution of the Japanese counterpart, stating that the reference (Sattler) was the most pertinent prior art.²⁹⁴ The court held that the inventor had acted with deceptive intent.²⁹⁵

However, *Merck v. Teva Pharmaceuticals*²⁹⁶ illustrates the fact-pattern where only one exposure to a non-disclosed reference was held not enough to sustain any finding of intent.²⁹⁷ This single exposure took the form of a twelve-page memo given to the inventor, where the non-disclosed reference (a single page) was stapled to the back of the memo.²⁹⁸ In other words, *Merck* demonstrates the situation where deceptive intent was an issue, but where the court refrained from finding deceptive intent.²⁹⁹

3. Intent To Deceive Inferred from the Totality of the Circumstances

Deceptive acts, one step removed from patent examination activities, or even totally remote from the patent prosecution process, can also be used to infer intent to deceive the USPTO. In *Jack Frost Laboratories, Inc. v. Physicians & Nurses Manufacturing Corp.*,³⁰⁰ a finding of inequitable conduct for failing to disclose a material reference was inferred from a number of acts having no relevance to proceedings before the USPTO.³⁰¹ These deceptive acts included those of the inventor's wife, that is, the inventor's wife's decisions to destroy company records.³⁰²

In *DaimlerChrysler AG v. Feuling Advanced Technologies, Inc.*,³⁰³ an inappropriate clause in a written agreement (a settlement agreement) prepared by the patent owner turned the tide against the patent owner (Feuling), and persuaded

²⁹⁰ No. 01-1637-IEG (RBB), 2003 U.S. Dist. LEXIS 18465 (S.D. Cal. Oct. 10, 2003).

²⁹¹ *Id.* at *60, *62.

²⁹² *Id.* at *73.

²⁹³ 789 F.2d 886 (Fed. Cir. 1986).

²⁹⁴ *Id.* at 891.

²⁹⁵ *Id.*

²⁹⁶ 288 F. Supp. 2d 601 (D. Del. 2003), *rev'd on other grounds*, 395 F.3d 1364 (Fed. Cir. 2005) (finding erroneous the district court's claim construction).

²⁹⁷ *Id.* at 633.

²⁹⁸ *Id.*

²⁹⁹ *Id.*

³⁰⁰ Nos. 96-1114, 96-1430, 96-1543, 1997 U.S. App. LEXIS 26138 (Fed. Cir. Sept. 23, 1997), *aff'g* 901 F. Supp. 718 (S.D.N.Y. 1995).

³⁰¹ *Id.* at *18-19.

³⁰² *Jack Frost Labs.*, 901 F. Supp. at 727.

³⁰³ 276 F. Supp. 2d 1054 (S.D. Cal. 2003).

the court to infer deceptive intent from Feuling's non-disclosures before the USPTO.³⁰⁴ The settlement agreement was not relevant to any proceedings before the USPTO.³⁰⁵

4. Abstracts and Foreign Language References

Submission of an abstract, a foreign language publication, or a partial translation supplied with a foreign language publication can raise the issue of failure to comply with the duty to disclose, and can lead to a holding of inequitable conduct.

*Bristol-Myers Squibb Co. v. Ben Venue Laboratories*³⁰⁶ provides the following lesson regarding abstracts. Where an *abstract* is published and where a later-published *complete report* is published, and where the two references reach different conclusions or have conflicting results, both references are still material and should be disclosed. But where the conclusions of both documents are the same, they would be considered to be cumulative, thus relieving the duty to disclose both documents.

*Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*³⁰⁷ provides guidance regarding foreign language references. Non-English references are sometimes submitted in an IDS. Submission of a non-English reference, without an English translation, cannot in itself result in a finding of intent to deceive.³⁰⁸ Moreover, submission of a non-English reference along with a partial English translation, will not necessarily suggest any intent to deceive.³⁰⁹ However, intent to deceive was found because the partial translation focused on less material portions, leaving the examiner with the false impression that the examiner did not need to conduct any further translation.³¹⁰ The untranslated portion of the Japanese reference contained a more complete combination of the elements claimed in the inventor's patent, demonstrating a high degree of materiality of this reference. Deceptive intent was also found because the inventor was fluent in Japanese, and also because the inventor had immense experience in prosecuting patents.³¹¹

*Key Pharmaceuticals v. Hercon Laboratories Corp.*³¹² illustrates the situation where submitting an abstract (Japanese application), but not the entire document, raised an issue of failure to comply with the duty to disclose. Although the court eventually held that the complete Japanese application was not material, the case demonstrates that submitting only an abstract can raise issues.³¹³ Similarly, in *LNP Engineering Plastics, Inc. v. Miller Waste Mills, Inc.*³¹⁴ submission of a partial translation of a foreign reference (Japanese Patent Publication No. 56-5714) and

³⁰⁴ *Id.* at 1063.

³⁰⁵ *See id.* (describing the terms of the settlement agreement).

³⁰⁶ 90 F. Supp. 2d 522 (D.N.J. 2000), *aff'd in part, rev'd in part*, 246 F.3d 1368 (Fed. Cir. 2001) (affirming the lower court's denial of summary judgment for inequitable conduct).

³⁰⁷ 204 F.3d 1368 (Fed. Cir. 2000).

³⁰⁸ *Id.* at 1378.

³⁰⁹ *Id.* (noting that "the duty in this case is the duty of candor, not a duty of translation").

³¹⁰ *Id.* at 1377.

³¹¹ *Id.* at 1376.

³¹² 161 F.3d 709 (Fed. Cir. 1998).

³¹³ *Id.* at 719.

³¹⁴ 275 F.3d 1347 (Fed. Cir. 2001).

failure to submit the complete translation raised issues of non-disclosure.³¹⁵ To avoid issues, it is best to submit complete translations. Note that the USPTO may provide free translation under 37 C.F.R. § 1.181, under *Ex Parte Jones*.³¹⁶

5. *Non-Disclosure of an Assignee*

Although the identity of an assignee is not disclosed by way of an IDS, failure to properly identify an assignee can help establish a pattern of deceit, where the issue is deceptive non-disclosure of material information. Ownership can have direct bearing on patentability, as the nature of the ownership can influence rejections under 35 U.S.C. § 102(e) and for double patenting. Non-disclosure of an assignee (Columbia University) was an issue in *Bayer AG v. Housey Pharmaceuticals, Inc.*³¹⁷ The opinion found that the non-disclosure of ownership had reinforced the pattern of concealment and possible deception.³¹⁸ The outcome was a holding of inequitable conduct.³¹⁹

6. *Improper Disclosure of Small Entity Status*

Improper disclosure of small entity status tends to arise when a small entity assigns or licenses a patent to a large entity, and where the small entity fails to change its status from small entity to large entity.³²⁰ Where assignment or licensing to a large entity has occurred, it is no longer proper to claim small entity status in paying fees to the USPTO.³²¹

Improper assertion of small entity status was an issue where the court reviewed an applicant's failure to disclose prior art publications. In *DaimlerChrysler AG v. Feuling Advanced Technologies, Inc.*,³²² the court found that inappropriate, repeated assertions of small entity status tipped the scales against the applicant, and the patent was rendered unenforceable for inequitable conduct.³²³ The opinion observed that the inventor (James Feuling) had improperly claimed small entity status and had paid reduced fees at least seven times.³²⁴ The opinion added that if the matter of small entity status had been the only issue, the court would not have rendered a holding of unenforceability, because of the fact that failure to pay appropriate fees does not directly relate to patentability.³²⁵ In view of the variety of forms taken by the inventor's deceptive behaviors, it is clear that Mr. Feuling was fooling. Improper assertion of small entity status was also an issue in *Ulead Systems, Inc. v. Lex*

³¹⁵ *Id.* at 1360.

³¹⁶ 62 U.S.P.Q.2d 1206, 1208–09 (B.P.A.I. 2001).

³¹⁷ No. 01-148-SLR, 2003 U.S. Dist. LEXIS 22411 (D. Del. Dec. 4, 2003).

³¹⁸ *Id.* at *46.

³¹⁹ *Id.* at *47.

³²⁰ See 37 C.F.R. § 1.27(a)(2) (2006).

³²¹ *Id.* § 1.27(a)(2)(i).

³²² 276 F. Supp. 2d 1054 (S.D. Cal. 2003).

³²³ *Id.* at 1067.

³²⁴ *Id.* at 1061.

³²⁵ *Id.* at 1062.

Computer & Management Corp.,³²⁶ where the court pointed out that Lex (a large entity) had repeatedly claimed small entity status, saving \$25,000 in maintenance fees over the past ten years.³²⁷ Because of failure to establish intent, the Federal Circuit refrained from a holding of inequitable conduct.³²⁸

7. *Burying and Intent To Deceive*

Burying is a frequent issue relating to the duty to disclose. “Burying” refers to the submission of a highly relevant prior art reference by way of an IDS, where the IDS is also used to submit dozens or hundreds of less relevant references. In *Molins PLC v. Textron, Inc.*,³²⁹ a reference (Wagenseil) was disclosed in an IDS, but the reference was provided in an eleven page list of ninety-four references.³³⁰ The court characterized the buried manner by which the Wagenseil references were disclosed as tantamount to failing to disclose them at all.³³¹

In *Cordis, Corp. v. Medtronic AVE, Inc.*,³³² submission of a material reference along with sixty other references was considered burying.³³³ The holding hinged on deceptive intent to submit a reference in a *parent* patent application.³³⁴ Even though the reference was properly disclosed in an IDS submitted during the prosecution of the *daughter* patent application, it was submitted in buried form. Because of failure to submit the reference in the parent application, and because submission in the daughter application was in a buried form, the court rendered both patents unenforceable.³³⁵

*IDEC Pharmaceuticals v. Corixa Corp.*³³⁶ characterized burying as disclosure of a material reference in a list of nearly 100 references.³³⁷ The holding of inequitable conduct was based on disclosure by an improper method (in the specification rather than in an IDS) and on deceptive elimination of the descriptive title of the reference.³³⁸ Thus, inequitable conduct was held because of three factors: burying, improper disclosure of the reference, and deception regarding the title.³³⁹

*Rohm & Haas Co. v. Crystal Chemical Co.*³⁴⁰ concerned the submission of information during an interview with the examiner. The information, which could also have been submitted by way of an IDS, consisted of confidential laboratory data, where the data raised doubts as to the effectiveness of the claimed invention, an

³²⁶ 351 F.3d 1139 (Fed. Cir. 2003).

³²⁷ *Id.* at 1153.

³²⁸ *Id.* at 1150.

³²⁹ 48 F.3d 1172 (Fed. Cir. 1995).

³³⁰ *Id.* at 1182–83.

³³¹ *Id.*

³³² 194 F. Supp. 2d 323 (D. Del. 2002) *rev'd on other grounds*, 339 F.3d. 1352 (Fed. Cir. 2003).

³³³ *Id.* at 368.

³³⁴ *Id.*

³³⁵ *Id.*

³³⁶ No. 01-1637-IEG (RBB), 2003 U.S. Dist. LEXIS 18465 (S.D. Cal. Oct. 10, 2003).

³³⁷ *Id.* at *62.

³³⁸ *Id.* at *63.

³³⁹ *Id.* at *70–71.

³⁴⁰ 722 F.2d 1556 (Fed. Cir. 1983).

herbicide.³⁴¹ The information took the form of a 3,771 page mountain of largely irrelevant laboratory results.³⁴² The court rendered the patent invalid on the basis of burying.³⁴³

At its extreme, burying can take the form of including the most relevant prior art reference in large numbers of unrelated documents in “citation dumps.” Actual citation dumps include those that list 700 items or nearly 3,000 items.³⁴⁴

At an earlier time, the USPTO required the IDS to include a concise statement of relevance of each reference, that is, “roadmapping.”³⁴⁵ This earlier policy helped prevent burying, but the policy was discontinued. More recently, the USPTO proposed reviving this policy, but the proposal was not adopted.³⁴⁶

And still more recently, in July 2006, the USPTO again proposed reviving the policy of requiring roadmapping.³⁴⁷ However, as shown by published comments from patent practitioners published in the Federal Register, the responses from the public were unanimous in their opposition to the requirement for roadmapping.

8. Evidence of Ignorance Can Cure Intent: Evidence of Education or Awareness Can Show Intent

When faced with questions of intent to deceive the USPTO, an inventor sometimes argues he is not familiar with patent law, is an absent-minded professor who always left the nuts and bolts to his lawyers, is a man of science who has no time for legalese, or is a foreigner unfamiliar with U.S. patent law.³⁴⁸ In *McGinley v. Franklin Sports, Inc.*,³⁴⁹ an argument for lack of intent to deceive took the form of an argument that the attorney did not understand the invention.³⁵⁰

*Loral Fairchild, Inc. v. Victor Co. of Japan, Ltd.*³⁵¹ discloses a unique situation where ignorance was used to avoid a finding of intent to deceive.³⁵² In the legal

³⁴¹ *Id.* at 1559.

³⁴² *Id.* at 1564.

³⁴³ *Id.* at 1572.

³⁴⁴ Changes To Implement the Patent Business Goods, 63 Fed. Reg. 53,498 (Oct. 5, 1998); 1215 Off. Gaz. Pat. Office 87 (Oct. 27, 1998).

³⁴⁵ *Pall Corp. v. PTI Techs., Inc.*, 259 F.3d 1383 (Fed. Cir. 2001); 37 C.F.R. § 1.98 (2006).

³⁴⁶ Changes To Implement the Patent Business Goods, 63 Fed. Reg. at 53,498; Changes To Implement the Patent Business Goods, 64 Fed. Reg. 53,772 (Oct. 4, 1999); Changes To Implement the Patent Business Goods, 65 Fed. Reg. 54,604 (Sept. 8, 2000) (to be codified at 37 C.F.R. pts. 1, 3, 5, 10).

³⁴⁷ Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808–10 (July 10, 2006); United States Patent and Trademark Office, Comments on Changes to Information Disclosure Statement Requirements and Other Related Matters, <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab95/ids.htm> (last visited Feb. 19, 2008).

³⁴⁸ *Kolmes v. World Fibers Corp.*, 107 F.3d 1534 (Fed. Cir. 1997); *FMC Corp. v. Hennessy Indus. Inc.*, 836 F.2d 521 (Fed. Cir. 1987); *DaimlerChrysler AG v. Feuling Advanced Techs., Inc.*, 276 F. Supp. 2d 1054 (S.D. Cal. 2003); *Jack Schwartz Shoes, Inc. v. Skechers, U.S.A., Inc.*, 233 F. Supp. 2d 512 (S.D.N.Y. 2000).

³⁴⁹ 92 F. Supp. 2d 1216 (D. Kan. 2000), *aff'd in part, rev'd in part*, 262 F.3d 1339 (Fed. Cir. 2001).

³⁵⁰ *Id.* at 1222.

³⁵¹ 61 U.S.P.Q.2d 1943 (E.D.N.Y. 2002).

³⁵² *Id.* at 1948.

department of Loral Fairchild Corp., a first attorney prosecuted a first application while a second attorney prosecuted a second application.³⁵³ The claims of both applications covered the same technology.³⁵⁴ A material reference (Erb) was cited by the examiner in the divisional application.³⁵⁵ However the attorney failed to notify the second attorney of this reference.³⁵⁶ During litigation, the second attorney was accused of deceptive intent due to the non-disclosure of the Erb reference in the second application.³⁵⁷ However, the court held for lack of intent, due to ignorance.³⁵⁸

From the available case law, *In re Harita*³⁵⁹ contains the largest number of arguments for lack of intent to deceive, due to ignorance.³⁶⁰ The inventor successfully avoided a finding of intent by arguing ignorance due to the fact that he was Japanese, Japanese patent law does not have a duty to disclose after a patent application has been filed, and, hence, he was not aware of the U.S. requirement for duty to disclose after the patent application is filed.³⁶¹ Moreover, once the inventor became aware of the non-disclosed reference, he properly disclosed it by way of a reissue patent application, a format generally not accepted for curing an earlier deceptive non-disclosure.³⁶² The result was that the inventor successfully avoided a finding of inequitable conduct.³⁶³

Conversely, heightened competence can establish intent to deceive. For example, in *DaimlerChrysler AG v. Feuling Advanced Technologies, Inc.*,³⁶⁴ intent to deceive was demonstrated by the existence of the inventor's letters containing savvy discussions of claim language and recommendations for claim strategy.³⁶⁵ In *Ulead Systems, Inc. v. Lex Computer & Management Corp.*,³⁶⁶ intent was demonstrated by evidence that the attorney did, in fact, understand that small entity fees needed to be properly disclosed, where the evidence took the form of the fact that the attorney had attended a lecture in patenting procedure that covered small entity fees.³⁶⁷ Similarly, in *Molins PLC v. Textron, Inc.*,³⁶⁸ evidence for deceptive intent took the form of documentation that the patent agent was a seasoned patent practitioner.³⁶⁹ Consistently, *Digital Control Inc. v. Charles Machine Works*³⁷⁰ characterized the applicant as an extremely experienced inventor who had applied for numerous patents and was aware of the duty of candor.³⁷¹

³⁵³ *Id.* at 1947.

³⁵⁴ *Id.* at 1946.

³⁵⁵ *Id.*

³⁵⁶ *Id.* at 1947.

³⁵⁷ *Id.* at 1946.

³⁵⁸ *Id.*

³⁵⁹ 847 F.2d 801 (Fed. Cir. 1988).

³⁶⁰ *Id.* at 806–07.

³⁶¹ *Id.*

³⁶² *Id.* at 807.

³⁶³ *Id.* at 809.

³⁶⁴ 276 F. Supp. 2d 1054 (S.D. Cal. 2003).

³⁶⁵ *Id.* at 1062, 1067.

³⁶⁶ 130 F. Supp. 2d 1137 (C.D. Cal. 2001), *vacated*, 351 F.3d 1139 (Fed. Cir. 2003).

³⁶⁷ *Id.* at 1145.

³⁶⁸ 48 F.3d 1172 (Fed. Cir. 1995).

³⁶⁹ *Id.* at 1181–82.

³⁷⁰ 437 F.3d 1309 (Fed. Cir. 2006).

³⁷¹ *Id.* at 1319–20.

To conclude, the Federal Circuit readily infers deceptive intent, in the absence of a smoking gun, where it can be shown that the inventor or attorney has a heightened degree of competence or understanding or experience regarding the duty to disclose.

9. Can Intent To Deceive Be Cured Where an Examiner Finds a Non-Disclosed Reference on Her Own?

If an applicant fails to disclose a material reference with intent to deceive, and if an examiner independently finds the reference, will the examiner's independent finding cure the finding of intent? The Federal Circuit has been inconsistent on this matter. In *A.B. Dick Co. v. Burroughs Corp.*,³⁷² and *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*,³⁷³ an examiner's independent finding *did not cure intent*,³⁷⁴ while in *Molins PLC v. Textron, Inc.*,³⁷⁵ an examiner's independent finding *did cure intent*.³⁷⁶ An early case, *Orthopedic Equipment Co. v. All Orthopedic Appliances, Inc.*,³⁷⁷ addressed this situation but came to no conclusion on the matter.³⁷⁸

In *Litton Systems, Inc. v. Honeywell, Inc.*,³⁷⁹ the lower court applied the rule of *A.B. Dick*³⁸⁰ while the Federal Circuit applied the rule from *Molins*,³⁸¹ observing that *Molins* was a more recent authority.³⁸² In their article, William C. Rooklidge and Matthew F. Weil observed that, with regard to *A.B. Dick*, the Federal Circuit has turned its back on this case and has chosen to ignore it.³⁸³

In *A.B. Dick*, an applicant failed to disclose a reference (Magarvey) with deceptive intent, but the examiner later found Magarvey on his own, and rejected fourteen of the claims (in view of Magarvey), claims that the examiner had previously found allowable.³⁸⁴ The court held that an examiner's independent discovery of a non-disclosed reference will *not cure intent*.³⁸⁵

In *Molins*, the Federal Circuit held that if there was non-disclosure of a reference (Lemelson) with deceptive intent, deceptive *intent could be cured* where the

³⁷² 798 F.2d 1392 (Fed. Cir. 1986).

³⁷³ 326 F.3d 1226 (Fed. Cir. 2003).

³⁷⁴ *A.B. Dick Co.*, 798 F.2d at 1397; *Bristol-Myers Squibb Co.*, 326 F.3d at 1241.

³⁷⁵ 48 F.3d 1172 (Fed. Cir. 1995).

³⁷⁶ *Id.* at 1189.

³⁷⁷ 707 F.2d 1376 (Fed. Cir. 1983).

³⁷⁸ *Id.* at 1383–84.

³⁷⁹ 87 F.3d 1559 (Fed. Cir. 1996) (holding that the district court abused its discretion in finding inequitable conduct), *rev'g* Nos. CV 90-93 MRP, CV 90-4823 MRP, 1995 U.S. Dist. LEXIS 729 (C.D. Cal. Jan. 4, 1995), *vacated*, 520 U.S. 1111 (1997) (remanding the case back to the Federal Circuit to further consider its infringement analysis in light of the Supreme Court's *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) decision regarding the doctrine of equivalents).

³⁸⁰ *Litton Sys.*, 1995 U.S. Dist. LEXIS 729, at *111.

³⁸¹ *Litton Sys.*, 87 F.3d at 1571.

³⁸² *Id.* at 1578 (Bryson, J., concurring in part and dissenting in part).

³⁸³ William C. Rooklidge & Matthew F. Weil, *Stare Un-Decisis: The Sometimes Rough Treatment of Precedent in Federal Circuit Decision-Making*, 80 J. PAT. TRADEMARK OFF. SOC'Y. 791, 807 (1998).

³⁸⁴ *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1397–98 (Fed. Cir. 1986).

³⁸⁵ *Id.*

examiner later independently found the reference.³⁸⁶ Similarly, *Sash Controls, Inc. v. Talon, L.L.C.*³⁸⁷ held that where an examiner independently finds a non-disclosed reference, it is not to be considered as withheld from the USPTO.³⁸⁸

But note the dissent in *Molins*. The dissent observed that in *Scripps Clinic & Research Fund v. Genentech, Inc.*,³⁸⁹ the non-disclosed reference (Meyer) was held to be non-material, and that the holding in *Scripps* regarding this matter was not a holding, but only dicta.³⁹⁰

Litton Systems concerned non-disclosure of a reference (Laznovsky article).³⁹¹ The lower court described a smoking gun type of intent to deceive.³⁹² The smoking gun intent took the form of the applicant's disclosure of the 1977 Veeco catalogue, but where two pages were missing from the catalogue, where the missing pages appeared as "ghosts" of the missing pages, and where these missing pages described the non-disclosed reference.³⁹³ The examiner independently found the non-disclosed reference.³⁹⁴ The lower court held that the examiner's finding failed to cure the intent, citing *A.B. Dick*.³⁹⁵ On the other hand, the upper court cited *Molins* as the more recent law and held that the examiner's finding did indeed cure the deceptive intent.³⁹⁶

The Federal Circuit in *Bristol-Myers Squibb* concerned the unique situation where *the examiner had discovered the non-disclosed references on her own but had not considered the references*.³⁹⁷ In view of the fact that the examiner had independently discovered the reference, the rule of *Molins* would suggest that the examiner's discovery would cure the intent to deceive. However, the record (the file history) demonstrated that the examiner had failed to actually read the reference. The court held for inequitable conduct for failure to disclose, and rendered the patent unenforceable.³⁹⁸

The author suggests that the Federal Circuit formally address the question of whether an examiner's independent finding of a material reference can, or cannot, cure intent to deceive. Duty to disclose is a frequent, and almost automatic, issue during patent litigation. The examiner has, at hand, powerful computer searching tools for finding prior art references, and readily finds obscure publications that the inventor might hope remain obscure. In view of these facts, the author believes that it is imperative that the Federal Circuit formally decide on this question.

³⁸⁶ *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1189 (Fed. Cir. 1995) (citing *Scripps Clinic & Research Fund v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991)).

³⁸⁷ Nos. 98-1152, 98-1182, 1999 U.S. App. LEXIS 994 (Fed. Cir. Jan. 27, 1999).

³⁸⁸ *Id.* at *14.

³⁸⁹ 927 F.2d 1565.

³⁹⁰ *Molins PLC*, 48 F.3d at 1190 (Nies, J., dissenting).

³⁹¹ *Litton Sys., Inc. v. Honeywell, Inc.* Nos. CV 90-93 MRP, CV 90-4823 MRP, 1995 U.S. Dist. LEXIS 729, at *27-28 (C.D. Cal. Jan. 4, 1995), *aff'd in part, rev'd in part*, 87 F.3d 1559, 1579 (Fed. Cir. 1996), *vacated*, 520 U.S. 1111 (1997).

³⁹² *Id.* at *114-15.

³⁹³ *Id.*

³⁹⁴ *Id.*

³⁹⁵ *Id.* at *111.

³⁹⁶ *Litton Sys.*, 87 F.3d at 1571.

³⁹⁷ *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1231 (Fed. Cir. 2003).

³⁹⁸ *Id.* at 1242.

10. *Late Submission of a Material Reference*

Late submission of a material reference can lead to a finding of intent to deceive, even though the reference was properly disclosed by way of an IDS. *Buzzelli v. Minnesota Mining & Manufacturing Co.*³⁹⁹ concerned a patent claiming methods for setting hair.⁴⁰⁰ Inequitable conduct was found where material references were submitted at the last minute, that is, after the final fee had been paid, and only two weeks before the patent issued.⁴⁰¹ There was a contributing issue, namely that the examiner had never read or considered the reference.⁴⁰² This issue contributed to the finding of inequitable conduct.⁴⁰³ Similarly, late submission of a reference during the prosecution of a reissue application was an issue in *Bristol-Myers Squibb*.⁴⁰⁴

11. *Infectious Unenforceability*

Where inequitable conduct occurs in the prosecution of a first patent application, the doctrine of infectious unenforceability renders unenforceable related patents and patent applications. From time to time, the doctrine of infectious unenforceability has been identified with the Doctrine of Unclean Hands.⁴⁰⁵

Infectious unenforceability requires that there be an immediate and necessary relation between the claims in the patent where inequitable conduct is found, and the claims in the related patent.⁴⁰⁶ A showing that the claims in the two patents are to two different inventions, based on a showing that the claims were separated by a restriction requirement, will not necessarily alone be sufficient to rebut a finding of infectious unenforceability.⁴⁰⁷ What is needed to rebut this finding is a showing that the claims in the two patents are to *mutually exclusive inventions*.⁴⁰⁸

*Monsanto Co. v. Bayer Bioscience, N.V.*⁴⁰⁹ concerned a patent that claimed expression of *Bacillus thuringiensis* toxin (“BT toxin”) in a plant cell.⁴¹⁰ The inventor filed a Declaration swearing that he believed the invention would work in *any plant cell*, even though he knew this statement to be false (the invention did not work for the cells of the cotton plant). The submission of this deceptive Declaration constituted an act of inequitable conduct.⁴¹¹

³⁹⁹ 182 U.S.P.Q. 307 (E.D. Mich. 1974), *aff'd*, 521 F.2d 1162 (6th Cir. 1975).

⁴⁰⁰ *Id.* at 308.

⁴⁰¹ *Id.* at 310.

⁴⁰² *Id.*

⁴⁰³ *Id.* at 310–11.

⁴⁰⁴ *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1236 (Fed. Cir. 2003).

⁴⁰⁵ R.J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 99 (1993).

⁴⁰⁶ *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 522, 537 (D.N.J. 2000).

⁴⁰⁷ *Id.* at 538.

⁴⁰⁸ *Id.* at 539.

⁴⁰⁹ 264 F. Supp. 2d 852 (E.D. Mo. 2002), *rev'd*, 363 F.3d 1235 (Fed. Cir. 2004).

⁴¹⁰ *Id.* at 854.

⁴¹¹ *Id.* at 861–62.

The court rendered the patent unenforceable, but also rendered all related patents unenforceable (three related patents).⁴¹² All four patents contained claims encompassing any plant cells (all types of plant cells) (Table 1). None of the claims restrict the “plant cell” to any specific type of plant cell, such as a tobacco plant cell, cotton plant cell, or tomato plant cell. The claim element “plant cell” or “plant cells” encompasses cells from cotton, tobacco, tomato, wheat, and strawberry plants. Because of inequitable conduct occurring in U.S. Patent No. 5,254,799, the court rendered all four patents unenforceable. Infectious unenforceability is thus demonstrated because of the fact that inequitable conduct occurred during the prosecution of the first patent, where the claims of the first patent contained an identical element as in the three related patents.⁴¹³

Table 1. Infectious unenforceability in *Monsanto v. Bayer*

U.S. Pat. No.	Claim No.	Claim element encompassing any plant cell or all plant cells.
5,254,799	1	“A plant cell . . . which contains a chimeric gene.” ⁴¹⁴
5,545,565	14	“The chimeric gene . . . expressed in plant cells.” ⁴¹⁵
5,767,371	13	“A plant cell comprising the chimeric gene of claim 1.” ⁴¹⁶
6,107,546	1	“A method of protecting a plant cell from Lepidopteran insects, comprising producing in said plant cell.” ⁴¹⁷

Will infectious unenforceability in a first patent result in a rendering of unenforceability of the claims of a second, related patent if the claims in the second patent had been amended or had been cancelled and replaced by new claims? According to *Baxter International, Inc. v. McGaw, Inc.*,⁴¹⁸ cancellation or amendment of a claim “tainted” by inequitable conduct will not excuse the patentee’s intentional failure to disclose material references.⁴¹⁹

The above situations are to be distinguished from the situation where the claims in a second, related patent are in no way material to the patent in dispute. Here, infectious unenforceability does not apply, and the second patent will not be rendered unenforceable. In *Baxter*, the non-disclosed reference (Borla septum) was relevant only to Baxter’s claims to a septum.⁴²⁰ Where the prosecution of a parent patent (U.S. Patent No. 5,167,648; claims to septum) involved inequitable conduct, infectious unenforceability applied only to U.S. Patent No. 5,171,234 (claims to

⁴¹² *Id.* at 862.

⁴¹³ *See id.* at 854.

⁴¹⁴ U.S. Patent No. 5,254,799, col.60 (filed July 23, 1990).

⁴¹⁵ U.S. Patent No. 5,545,565, col.116 (filed May 22, 1995).

⁴¹⁶ U.S. Patent No. 5,767,371, col.13 (filed June 2, 1995).

⁴¹⁷ U.S. Patent No. 6,107,546, col.61 (filed June 5, 1995).

⁴¹⁸ 149 F.3d 1321 (Fed. Cir. 1998).

⁴¹⁹ *Id.* at 1332; *see also* *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984) (“An applicant who . . . has withheld from the PTO prior art material to a claim in a parent application should not be exculpated simply because, by fortuitous circumstances”).

⁴²⁰ *Baxter Int’l*, 149 F.3d at 1331–32.

septum), but not to U.S. Patent No. 5,158,554 (claims to blunt cannula but *no claims to septum*) (Table 2). Inequitable conduct due to failure to disclose the Borla reference (Borla septum) resulted in a rendering of unenforceable two patents containing claims relating to a septum, but did not result in rendering unenforceable of a related patent (5,158,554) containing claims to a blunt cannula, but containing no limitation relating to “septum.” *Monsanto* and *Baxter* disclose clear-cut applications of the dramatic doctrine of infectious unenforceability.

Infectious unenforceability was also an issue in, for example, *eSpeed, Inc. v. BrokerTec U.S.A., L.L.C.*,⁴²¹ where the lower court applied the doctrine, and where the Federal Circuit did not reverse any component of the lower court’s decision, but affirmed on grounds other than infectious unenforceability.⁴²²

Table 2. Infectious Unenforceability in *Baxter International, Inc. v. McGaw, Inc.*

U.S. Pat. No.	Claim No.	Claim with septum element
5,167,648	36	“A method making a pre-slit injection site having a housing and a septum comprising the sequential steps of: forming a fluid flow path through the housing; inserting the septum into an end region of the housing; applying radially directed resealing forces to the <i>septum</i> .” ⁴²³
5,171,234	1	“A method of effecting a transfer of a fluid to a receiver using a resealable injection site with a pre-slit [<i>sic</i> pre-slit] <i>septum</i> .” ⁴²⁴
		Claim not containing septum element
5,158,554	1	“A cannula . . . comprising . . . a distal end tube in the form of a blunt piercing connector member.” ⁴²⁵

12. Can Inequitable Conduct Early in the Prosecution of a Patent Be Cured by Actions Taken Later on in the Prosecution of the Same Patent?

Where a claim cancellation totally removes claims having relevance to the non-disclosed material reference, intent to deceive can likely be cured by the cancellation. According to Rule 56, “The duty to disclose information exists . . . until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned.”⁴²⁶

⁴²¹ 480 F.3d 1129 (Fed. Cir. 2007).

⁴²² *Id.* at 1136–37.

⁴²³ U.S. Patent No. 5,167,648, cols.13–14 (filed June 11, 1990) (emphasis added).

⁴²⁴ U.S. Patent No. 5,171,234, cols.11–12 (filed June 12, 1990) (emphasis added).

⁴²⁵ U.S. Patent No. 5,158,554, col.11 (filed June 12, 1990).

⁴²⁶ 37 C.F.R. § 1.56(a) (2006).

*Fox Industries, Inc. v. Structural Preservation Systems, Inc.*⁴²⁷ sheds some light on the notion that claim amendments or cancellation can relieve the duty to disclose.⁴²⁸ The applicant failed to disclose a reference (FX-70 sales brochure).⁴²⁹ Subsequently, the claims were amended, where the device shown by the FX-70 sales brochure no longer had relevance to the device covered by the amended claim, that is, to the claim in its new amended form.⁴³⁰ However, the court held that this amendment did *not cure* the non-disclosure, as the sales brochure still had some relevance to the other pending claims.⁴³¹ The court found inequitable conduct, and the patent was rendered unenforceable.⁴³²

13. With Non-Disclosure of a Material Reference, with Intent To Deceive, in a Parent Application, Submission of the Same Reference in a Daughter Application May or May Not Cure the Deceptive Intent

Can timely disclosure of a material reference in a daughter patent application cure deceptive non-disclosure of the same reference occurring during prosecution of the parent application? In *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*,⁴³³ submission during prosecution of the daughter succeeded,⁴³⁴ while in *Cordis Corp. v. Medtronic AVE, Inc.*,⁴³⁵ submission during prosecution of the daughter failed to cure the intent that had occurred during prosecution of the parent.⁴³⁶

In *Applied Materials*, the applicant had withheld a material reference (Hart patent), apparently with deceptive intent, during prosecution of a parent application but later disclosed it during the prosecution of a daughter application.⁴³⁷ The court held that disclosure of the prior art had cured the alleged misrepresentations.⁴³⁸

The *Cordis* opinion held the parent patent unenforceable for the complete failure to disclose the Hillstead reference during the prosecution of the parent application.⁴³⁹ The court also held the daughter patent unenforceable because, even though Hillstead was cited in the course of the prosecution of the daughter, it was cited in a *buried form*.⁴⁴⁰

From the tenor of all the cases cited in this essay, it can be doubted that citation of a non-disclosed reference in a daughter application can reliably cure non-

⁴²⁷ 922 F.2d 801 (Fed. Cir. 1990), *aff'd* 6 U.S.P.Q.2d 1577 (D. Md. 1988).

⁴²⁸ *Id.* at 803–04 (stating that the duty of candor and good faith extends throughout the patent's prosecution, "in light of the amendments made to it" (citing *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988))).

⁴²⁹ *Fox Indus., Inc.*, 6 U.S.P.Q.2d at 1580.

⁴³⁰ *Id.* at 1581.

⁴³¹ *Fox Indus. Inc.*, 922 F.2d at 804.

⁴³² *Id.*

⁴³³ 30 U.S.P.Q.2d 1967 (N.D. Cal. 1994), *aff'd*, 104 F.3d 376 (Fed. Cir. 1996).

⁴³⁴ *Id.* at 1969.

⁴³⁵ 194 F. Supp. 2d 323 (D. Del. 2002), *rev'd on other grounds*, 339 F.3d 1352 (Fed. Cir. 2003).

⁴³⁶ *Id.* at 368.

⁴³⁷ *Applied Materials*, 30 U.S.P.Q.2d at 1967.

⁴³⁸ *Id.* at 1969.

⁴³⁹ *Cordis*, 194 F. Supp. 2d at 367–68.

⁴⁴⁰ *Id.* at 368.

disclosure with deceptive intent in the parent application. The best approach might be to disclose the reference in the daughter application, where the filing includes an explanation why the reference had not been disclosed in the parent application.

14. Disclosure or Citation of a Reference in a Parent Application Can Cure Failure To Disclose the Reference in the Daughter Application

Failure to re-submit the previously disclosed references will not lead to a holding of failure to fulfill the duty to disclose.⁴⁴¹ The best approach is to re-submit the IDS in any daughter applications, but where there is no need to re-submit actual copies of the references.

15. Examiner's Initials

A number of cases have highlighted the fact that an examiner's initials, or lack thereof, can be influential in reaching a finding of intent to deceive.⁴⁴² With consideration of each reference, the examiner places her initials next to the name of each reference. In some opinions, lack of initials can enhance an argument for intent to deceive, while in other opinions, lack of initials were found not relevant to intent to deceive. The *Fiskars Inc. v. Hunt Manufacturing Co.*⁴⁴³ opinion found that lack of initials does not shed light on intent to deceive, writing that an applicant is not required to tell the USPTO twice about the same prior art.⁴⁴⁴

16. Description of a Non-Disclosed Reference by Way of Commentary, About the Reference, in the Specification Can Cure Intent

Material references are properly disclosed by way of an IDS. Mere identification of the reference somewhere in the specification of the patent cannot satisfy the duty

⁴⁴¹ See, e.g., *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998) (stating that a reference that was included in the parent patent's prosecution "need not to be resubmitted" in the daughter patent); *Advanced Respiratory, Inc. v. Electromed, Inc.*, 65 U.S.P.Q.2d 1048, 1051 (D. Minn. 2002) (emphasizing that the prior art reference in the parent patent's application and continuation is no basis for inequitable conduct); MPEP, *supra* note 45, § 609.02 ("Information which has been considered by the Office in the parent application of a continued prosecution application . . . need not be resubmitted in the continuing application to have the information considered and listed on the patent.").

⁴⁴² See, e.g., *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1236 (Fed. Cir. 2003) (articulating that the prior art at issue for inequitable conduct was deemed not to be read because the examiner never initialed the reference); *Toro Co. v. SCAG Power Equip., Inc.*, No. 8:01CV279, 2003 U.S. Dist. LEXIS 603, at *10 (D. Neb. Jan. 15, 2003) (involving whether an examiner's initial of a prior art reference meant he had read the art); *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 379, 384 (D. Del. 2000) (ruling that the material in questions was considered by the examiner because of their initials).

⁴⁴³ 221 F.3d 1318 (Fed. Cir. 2000).

⁴⁴⁴ *Id.* at 1327.

to disclose. However, identification of the reference can be relevant to this duty, as it can cure allegations of intent to deceive.

In *Transclean Corp. v. Bridgewood Services, Inc.*,⁴⁴⁵ the court observed that the inventor had repeatedly identified the non-disclosed reference (Becnel patent) in the specification.⁴⁴⁶ The Becnel patent was identified at least nine times in the patent.⁴⁴⁷ Because of the fact that the Becnel patent was identified many times in the specification of the patent application, and because the examiner had penciled his initials in the actual patent specification, right next to the description of the Becnel, the court refrained from a holding of deceptive intent.⁴⁴⁸

The same fact-pattern occurred in *Bayer AG v. Housey Pharmaceuticals, Inc.*⁴⁴⁹ The inventor, Dr. Housey, had failed to disclose properly two references (Uehara and Hsiao references) by way of an IDS.⁴⁵⁰ Although the opinion contained allegations of deceptive intent, e.g., submitting fabricated data and failing to list the correct inventors, the opinion observed that the inventor had identified the non-disclosed references several times in the specification, and refrained from a holding of deceptive intent in the non-disclosure.⁴⁵¹ Similarly, in *Panduit Corp. v. Band-It-Idex, Inc.*⁴⁵² the court observed that a reference had also been prominently discussed in the specification.⁴⁵³

To conclude, the best approach in disclosure might be to submit all references identified in the patent specification by way of an IDS. However, where an oversight results in a non-disclosure, the patentee during litigation might find hope in saving the patent by directing the court's attention to the specification's commentary about the non-disclosed reference, or to the specification's repeated identification of the reference.

17. An Applicant Can Cure His Own Intent Only If the Applicant Also Discloses That a Misrepresentation Had Occurred—The Procedure of Rohm & Haas

Rohm & Haas Co. v. Crystal Chemical Co.,⁴⁵⁴ illustrates the concept that once a deceptive material omission has occurred, an inventor or applicant can try later to cure the deceptive intent.⁴⁵⁵ In *Rohm & Haas*, an applicant had omitted herbicidal test data in an affidavit submitted early in prosecution of a patent application.⁴⁵⁶ The affidavit provided herbicidal test data from experiments conducted in May

⁴⁴⁵ No. 97-2298 (RLE), 2000 U.S. Dist. LEXIS 19870 (D. Minn. Nov. 1, 2000), *aff'd*, 290 F.3d 1364 (Fed. Cir. 2002).

⁴⁴⁶ *Id.* at *6.

⁴⁴⁷ *Id.*

⁴⁴⁸ *Id.* at *11.

⁴⁴⁹ 128 F. App'x 767 (Fed. Cir. 2005).

⁴⁵⁰ *Id.* at 770.

⁴⁵¹ *Id.* at 770–71 (vacating and remanding the district's decision of inequitable conduct because the lower court clearly erred in deciding there was intent to deceive).

⁴⁵² No. 00-C-1461, 2000 U.S. Dist. LEXIS 11111 (N. D. Ill. June 23, 2000), *aff'd*, 25 F. App'x 836 (Fed. Cir. 2001).

⁴⁵³ *Id.* at *54–61.

⁴⁵⁴ 722 F.2d 1556 (Fed. Cir. 1983).

⁴⁵⁵ *Id.* at 1572.

⁴⁵⁶ *Id.* at 1559.

(springtime), but *deceptively omitted test data* generated in December (winter).⁴⁵⁷ The court held that the affidavit contained misrepresentations, where these misrepresentations were instrumental in persuading the examiner to allow the claims.⁴⁵⁸ At a later time during the prosecution of the patent, the applicant disclosed the omitted test results, however, this disclosure failed to contain any indication that there had earlier been a misrepresentation of the fact.⁴⁵⁹ The court held that the applicant's attempts to cure his own intent had failed because the applicant failed to inform the USPTO of his own intent to deceive.⁴⁶⁰ The *Rohm & Haas* cure procedure requires submitting the earlier non-disclosed reference, but also informing the USPTO of the intent to deceive the USPTO.

Lipman v. Lehman,⁴⁶¹ which cited and applied the cure procedure of *Rohm & Haas*, did not involve any patent application. But it did involve the duty to disclose information in the course of business conducted with the USPTO.⁴⁶² An attorney (Lipman) was asked to submit a collection of affidavits to the USPTO in support of the character of a patent attorney, Mr. Wallace.⁴⁶³ After submitting the affidavits (seventeen affidavits), four of the affiants sent Mr. Lipman a letter stating that they changed their mind, and that the four affidavits should no longer be used by either Mr. Lipman or by Mr. Wallace.⁴⁶⁴

Mr. Lipman's problems began a few days later, when he submitted a petition in support of Mr. Wallace's character, where the petition referred to all seventeen affidavits.⁴⁶⁵ The petition referred to all seventeen affidavits even though Mr. Lipman knew that four of affiants had changed their mind.⁴⁶⁶ Mr. Lipman's problems got even worse, about two months later, when he sent a letter to the USPTO requesting that the patent office no longer rely on the four false affidavits.⁴⁶⁷ In a nutshell, the problem was that Mr. Lipman had tried to cure his earlier misrepresentation, but had not used the cure procedure of *Rohm & Haas*. What Mr. Lipman had failed to do was *to disclose that an actual misrepresentation had been made*.⁴⁶⁸ The consequence was a threat of suspension directed to Mr. Lipman.⁴⁶⁹

The U.S. District Court for the Northern District of California, in *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*,⁴⁷⁰ also considered the *Rohm & Haas* cure procedure.⁴⁷¹ The court narrowly construed *Rohm & Haas*, and held that the *Rohm & Haas* cure procedure was *not applicable where*

⁴⁵⁷ *Id.* at 1560.

⁴⁵⁸ *Id.* at 1571.

⁴⁵⁹ *Id.* at 1572–73.

⁴⁶⁰ *Id.* at 1573.

⁴⁶¹ No. 95-0774 (RCL), 1996 U.S. Dist. LEXIS 10479 (D.D.C. July 19, 1996), *aff'd sub nom.* *Lipman v. Dickinson*, 174 F.3d 1363 (Fed. Cir. 1999).

⁴⁶² *Id.* at *4.

⁴⁶³ *Id.* at *2.

⁴⁶⁴ *Id.* at *3–4.

⁴⁶⁵ *Id.* at *5–7.

⁴⁶⁶ *Id.* at *18–22.

⁴⁶⁷ *Id.* at *10.

⁴⁶⁸ *Id.* at *25.

⁴⁶⁹ *Id.* at *29–30.

⁴⁷⁰ 30 U.S.P.Q.2d 1967 (N.D. Cal. 1994), *aff'd*, 104 F.3d 376 (Fed. Cir. 1996).

⁴⁷¹ *Id.* at 1969.

the patent examiner could independently assess the veracity of the alleged misstatements by examining the prior art.⁴⁷² In *Applied Materials*, the non-disclosed reference was a typical prior art patent, easily discovered by any examiner. The author suggests that the Federal Circuit formally address the validity of the *Rohm & Haas* cure procedure, and speak on whether it applies only to prior art that is obscure to the examiner, or if it also applies to prior art easily found by the examiner.

H. Confidential Information

Regarding litigation, the case law provides a great deal of guidance on the duty to disclose confidential materials and protection of these materials. During litigation, confidential documents are protected by doctrines such as attorney work-product and attorney-client privilege.⁴⁷³ However, guidance regarding the duty to disclose confidential materials in proceedings before the USPTO is sparse. From the available case law from the Federal Circuit, the consistent rule is that if the confidential information has some bearing on the validity of the claims, then it should be disclosed; but if it has only tangential relation to the claims and has no direct bearing on claim validity, then it need not be disclosed. In other words, if non-disclosed test results are only relevant to *non-claimed aspects* of the applicant's research work, then the test results need not be disclosed.

In *Jack Frost Laboratories, Inc. v. Physicians & Nurses Manufacturing Corp.*,⁴⁷⁴ the inventor had failed to disclose test results showing that the product, when made of *high density polyethylene*, was inoperable.⁴⁷⁵ What was inoperable was that when the invention (a plastic bag) was microwaved for three minutes, the result was that the bag ruptured. The patent claim read: "A microwave gel pack comprising: a completely sealed envelope . . . [that does] not rupture or separate at the seams thereof when subjected to said microwave energy for a period of time exceeding about two minutes but not exceeding about four minutes."⁴⁷⁶ The district court observed that the test results demonstrated that the bag failed to meet the requirements of the claim and, on this basis, held that the test results were material to the claims and needed to be disclosed to the USPTO.⁴⁷⁷ Intent to deceive was inferred by the inventor's repeated lack of candor, which included failure to disclose the test results, failure to disclose a sale, self-contradictory testimony during litigation, and

⁴⁷² *Id.*

⁴⁷³ *In re* Echostar Commc'ns Corp. 448 F.3d 1294, 1300–02 (Fed. Cir. 2006); *In re* Spalding Sports Worldwide, Inc., 203 F.3d 800, 805 (Fed. Cir. 2000); Paul R. Rice, *Attorney-Client Privilege: Continuing Confusion About Attorney Communications, Drafts, Pre-Existing Documents, and the Source of the Facts Communicated*, 48 AM. U. L. REV. 967, 1001 (1999). See generally Jonathan G. Musch, *Attorney-Client Privilege and the Patent Prosecution Process in the Post-Spalding World*, 81 WASH. U. L.Q. 175 (2003) (summarizing the history and current law on attorney-client privilege).

⁴⁷⁴ Nos. 96-1114, 96-1430, 96-1543, 1997 U.S. App. LEXIS 26138 (Fed. Cir. Sept. 23, 1997), *affg.* 901 F. Supp. 718, 728 (S.D.N.Y. 1999).

⁴⁷⁵ *Id.* at *10–11.

⁴⁷⁶ U.S. Patent No. 4,756,311 col.6 l.46–64 (filed May 15, 1985).

⁴⁷⁷ *Jack Frost Labs.*, 901 F. Supp. at 728.

destruction of company records.⁴⁷⁸ The court held for inequitable conduct and rendered the patent unenforceable.⁴⁷⁹

In *Cargill, Inc. v. Canbra Foods, Ltd.*,⁴⁸⁰ the inventor failed to disclose laboratory data (“oven data”) which, if submitted, would have “stood in the way of portraying IMC 130 [the invention] as something more than an incremental improvement.”⁴⁸¹ Intent to deceive was inferred from the fact that there were “multiple occasions that called for disclosure of the omitted data.”⁴⁸² The court rendered the patent unenforceable for inequitable conduct.⁴⁸³

Prophetic examples are a conventional component of many patent applications. Usually, the prophetic examples serve to supplement disclosures of existing examples comprising actual laboratory data. In *Novo Nordisk Pharmaceuticals, Inc. v. Biotechnology General Corp.*,⁴⁸⁴ a patent was rendered unenforceable on the basis of a prophetic example, where later-conducted research by the inventor demonstrated that the prophetic example did not work.⁴⁸⁵ The relevant forum for disclosing the new laboratory data was an Interference Proceeding conducted at the Board of Patent Appeals and Interferences. A contributing factor to the finding of inequitable conduct was the fact that the prophetic example was disclosed, in the patent, in the past tense.⁴⁸⁶ Disclosing a prophetic example in the past tense generally results in harsh consequences for the patentee.

In *Syntex (U.S.A.) LLC v. Apotex, Inc.*,⁴⁸⁷ the adverse party accused the patent owner of failing to disclose results with a chemical called oxtoxynol 12.5.⁴⁸⁸ The adverse party argued that the court should render the patent invalid for inequitable conduct. The court observed that the non-disclosed test results had some relevance to the field of research, and could be interpreted as establishing some weakness in the applicant’s research, but were not relevant to aspects of this work described by the claims.⁴⁸⁹ The court refrained from finding inequitable conduct.⁴⁹⁰

Similarly, the Federal Circuit in *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*⁴⁹¹ and the United States District Court for the District of Delaware in *Applera Corp. v. Micromass UK Ltd.*,⁴⁹² held that non-disclosed confidential laboratory data was non-material, as the data was not relevant to the claims.⁴⁹³

⁴⁷⁸ *Id.* at 729.

⁴⁷⁹ *Jack Frost Labs.*, 1997 U.S. App. LEXIS 26138, at *19.

⁴⁸⁰ 476 F.3d 1359 (Fed. Cir. 2007).

⁴⁸¹ *Id.* at 1367.

⁴⁸² *Id.* at 1366.

⁴⁸³ *Id.* at 1362.

⁴⁸⁴ 424 F.3d 1347 (Fed. Cir. 2005).

⁴⁸⁵ *Id.* at 1362.

⁴⁸⁶ *Id.* at 1361.

⁴⁸⁷ 407 F.3d 1371 (Fed. Cir. 2005).

⁴⁸⁸ *Id.* at 1377.

⁴⁸⁹ *Id.* at 1383.

⁴⁹⁰ *Id.* at 1385.

⁴⁹¹ 471 F.3d 1369 (Fed. Cir. 2006).

⁴⁹² 204 F. Supp. 2d 724 (D. Del. 2002), *aff’d*, 60 F. App’x 800 (Fed. Cir. 2003).

⁴⁹³ *Eli Lilly & Co.*, 471 F.3d at 1383; *Applera Corp.*, 204 F. Supp. at 762–64.

In *Senior Industries, Inc. v. Thomas & Betts Corp.*,⁴⁹⁴ the inventor, Mr. Franks, had knowledge of a prior art device (the Graves invention) but did not disclose the Graves invention to the USPTO.⁴⁹⁵ Mr. Franks possessed a rough drawing of the Graves invention as well as a letter stating that the Graves invention preceded his own by several years.⁴⁹⁶ The rough drawing was a confidential document, and was not a publication available to the public.⁴⁹⁷ Mr. Franks had also signed the non-disclosure agreement, which precluded him from divulging information.⁴⁹⁸ The non-disclosure agreement shows that the Graves invention was not in the public knowledge.⁴⁹⁹ Although the court did not find enough in George Franks' activities to support a finding of intent to deceive the USPTO,⁵⁰⁰ the opinion, in dicta, wrote the court does not condone the withholding of potentially important information where doubt exists and the filing party unilaterally decides that the information should not be considered.⁵⁰¹

*CFMT, Inc. v. Yieldup International Corp.*⁵⁰² described several categories of confidential laboratory data, where the data was negative and not disclosed: (1) non-disclosed data that is negative but does not contradict the claims⁵⁰³; (2) non-disclosed data that is negative to the extent that it does not render the claim non-enabled, but merely shows that the invention does not give results good enough to guarantee commercial success; (3) non-disclosed data that is negative to the extent that it proves that the claim is non-enabled and should result in invalidation under 35 U.S.C. § 112; and (4) non-disclosed data that is negative to the extent that it is contrary to other, better data, submitted to the USPTO to support arguments that the invention is non-obvious.⁵⁰⁴ *CFMT* suggested that the first and second data types are not material, while the third and fourth data types are material and should be disclosed to avoid a holding of inequitable conduct.⁵⁰⁵ Non-disclosure of a confidential document, an Abstract presented at a scientific meeting, was also an issue in *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*.⁵⁰⁶

*PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*⁵⁰⁷ concerned the failure to disclose confidential information, where this information took the form of details of ongoing communications between collaborators.⁵⁰⁸ Communications with an outside collaborator, contractor, or custom manufacturer, are generally confidential.

⁴⁹⁴ No. 98-C-5842, 2002 U.S. Dist. LEXIS 18995 (N.D. Ill. Sept. 20, 2002).

⁴⁹⁵ *Id.* at *45–46.

⁴⁹⁶ *Id.* at *46, *52.

⁴⁹⁷ *Id.* at *53.

⁴⁹⁸ *Id.*

⁴⁹⁹ *Id.*

⁵⁰⁰ *Id.* at *54.

⁵⁰¹ *Id.*

⁵⁰² 349 F.3d 1333 (Fed. Cir. 2003).

⁵⁰³ In *CFMT*, the data did not contradict the claims because the non-disclosed experimental setup lacked one of the elements required by the claims, where the claims required a closed system to protect from dust, and the omitted element in the experimental setup was the closed system. *Id.* at 1337.

⁵⁰⁴ *Id.* at 1342.

⁵⁰⁵ See generally *id.* at 1342 (discussing non-disclosure of negative test data).

⁵⁰⁶ 90 F. Supp. 2d 522, 529 (D.N.J. 2000).

⁵⁰⁷ 225 F.3d 1315 (Fed. Cir. 2000).

⁵⁰⁸ *Id.* at 1319.

The inventors listed on the patent for a particle used for perfusive chromatography were Drs. Afeyan, Regnier, and Dean.⁵⁰⁹ These inventors had invented a coating for the claimed particle.⁵¹⁰ But the particle itself was made by another party, namely, Drs. Warner and Lloyd of Polymer Labs.⁵¹¹ Unfortunately for these three named inventors, they had failed to disclose their collaboration with the scientists at Polymer Labs, a collaboration that had included frequent conversations.⁵¹²

The Federal Circuit held that a disclosure of the true nature of the relationship between the two groups of scientists would have been important to a reasonable examiner's consideration of the inventorship question, and held that the patent unenforceable for inequitable conduct.⁵¹³

Where an applicant chooses to disclose proprietary information or a trade secret, the USPTO suggests labeling the information as such in a sealed, labeled envelope, and submitting a petition to expunge the citation.⁵¹⁴ The sealed envelope should contain a label reading, "PROPRIETARY MATERIAL NOT OPEN TO PUBLIC. TO BE OPENED ONLY BY USPTO EXAMINER. DO NOT SCAN."⁵¹⁵ However, if the examiner actually considers the proprietary information or trade secret to be material, the petition to expunge will be denied.⁵¹⁶

Applicants should refrain from disclosing information that is subject to a confidentiality agreement. For example, data resulting from collaboration between an inventor from Company A and an inventor from Company B might be subjected to such an agreement. The issue is that the file history can become publicly available at the time that the application is published or at the time that the patent issues. The duty of confidentiality towards a third party, and the duty to disclose to the USPTO, represent potential conflicting duties. As observed by Simone A. Rose and Debra R. Jessup, this conflict is distinguished by the fact that breach of confidentiality can result in suspension, while non-disclosure can result in inequitable conduct.⁵¹⁷

I. Non-Uniform Application By the Courts of the Two Standards of Materiality

According to the USPTO, a goal of the March 1992 amendment to Rule 56 was to provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct.⁵¹⁸ However, the decade following this amendment has been characterized by uneven application of the new standard by the courts.

⁵⁰⁹ *Id.* at 1317.

⁵¹⁰ *Id.* at 1319.

⁵¹¹ *Id.*

⁵¹² *Id.*

⁵¹³ *Id.* at 1322–23.

⁵¹⁴ MPEP, *supra* note 45, § 724.02.

⁵¹⁵ *Id.*

⁵¹⁶ *Id.* §§ 724.02, 724.05; Changes To Implement the Patent Business Goals, 63 Fed. Reg. 53,498 (Oct. 5, 1998), 1215 Off. Gaz. Pat. Office 87 (Oct. 27, 1998).

⁵¹⁷ Simone A. Rose & Debra R. Jessup, *Whose Rules Rule? Resolving Ethical Conflicts During the Simultaneous Representation of Clients in Patent Prosecution*, 12 FED. CIR. B.J. 571, 573–74 (2003).

⁵¹⁸ Duty of Disclosure, *supra* note 15, at 2023.

The Federal Circuit, as well as the U.S. District Courts, has taken non-uniform approaches to the pre-March 1992 and post-March 1992 standards. For patents *prosecuted before* March 1992, nearly all courts properly described/applied the pre-March 1992 standard, though in a few cases, the court has improperly described/applied the post-March 1992 standard.

For patents *prosecuted entirely after* March 1992, some courts have described/applied either the pre-March 1992 standard while other courts have described/applied the post-March 1992 standard. Here, courts using the earlier standard can be considered to be anti-patent holder courts, while the courts using the latter standard are pro-patent holder, relative to each other.

In some cases, the court described or applied an aggregated standard, where application of the aggregated standard has the same effect as applying only the pre-March 1992 standard. Thus, courts using the aggregated standard can be considered anti-patent holder.

1. Pro-Patenting and Anti-Patenting Courts

From the Federal Circuit, *Molins PLC v. Textron Inc.*,⁵¹⁹ *Life Technologies, Inc. v. Clontech Laboratories, Inc.*,⁵²⁰ and *Elk Corp. of Dallas v. GAF Building Materials Corp.*,⁵²¹ concerned patents prosecuted entirely before March 1992, where these courts properly described (or described and applied) only the pre-March 1992 standard.

In *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*,⁵²² from the Federal Circuit, the patent was prosecuted entirely after March 1992, but the court described only the pre-March 1992 standard, hence this court could be construed as *anti-patenting*. Similarly, in cases from the U.S. district courts, *DaimlerChrysler AG v. Feuling Advanced Technologies, Inc.*,⁵²³ *Emerson Electric Co. v. Spartan Tool, L.L.C.*,⁵²⁴ *Schnadig Corp. v. Collezione Europa U.S.A.*,⁵²⁵ and *Ashland Products, Inc. v. Truth Hardware Corp.*,⁵²⁶ were *anti-patenting*.

In contrast, in other instances, the courts have applied only the post-March 1992 standard. For example, the U.S. District Court for the District of Delaware, in *Applera Corp. v. Micromass UK Ltd.*⁵²⁷ concerned a patent filed in November 1989, a time when the Federal Circuit and USPTO both utilized the broad standard. However, the opinion blatantly applied a very narrow standard of materiality. The court held that a non-disclosed reference was not material, despite the fact that the examiner had initially found it highly relevant to the claims.⁵²⁸ To view the complete picture, the court held the non-disclosed reference to be not material, because “that

⁵¹⁹ 48 F.3d 1172 (Fed. Cir. 1995).

⁵²⁰ 224 F.3d 1320 (Fed. Cir. 2000).

⁵²¹ 168 F.3d 28 (Fed. Cir. 1999).

⁵²² 267 F.3d 1370, 1378–79 (Fed. Cir. 2001).

⁵²³ 276 F. Supp. 2d 1054 (S.D. Cal. 2003).

⁵²⁴ 223 F. Supp. 2d 856 (N.D. Ohio 2002).

⁵²⁵ No. 01-C-1697, 2002 U.S. Dist. LEXIS 19083 (N.D. Ill. Oct. 2, 2002).

⁵²⁶ No. 99-C-5786, 2003 U.S. Dist. Lexis 11362 (N.D. Ill. July 1, 2003).

⁵²⁷ 204 F. Supp. 2d 724 (D. Del. 2002), *aff'd*, 60 F. App'x 800 (Fed. Cir. 2003).

⁵²⁸ *Id.* at 760.

rejection was subsequently withdrawn,”⁵²⁹ adding that, “[t]o base a finding of materiality solely on the Examiner’s initial assessment of the prior art, without considering the bases . . . or reasonableness of the rejection, would make material every prior art reference on which a rejection . . . is based.”⁵³⁰ This court can be construed as pro-patent holder, even though its application of the law appears incorrect. To give another example, in *Novadigm, Inc. v. Marimba, Inc.*,⁵³¹ the U.S. District Court for the Northern District of California held that only the post-March 1992 standard could be applied for patents prosecuted solely after March 1992.⁵³² This court also could be viewed as pro-patent holder. Courts selectively applying the post-March 1992 standards to patents prosecuted entirely after March 1992 can be construed as being pro-patent holders, where these courts included *Novadigm, Beam Laser Systems, Inc. v. Cox Communications, Inc.*,⁵³³ *Eastern America Trio Products, Inc. v. Tang Electronic Corp.*,⁵³⁴ *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*,⁵³⁵ *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*,⁵³⁶ and *Strandtek International, Inc. v. Minnesota Mining and Manufacturing, Inc.*⁵³⁷

A conclusion can be made regarding the U.S. District Courts—for patents prosecuted entirely after March 1992, most of the courts have described only the pre-March 1992 standard, and thus most of the courts were anti-patenting.

A number of cases have concerned two patents, one prosecuted before March 1992, and the other entirely after March 1992. In *Beam Laser*, the court described both pre-March 1992 and post-March 1992 standards as two separate standards, and surgically applied these two separate standards to two respective patents (the ’883 and ’825 patents), one prosecuted before and the other after March 1992, writing that the first standard for materiality applies to the ’883 patent, and the second applies to the ’825 patent.⁵³⁸ Similarly, the U.S. District Court for the Southern District of New York has also surgically separated the application of both standards.⁵³⁹

In contrast, an aggregated, or combined, standard has been set forth in a number of cases, i.e., a standard where the court is free to pick and choose among elements of the aggregated standard, and decide which part to apply. For example, in *Argus Chemical Corp. v. Fibre Glass-Evercoat Co.*,⁵⁴⁰ an early case from the Federal Circuit, the court set forth an aggregated standard.⁵⁴¹ This opinion, as well as the more recent *Digital Control Inc. v. Charles Machine Works*,⁵⁴² characterized the aggregated standard as one where the threshold of materiality can be established by any one of four tests.⁵⁴³ In other words, the aggregated standard is one where the

⁵²⁹ *Id.*

⁵³⁰ *Id.*

⁵³¹ No. C-97-20194-JW, 2000 U.S. Dist. LEXIS 2315 (N.D. Cal. Jan. 4, 2000).

⁵³² *Id.* at *6 n.1.

⁵³³ No. 2:00-cv-195, 2001 U.S. Dist. LEXIS 11864 (E.D. Va. June 27, 2001).

⁵³⁴ 97 F. Supp. 2d 395 (S.D.N.Y. 2000).

⁵³⁵ 120 F.3d 1253 (Fed. Cir. 1997).

⁵³⁶ 204 F.3d 1368 (Fed. Cir. 2000).

⁵³⁷ No. 1:99-CV-961, 2000 U.S. Dist. LEXIS 17552 (W.D. Mich. Nov. 20, 2000).

⁵³⁸ *Id.* at *10 n.3.

⁵³⁹ 97 F. Supp. 2d 395 (S.D.N.Y. 2000).

⁵⁴⁰ 759 F.2d 10 (Fed. Cir. 1985).

⁵⁴¹ *Id.* at 14.

⁵⁴² 437 F.3d 1309 (Fed. Cir. 2006).

⁵⁴³ *Id.* at 1314–15.

court is free to pick and choose among the available standards, and to apply the chosen standard.

CONCLUSION

Materiality is the first prong of inequitable conduct, as it applies to the duty to disclose. However, the Federal Circuit has refrained from providing guidance as to the proper standard for materiality. By writing, “We leave for another day a final disposition of this issue,”⁵⁴⁴ the Federal Circuit has admitted that an uncertainty exists regarding the two separate standards for the duty to disclose. Lack of guidance has also resulted from the Federal Circuit committing itself to the narrow administrative law standard in some opinions,⁵⁴⁵ but abandoning this stance in later opinions. As documented in this essay, the Federal Circuit appears to prefer the co-existence of both standards of materiality. The end effect is that the narrower post-March 1992 standard has been made redundant in the context of the federal courts (though not in the context of proceedings before the USPTO). In other words, the aggregated standard subsumes the narrower standard and is, in effect, exactly the same as the broader standard.

This uncertain standard has influenced the primary behavior of patent applicants, where the result, at least in the biotechnology arts, is the frequent submission of Information Disclosure Statements supplying a great number of references. The problem with submitting fifty to one-hundred or more references is that it places an undue burden on the examiner and likely compromises the quality in the examination process.

Intent to deceive is the second prong of inequitable conduct. Intent is almost always established by evidence that the applicant was repeatedly exposed to the reference in question, and only rarely established by the direct evidence of a “smoking gun.” The case law suggests at least two avenues for mitigating alleged intent, namely, the examiner’s independent finding of the non-disclosed reference, and the *Rohm & Haas* cure procedure. Unfortunately, the Federal Circuit has not provided consistent guidance on these two avenues. The author suggests that the Federal Circuit formally address the question of whether *an examiner’s independent finding* of a material reference can, or cannot, cure intent to deceive. Also, the author suggests that the Federal Circuit formally address the validity of the *Rohm & Haas cure procedure* relating to an inventor’s ability to cure her own deceptive intent, and speak on whether it applies only to prior art that is obscure to the examiner, or if it also applies to prior art easily found by the examiner.

⁵⁴⁴ *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003).

⁵⁴⁵ *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 410 F.3d 690 (Fed. Cir. 2005), *reh’g granted*, 438 F.3d 1123 (Fed. Cir. 2006).