Liar Liar Pants On Fire: Towards A Narrow Construction For Inequitable Conduct As Applied To The Prosecution Of Medical Device And Drug Patent Applications

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LIAR LIAR PANTS ON FIRE: TOWARDS A NARROW CONSTRUCTION FOR INEQUITABLE CONDUCT AS APPLIED TO THE PROSECUTION OF MEDICAL DEVICE AND DRUG PATENT APPLICATIONS

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"Whoever has even once become notorious by base fraud, even if he speaks the truth, gains no belief."

I. INTRODUCTION

As with most litigation, a lawsuit would be simple if the plaintiff only had to prove its own case-in-chief. The only defense would be whether the defendant is liable on the plaintiff’s case-in-chief and alternate defenses would not be allowed. But of course this fantasy is simply that, a fantasy. Defenses abound. In patent litigation, these defenses may often be the only way of escaping. A defendant charged with patent infringement can defend on many grounds temporally related to the patent’s life, such as activities that occurred before the patentee filed for its patent. These defenses include the traditional patentability statutes, such as novelty destroying or obviousness statutes. The infringer may also examine activities that occur during the patent application process. These defenses may include prosecution history estoppel, common law fraud, or inequitable conduct. Finally, the infringer may examine activities that might have occurred after patent issuance, such as laches, equitable estoppel, reexamination, or reissue.

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1 PHAEDRUS, BOOK I, FABLE 10, 1.


3 Prosecution history estoppel essentially means that the patent applicant said something to obtain the patent and is now illegally attempting to recant in order to expand the scope of the patent claims. See Warner-Jenkinskin Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 30-34, 41 U.S.P.Q.2d 1865 (1997). For common law fraud, see infra notes 12-13, 32. For inequitable conduct, see infra notes 9-11, 32.

Patents play an important role in commerce and thus are “issues of great moment to the public.” As noted by the Supreme Court in Precision Instrument v. Automotive Maintenance Machinery Co.:  

A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the “Progress of Science and Useful Arts.” At the same time, a patent is an exception to the general rule against monopolies and to the right to access a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such patents are kept within their legitimate scope.  

This article generally discusses inequitable conduct during the patent application process and, more specifically, relates to issues that may arise in medical experimentation, research, and development. It also notes that in order to foster a better patent examination system, to protect applicants from being maligned by defense attorneys, to protect the valuable intellectual property rights that companies possess, and as a matter of good social policy, applicants ought to disclose more, rather than less, information, especially in the medical fields. A stricter construction of the inequitable conduct defense will provide invaluable guidance to the medical device or drug company as to permissible and impermissible conduct. Part I begins with an introduction to inequitable conduct. Part II discusses the evidentiary standards used to evaluate inequitable conduct. Part III and its subparts discuss the “materiality” prong of the test. Part IV and its subparts discuss the “intent” prong. Part V concludes discussing the need and policy reasons for a narrower construction. Finally, Table I provides a twelve-year summary of Federal Circuit decisions.  

Inequitable conduct, also known as “fraud on the Patent Office,” entails a two-step process: first a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent “in light of all the circumstances” to determine whether the applicant’s conduct is so culpable that the patent should be held unenforceable.  

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7 See Shashank Upadhye, To Use or Not to Use: Reforming Patent Infringement, the Public Use Bar, and the Experimental Use Doctrine as Applied to Clinical Testing of Pharmaceutical and Medical Device Inventions, 4 MINN. INT’L PROP. REV. 1 (2002) (discussing how public use during medical research can affect patent validity).  
8 By “strict,” it is meant that the courts ought to construe cases in such a regard as to send clear messages that certain conduct will not be tolerated.  

As such, the applicant must fail to disclose material and relevant information, or, if the applicant does submit information, that information must somehow be false or misleading. In addition, the applicant must fail to make the submission (or make the false submission) with an intent to deceive the Patent Office. A distinction exists between common law fraud and inequitable conduct. To this end, the Federal Circuit prefers to refer to common law fraud as “fraud” and misbehaviour before the Patent Office as “inequitable conduct.” While inequitable conduct was defined above, common law fraud or “Walker Process fraud” requires proof of:  

1. a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.  

The flip side to proving one’s failure to disclose is a duty to be candid and disclose the relevant and material information. This duty of candor in inequitable conduct stems from early equitable doctrine of clean hands in that a patentee who came to court to enforce the patent ought to have acted candidly in obtaining that patent. The historical reason for imposing a duty of candor was “that whenever a party who, as actor, seeks to set the judicial machinery in motion and obtain some remedy, has violated conscience, or good faith, or other equitable principle, in his prior conduct, then the doors of the court will be shut against him in limine.”  

So who can be accused of inequitable conduct? Who is involved in the inequitable conduct inquiry? The Supreme Court held that attorneys, agents, and applicants “who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it  

10 As used herein, the terms “information” and “references” are used interchangeably.  
14 Id. at 244-45.  
15 Id. (quoting JOSEPH J. PONZERINO, EQUITY JURISPRUDENCE § 397 (4th ed. 1918). The related doctrine of unclean hands bars the party (litigant) from benefiting from the court’s participation, but is not a grounds to find the patent unenforceable. Similarly, litigation misconduct, as a part of the doctrine of unclean hands, cannot be used to find the patent unenforceable. Aptix Corp. v. Quikturn Design Sys., 269 F.3d 1369, 1375-76, 60 U.S.P.Q.2d 1702, 1709-10 (Fed. Cir. 2001). Aptix concerned flagrant series of litigation misconduct including falsifying documents, failure to provide discovery, and outright false testimony that resulted in the complaint being dismissed. Id.; see also Aptix Corp. v. Quikturn Design Sys., No. 98-00762, 2000 WL 852813 (N.D. Cal. 2000), aff’d in part, rev’d in part, 269 F.3d 1369, 60 U.S.P.Q.2d 1705.
all facts concerning possible fraud or inequitableness underlying the applications in issue. These individuals owe the highest level of honesty and candor in reporting the material facts essential in the patent system. Any knowledge or action taken by the prosecuting attorney is considered chargeable to the applicant. This uncompromising duty continues throughout the prosecution of the patent application. Even though the parties may have changed during any later litigation, the inequitable conduct is measured against the standards in effect at the time of the prosecution of the patent. Quite simply, the inventors, the prosecuting attorneys, and the applicant company all may have duties to the Patent Office. The Supreme Court imposed this duty of candor in order to prevent the Patent Office from being classed among the "mute and helpless victims of deception and fraud." It is puzzling why inequitable conduct is an issue. Should applicants and attorneys not always be upstanding, "do the right thing," and be honorable? That is yet another fantasy. There are competing interests in inequitable conduct resolutions. The patentee, who procured the patent by inequitable conduct, has damaged the patent examining system and has obtained the Congressional grant of excluding a competitor from the field. Thus, the public suffers from this because a competitor, who might have normally entered the field, will not enter the field due to the patent. Competition is consequently stifled. On the other hand, infringers will often unjustifiably accuse a patentee of inequitable conduct and many times these accusations are unfounded, discourteous, and simply offensive. As the court noted in Burlington Industries v. Dayco Corp., these accusations are a "plague" on the patent system and the litigation process. To this end, the courts are very concerned that charging inequitable conduct as a matter of course is "a magic incantation to be asserted against every patentee." In one of its strongest statements, the court stated:

[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps. . . . They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself. A patent litigant should be made to feel, therefore, that an unsupported charge of "inequitable conduct in the Patent Office" is a negative contribution to the rightful administration of justice.

broadly than warranted in light of the limiting statements in the . . . article and the [invention submission report] and having done so had a reason not to submit these documents to the PTO." Id. at 1242, 66 U.S.P.Q.2d at 1492. This quote, if construed literally, can have a pernicious effect on small inventors because often times the patent attorney probes answers from small inventors to obtain broad coverage. By way of example, assume an inventor states that his invention is a ceramic doorknob. The patent attorney may probe the inventor to determine if the inventor only invented a ceramic doorknob or actually invented a mechanism for keeping a door closed. Arguably, the latter is more expansive because it covers doorknobs of any material, but also latches and doorstop. If the invention is described in the application as a generic mechanism for keeping doors closed but only includes one example of the ceramic doorknob, is this inequitable conduct that renders the patent unenforceable or ethically required zealous representation?


The duty of disclosure is a positive duty to disclose the information to the Patent Office. This duty is not satisfied simply by putting the information out in the public domain (e.g., by publication in a journal) hoping that the Patent Office will stumble upon it. Bristol-Myers Squibb v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1241, 66 U.S.P.Q.2d 1481 (Fed. Cir. 2003) ("In our view, RPR's argument misses the mark because RPR's duty of disclosure was to the PTO and publishing the article did not amount to RPR disclosing the article to the PTO."). The Bristol-Myers Squibb case also suggests a new, but pernicious, grounds for inequitable conduct by suggesting that a patent attorney expands the scope in the patent application so that the application is broader than the invention submission report submitted by the inventor somewhat commits inequitable conduct. The court stated that the district court concluded "that [the patent attorney] drew the patent application more
In her dissent in the recent *Hoffmann-LaRoche* case, Judge Newman stated:

"Litigation-induced assaults on the conduct of science and scientists, by aggressive advocates intent on destruction of reputation and property for private gain, produced the past "plague" of charges of "iniquitous conduct." A successful attack on the inventor or his lawyer will destroy the patent, no matter how valid the patent and how sound the invention. The uncertainties of the processes of scientific research, the vagaries of the inductive method, the complexities of patent procedures, and the twists of hindsight, all provided grit for this pernicious mill. Indeed, the prevalence of accusations of inequitable conduct in patent cases led judges to suspect that all scientists are knaves and all patent attorneys jackals. Today this court revives that misbegotten era."

There are also some strategic reasons to submit prior art to the Examiner and have the Examiner issue the patent over the prior art. Prior art should be submitted because once the reference is in front of the Examiner, the Examiner is presumed to have looked at it. This means that it will likely be very difficult for an infringer to successfully argue that the patent is invalid over this very piece of prior art that the Examiner examined and over which still decided to issue the patent. The Examiner is a presumed expert in the application of the patentability laws to that technology. Accordingly, arguing to convince a layperson jury or judge that the PTO Examiner/expert did not do his job properly will not often be a winning argument. In reality, an applicant that submits the prior art for evaluation reduces the universe of prior art that can be used against the applicant.

28 Id. at 1372.
29 At the outset, it is important to understand the concepts of "prior art" and "filing dates." "Prior art" is defined as documents or activities that can preclude the applicant from obtaining a patent because what the applicant has done is not new. See 35 U.S.C. § 102. Similarly, section 103 involves the concept of "obviousness," which is essentially rejecting a patent application because what the applicant has done, although new, is simply obvious over or is a trivial variation of what has been done in the past. 35 U.S.C. § 103. Filing dates measure the universe of prior art that can be used against the patent applicant. Novelty and obviousness are essentially measured against the patent application filing date. If the application is filed earlier than later, then the size of the universe of prior art that can be used against the applicant is smaller if the application is filed later. Therefore, applicants try to file applications before novelty destroying dates come and go. Sometimes, though, applicants do not file on time and these applicants can create their own prior art. See 35 U.S.C. §102(b). Or other people may do things to create prior art. See 35 U.S.C. §102(a)-(b). Inequitable conduct issues generally arise when applicants fail to disclose their self-created prior art or fail to disclose prior art that they know about.
30 See *In re Portola Packaging, Inc.*, 110 F.3d 786, 790, 42 U.S.P.Q.2d 1295, 1299 (Fed. Cir. 1997) (stating applicant's disclosure of a prior art reference presumes that the Examinee has looked at it); *Medtronic v. Daig*, 789 F.2d 903, 906, 229 U.S.P.Q. 664 (Fed. Cir. 1986) ("We presume that a fact finder reviews all evidence presented unless he explicitly expresses otherwise.").
31 See *In re Lee*, 277 F.3d 1338, 1345, 61 U.S.P.Q.2d 1430, 1435 (Fed. Cir. 2002) ("The patent examiner and the Board are deemed to have experience in the field of the invention.").

32 See *Kingsdown Med.*, 863 F.2d at 872, 9 U.S.P.Q.2d 1389. According to the doctrine of inequitable conduct, a patent is rendered unenforceable if the patent applicant acted inequitably before the PTO in prosecuting the patent. *Id.* The patent is not "invalid" but is rendered unenforceable. Regents of the Univ. of N.M. v. Knight, 321 F.3d 1111, 1121, 66 U.S.P.Q.2d 1001 (Fed. Cir. 2003) (stating that inequitable conduct renders patent unenforceable, but does not alter any ownership rights). The unenforceability is against all future defendants. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 316, 91 U.S.P.Q. 513 (1971). The Supreme Court has held that "once the claims of a patent are held invalid in a suit involving an alleged infringer, an unrelated party who is sued for infringement of those claims may repel the benefit of the invalidity decision under principles of collateral estoppel." *Mendenhall v. Barber Greene Co.*, 26 F.3d 1573, 1577, 31 U.S.P.Q.2d 1001, 1003 (Fed. Cir. 1994) (summarizing the Supreme Court's holding in *Blonder-Tongue*).

33 *id.* An unrelated accused infringer may likewise take advantage of an "unenforceability" decision under the collateral estoppel doctrine. *See Gen. Electric Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1413, 30 U.S.P.Q.2d 1149, 1155-56 (Fed. Cir. 1994) ("The principle of Blonder-Tongue . . . respecting collateral estoppel also applies to unenforceability."); *Hoffmann-LaRoche*, 323 F.3d at 1372 (describing whether inequitable conduct warrants "the sanction of rendering the patent unenforceable").

The penalties for common law fraud include invalidity as the patent in suit and to all related patents. *Novelpharma*, 141 F.3d at 1070, 46 U.S.P.Q.2d at 1105-06. A patentee liable for fraud may also be exposed to antitrust liability under the *Walker Process* antitrust theory. *Id.*; see also *Walker Process*, 382 U.S. at 177. But proving *Walker Process* fraud does not ipso facto establish antitrust liability. Rather, the infringer must still prove the two additional elements of section 2 of the Sherman Act, namely (1) the patentee must possess a monopoly power in the relevant market, and (2) the patentee must willfully acquire or maintain that monopoly power — as distinguished from growing or developing that power as a consequence of a superior product, business acumen, or historic accident. United States v. Grinnell Corp., 384 U.S. 563, 570 (1966). The 1998 *Novelpharma* decision made clear that fraudulent omissions, as well as fraudulent misrepresentations, may form the basis of a *Walker Process* claim. *See Novelpharma*, 141 F.3d at 1059, 46 U.S.P.Q.2d 1097. As with most antitrust claims, the penalties also include possible treble damages and attorney fees. *See Lochtie Corp. v. Ultrasil Ltd.,* 781 F.2d 861, 228 U.S.P.Q. 90 (Fed. Cir. 1985) (discussing antitrust penalties associated with enforcing a patent known to be non-infringing); *Hando and Co. v. Ethicon, Inc.*, 601 F.2d 986, 202 U.S.P.Q. 342 (9th Cir. 1979) (discussing antitrust penalties associated with enforcing a patent known to be invalid). The penalties for inequitable conduct generally involve only patent unenforceability and attorney fees. *Novelpharma*, 141 F.3d at 1070, 46 U.S.P.Q.2d at 1106.
market ought to be guarded carefully. This is a concern for drug or medical device companies that rely on incremental approaches to product development. There are some companies, such as medical companies, where years of research and development, millions of dollars in costs, massive venture capital funding, and extensive FDA related costs have been expended to produce the one product around which the company will be entirely built. For this company, all that work and money must result in a patent, otherwise more mature companies will drive the first company out. This is very real for a “one hit wonder” genetic engineering company that has only one blockbuster drug and the entire market capitalization is based on that drug. Therefore, for this company, the sin qua non of its very existence is obtaining adequate patent protection. The desire to obtain the patent becomes obviously paramount.

It is also believed that although inequitable conduct is charged so often, it is still difficult to prove. Therefore, the psychology of “not getting caught” increases the allure of committing inequitable conduct. In addition, there may be personal incentives by the individual inventors to not be forthright. For example, many companies have “inventor reward” systems in which prolific patenting companies will offer monetary compensation to the inventor for each invention disclosure filed, for each patent that issues, and possibly a share of royalties generated from the patent. So in addition to the employee’s normal salary, the bonus for patents issued also becomes a consideration.

II. EVIDENTIAL STANDARD AND BURDEN OF PROOF

The infringer bears the burden of proving inequitable conduct and this burden rests with the infringer for all aspects of the defense. Inequitable conduct requires proof by clear and convincing evidence. The “clear and convincing” evidentiary standard lies between “beyond a reasonable doubt” and

“preponderance of the evidence.” Clear and convincing means proof that the proposed fact is “highly probable.” A fact may be proved by clear and convincing evidence when there are contrary facts, but the court rejects those contrary facts. Similarly, the court must evaluate credibility of witnesses and may rely upon credibility even in the face of denial of facts to conclude that the party proposing the fact has met its burden by clear and convincing evidence. The standard of clear and convincing evidence is certainly met where there is “overwhelming evidence” of a fact, and where there are numerous facts demonstrating a pattern of misconduct. Proof to an absolute certainty is not required because the overarching goal of the court is to provide equity. A single act may be sufficient to find inequitable conduct. Multiple acts can be sufficient if the alleged information is highly material, because then it is easier to infer an intent to deceive. It does not require proof of multiple misrepresentations, omissions, or any type of pattern of misconduct.

40 Buildex Corp. v. Kason Indus., Inc., 849 F.2d 1461, 1463 (Fed. Cir. 1988).
42 Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1582 (Fed. Cir. 1996) (affirming district court holding of intent to deceive because contrary testimony was “more credible than that of the inventors”).
45 Brown v. Comm't of Internal Revenue Servic, 418 F.2d 574, 575 (9th Cir. 1969).
46 Demaco Corp. v. F. Von Langendorff Licensing Ltd., 851 F.2d 1387, 1395 (Fed. Cir. 1988).
47 But see Abbott Labs. v. Torpharm, Inc., 300 F.3d 1367, 1380, 60 U.S.P.Q.2d 1929, 1937 (Fed. Cir. 2002) (affirming the district court's ruling on summary judgment that Abbott did not commit inequitable conduct in failing to disclose a single X-ray diffraction study).
of candor is so important that courts routinely find inequitable conduct where even one misrepresentation has occurred.49

As a general principle under the balancing test, “materiality and intent are balanced -- a lesser quantum of evidence of intent is necessary when the omission or misrepresentation is highly material, and vice versa.”50 The two prongs of the inequitable conduct test are a balancing test, which means that the relative weakness in one factor can be rehabilitated by a superior showing in the other factor.51 That is, a higher level of materiality of the reference can rehabilitate the deficiency of proof of direct intent to deceive.52 It must be noted, however, that no matter how strong the materiality is, there must be some evidence of intent to deceive.53 As noted by the Federal Circuit in Allen Engineering Corp. v. Bartell Industries Inc.:54

Bartell has provided no direct evidence that Allen withheld information about the Red Rider with intent to deceive the PTO. Instead, Bartell argues that Allen was “at least grossly negligent” in withholding the Red Rider from the PTO, and that, on the basis of Argus Chemical Corp. v. Fibre Glass-Evercoat Co., 759 F.2d 10, 14-15, 225 U.S.P.Q. 1100, 1003 (Fed. Cir. 1985), Allen’s intent to deceive is shown by this gross negligence. However, even if Allen’s conduct amounted to gross negligence, this alone would not be sufficient to


51 Cataлина Lighting, Inc. v. Lamps Plus, Inc., 295 F.3d 1277, 1288-89, 63 U.S.P.Q.2d 1545, 1552 (Fed. Cir. 2002) (affirming jury verdict that no inequitable conduct was shown as “omitted;” art was simply cumulative and even if not cumulative, no matter how material a reference is, there must be some factual evidence of an intent to deceive).

52 Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1581-82, 42 U.S.P.Q.2d 1378, 1385-86 (Fed. Cir. 1997) (stating Gambro’s statements about the German prior art were best at simple exaggerations and do not rise to the level of gross falsifications; when the statements are minor overstatements about the reference’s materiality, the evidence of intent to deceive must be relatively strong).

53 Herbert v. Lisle Corp., 99 F.3d 1109, 1116, 40 U.S.P.Q.2d 1611, 1615 (Fed. Cir. 1996); N. Am. Oil Co. v. Star Brite Distribs., Inc., 46 Fed. Appx. 629, 631-32 (Fed. Cir. 2002) (discussing patentee argument that intent to deceive, when objective evidence is absent, can be inferred when knowledge and materiality are strong; however, intent to deceive cannot be inferred solely from the fact that information was not disclosed).

54 Catalina Lighting, 295 F.3d at 1288-89, 63 U.S.P.Q.2d at 1552 (affirming jury verdict that no inequitable conduct was shown as “omitted” art was simply cumulative and even if not cumulative, no matter how material a reference is, there must be some factual evidence of an intent to deceive).

On appeal, the standard of review is abuse of discretion; thus, a finding of no inequitable conduct will likely be upheld. A defendant must, therefore, make an excellent showing of inequitable conduct to win at trial. But the Federal Circuit may reverse a trial judge’s finding of inequitable conduct if other factual evidence exists to the contrary. For example, if a jury finds that the patentee did not create an invalidating public use of the patented invention prior to the critical date, then it is improper for a trial judge to find that the patent invalid via inequitable conduct in failing to disclose prior public uses or sales. Similarly, a jury finding that a patent is enabled will preclude a trial judge finding that the patent was invalid for failing to disclose an enabled invention. This should not be construed, however, for the proposition that jury trials are required for any inequitable conduct issue that is common to the invalidity defense.

In sum, the Federal Circuit reviews the underlying facts under the clear error standard to see if the underlying factual thresholds have been satisfied.

62 Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1420, 10 U.S.P.Q.2d 1682, 1685 (Fed. Cir. 1989); Gammbo Lundia, 110 F.3d at 1580, 42 U.S.P.Q.2d at 1385. For additional cases, see infra Table 1.

63 Herbert, 99 F.3d at 1117; Allied Colloids Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1577-78 (Fed. Cir. 1995); see also Schreiber Foods, Inc. v. Beatrice Cheese, Inc., 21 Fed. Appx. 727, 732-33 (Fed. Cir. 2002) (stating that because the facts did not indicate that the invention was on-sale for the purposes of section 102(b), there was no evidence of a failure to disclose the possible sale and thus no inequitable conduct).

64 See, e.g., Therma-Tru Corp. v. Peachtree Doors, Inc., 44 F.3d 988, 996 (Fed. Cir. 1995). But see S. Clay Prods., Inc. v. United Catalysts, Inc., 43 Fed. Appx. 379, 385-86, 64 U.S.P.Q.2d 1606 (Fed. Cir. 2002) (noting that the underlying questions of invalidity and inequitable conduct were so intertwined that proper resolution of the invalidity issues on remand would implicate the inequitable conduct issue); Gando Mfg., 820 F.2d at 1214-15.

65 See S. Clay Prods., 43 Fed. Appx. at 382-83, 64 U.S.P.Q.2d at 1609-10. The underlying “fact” determinations are reviewed under a clear error standard under Rule 52(a). PerSeptive Biosystems, Inc., 225 F.3d at 1319, 56 U.S.P.Q.2d at 1003. Clear error occurs when the Federal Circuit is left with the definite and firm conviction that a mistake has been committed. In re Graves, 69 F.3d 1147, 1151, 36 U.S.P.Q.2d 1697, 1700 (Fed. Cir. 1995); Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust, 508 U.S. 602, 623 (1993). The court can reverse under the clear error standard if the fact finding is so improbable as to be beyond the pale—see, e.g., Carr v. Allison Gas Turbine Div., 32 F.3d 1007, 1011 (7th Cir. 1994) (“incredible on the admitted facts”); Mar Oil v. Morrissey, 982 F.2d 830, 842 (2d Cir. 1993); United States v. Fidelity Capital Corp., 920 F.2d 827, 840 (11th Cir. 1991) (“unbelievable”); Todd v. Corporate Life Ins., 945 F.2d 204, 208 (7th Cir. 1991) (or internally inconsistent).

In other words, Federal Rule of Civil Procedure 52(a) prohibits the Federal Circuit from reversing a trial court based on clear error if: (a) the trial judge gave a plausible account of the conflicting evidence, Bennett v. Local Union No. 66, 958 F.2d 1429, 1433 (7th Cir. 1992); (b) witness credibility was critical; (c) the balancing of conflicting evidence was critical even though witness credibility was not an issue; or (d) the fact finder accepted certain testimony as fact even though it may seem outweighed by contrary testimony. Paul Mitch, Advocacy in the Federal Circuit, 4-5 (June 1991) (unpublished article, on file with the author). Therefore, a corollary, fact finding will be upheld under the clear error standard unless: (i) the PTO administrative board or trial judge grossly misanalyzed the evidence; (ii) the finding or ruling is simply unreasonable, illogical, inconsistent, or implausible; or (iii) as a matter of law, the facts duly found simply cannot support the conclusion. Id. A more colorful statement was made by the Seventh Circuit, which stated,

and, if so, then reviews the judgment of inequitable conduct under the clear and convincing standard.

III. PRONG I OF THE TEST - MATERIALITY: THE APPLICABLE RULES

Under the first prong of the inequitable conduct test the materiality of the information is evaluated. "Information is 'material' when there is a substantial likelihood that a reasonable [Examiner] would have considered the information important in deciding whether to allow the application to issue as a patent." The phrase "important in deciding" does not mean that the withheld information is sufficient to per se invalidate the claim. Rather, to be material, the information need only be within a reasonable Examiner’s realm of consideration in deciding whether to issue the patent. What the Examiner actually thought is utterly irrelevant. According to American Hoist, the disclosure standard is "not whether a reasonable Examiner would want to be aware of a particular thing, but whether, after he was aware of it, he would consider it important in deciding whether to reject one or more claims." This liberal standard applies to any information that the reasonable examiner would consider important.

"[T]he basic concept of inequitable conduct is a aware of a science, a § 102(b) [37 C.F.R. § 1.56(2003)] (2003); LaBounty Mfg., 958 F.2d at 1074; Merck, 873 F.2d at 1421; Specialty Composites v. Cabot, 845 F.2d 981, 992, 6 U.S.P.Q.2d at 1601, 1608 (Fed. Cir. 1988); J.P. Stevens, 747 F.2d at 1559; Am. Hoist & Derrick, 725 F.2d at 1362.

For example, the information would per se invalidate the claim if it anticipates. See 35 U.S.C. § 102(3) (2003).

Merck & Co., 873 F.2d at 1421.

W. Elec. Co. v. Piezo Tech., Inc., 860 F.2d 428, 433, 8 U.S.P.Q.2d 1853 (Fed. Cir. 1989) ("Inquiring into the importance that [the Examiner] may have placed on the representations, by testing his knowledge of prior art, is therefore wholly irrelevant.").

73 725 F.2d at 1362-63 n.2, 220 U.S.P.Q. at 773 n.2.

74 Bristol-Myers Squibb, 326 F.3d at 1234(Rhone-Poulenc ("Materiality is not limited to prior art but embraces any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent."). But see 37 C.F.R. § 1.56(b) (1992). Section 1.56(b) states:

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

Id. It "was not intended to constitute a significant substantive break with the previous standard."

Hoffmann-La Roche, 523 F.3d 1554, 1368 n.2.
Therefore, information materiality rests on whether that information was disclosed, withheld, or misleadingly disclosed. An allegation of materiality may be rebutted by a showing that: (a) the prior art was not material; (b) if the prior art was material, a showing that the applicant did not know of that art; (c) if the applicant knew of that art, a showing that the applicant did not know of its materiality; or (d) a showing that the applicant’s failure to disclose the art did not result from an intent to mislead the PTO. 72 Materiality is by no means a self-defining concept, especially when the subject matter of the patent is complex or subtle, which it often is in biotechnology or other medical inventions. 73 What is axiomatic, though, is that it can never be inequitable conduct to fail to submit non-material prior art, that is, irrelevant or immaterial prior art. Otherwise, the Office would be flooded with immaterial prior art and that applicants would always be guilty of inequitable conduct because an applicant will always know something that is irrelevant. 74

An applicant who has a reference that is material still need not disclose it to the Patent Office if that reference is merely cumulative of references previously submitted or is less material than the previously cited reference. 75 This is because that cumulative or less material art does not assist the Examiner in applying the art against the claims. 76 Similarly, an uncited reference that is less relevant than the art before the Examiner is not material either because the closest art is before the Examiner. 77 Thus, a reference is not material, all else being equal, if: (1) it is of the same scope as art already before the Examiner, or (2) it is of a lesser scope (or not as “close” to the invention) than art already before the Examiner. 78 Accordingly, this art need not be submitted because the patentability of the invention is not implicated.

A reference may be material though, not because it verbatim anticipates the claimed invention, under section 102, or provides the missing element in combination with other references under section 103, but may be material because it provides the teaching, suggestion, or motivation to combine other references, arriving at the claimed invention under section 103. Thus, one way to characterize uncited art is that although it is not the closest anticipatory art, the

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74 Examples of truly immaterial or irrelevant prior art to a medical invention would include cake recipes, love poems, etc., precisely the kind of information an Examiner would not need to know.
76 Gambro Landia, 110 F.3d at 1580, 42 U.S.P.Q.2d at 1384.

uncited art provides other more relevant features, such as the motivation to combine other closer art. 79

A. False Statements are Inherently Material

In a medically oriented patent application process, the applicant may make statements that are false. For example, the applicant may state that the “prior art fails to teach” a particular claimed element, when in fact it does. These inventions are often voluminous and include tens or hundreds of examples. 80 The applicant hopes that the Examiner will not carefully scrutinize the reference to find out if the reference does, in fact, teach the claimed element. Because the applicant states that the prior art fails to teach the claimed element and the applicant, presumably, has read the entire reference, this statement is patently false. In another common situation, because the medical field places great emphasis on “publishing” results in technical or academic journals, or presenting data results at conferences, the applicant may fail to disclose that the invention was published or disclosed. 81 The situations where falsification may occur are indeed endless. Accordingly, the submission of false information about what the prior art teaches or the failure to disclose that information is inherently material. 82 In addition, the applicant cannot feign ignorance to the reference’s materiality or cannot shield himself from numerous warnings that some relevant and material prior art must exist simply to defend on the grounds that he had no actual knowledge of the reference. 83 Thus, a reference may become material because it was made material by the applicant. This is true even if the false statements made to the PTO are deemed inherently material even though the falsity is unrelated to the ultimate issue at stake. 84 In Rohm & Haas Co. v. Crystal Chemical Co., 85 the submission of a false statement, in the form of an affidavit, was alone sufficient to find materiality. The court found that because the applicant submitted the affidavits to override the prior art and earn allowance of the claims, the applicant could not argue that the false affidavits were now somehow not material.

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79 LaBounty Mfg., 958 F.2d at 1075, 22 U.S.P.Q.2d at 1032. A withheld reference may also provide underlying teaching about the state of the art.
83 Gen. Electroc Music Corp., 19 F.3d at 1411 ("it may be true that the misrepresentations did not relate to an ultimate fact, but the use of willfully false testimony cannot be fully rinsed away with a solution composed primarily of legal semantics").
84 Rohm & Haas Co., 722 F.2d at 1570-71.
85 Id.
B. Failure to Disclose Relationship of the Affiant to Patent Applicant Is Materially Misleading

Refac International, Inc. v. Lotus Development Corp. 87 is illustrative of this type of affidavit chicanery. 88 In this case, during prosecution, the Examiner rejected the claims due to an inadequate disclosure. 89 The inventors, Landau and Pardo, tried to overcome the rejection by having Pardo submit an affidavit “testifying” as to how complete the application was and that a person of ordinary skill in the art would understand how to make and use the invention. 90 The Examiner rejected the inventor affidavit as being self-serving and therefore very unprobative. 91 Not to be undone, the prosecuting patent attorney asked the inventors to find three disinterested affiants of varying skill level to testify to the sufficiency of the disclosure. 92 The inventors found Bullen, Cikra, and Jones, who each filed affidavits that the disclosure was sufficient and that they could have produced the invention based on the disclosure coupled with generally known techniques. 93 Faced with this onslaught of affidavits, the Examiner allowed the application and the patent issued. 94

Consistent with the plague theory above, Lotus naturally defended alleging that the inventors committed inequitable conduct in filing the three affidavits. 95 When the underlying facts were examined, the truth emerged. All three affiants had substantial connections to the inventors. 96 In parsing through the affidavits, we district court, affirmed by the Federal Circuit, determined that Bullen worked with Landau at another company and implemented the patented invention at the company. 97 Thus, Bullen knew of the patented invention and had a relationship with Landau but failed to disclose this relationship to the Examiner. 98 Nonetheless, the district court did not find this failure to constitute inequitable conduct because the court believed that the inventors failed to appreciate that such relationship could be relevant or that the prior knowledge of that implementation was relevant. 99 Similarly, the court found that the Cikra affidavit was tainted because Cikra worked with the inventors to integrate the invention with another software platform and intimately knew the underlying source code. 100 But the court found that this was not inequitable conduct in failing to disclose this relationship, although it was a closer call. 101

The Jones affidavit caused the true damage. In holding that the inventors committed inequitable conduct in submitting the Jones affidavit and failing to disclose the prior relationship, the court found the following points relevant:

(a) Jones had worked for the inventors for eight weeks within six months of executing his affidavit (presumably meaning that Jones had recent and extended knowledge of the invention);
(b) Jones, whilst working with the inventors’ company, had intimate knowledge of the invention;
(c) Jones had been instructed in the use and operation of the invention, including examining the source code and other documentary materials; and
(d) Jones drafted the text that ultimately became the invention’s instruction manual. 102

Accordingly, Jones’ intimate and extensive knowledge of the invention contradicted the very essence of being a disinterested affiant. 103 The failure to disclose this extensive level of involvement constituted inequitable conduct because the inventors duped the Examiner into believing that the affidavit was disinterested and that the affiant was testifying about the sufficiency of the disclosure without knowledge of the intricacies of the invention. 104 In fact, Jones testified about the sufficiency of the disclosure based on his preexisting and intimate knowledge of the invention. 105 The Examiner had no way of determining Jones’ prior affiliation or knowledge base and had no way of contradicting Jones’ testimony. As a result, Jones’ affidavit was inherently material because of the affirmative act in submission, the misleading character of the affidavit, and because of “the inability of the Examiner to investigate the facts.” 106 In sum, the court found that the inventors committed inequitable conduct by failing to disclose the underlying relationships of the affiants to the inventors, especially when the purpose of the affidavits was to convince the Examiner that disinterested affiants were finding the disclosure sufficient. Each affidavit was material in allowing the claims and thus the inventors were foreclosed from arguing that the misleading affidavit was not the affidavit that caused the patent to issue. 107

87 81 F.3d 1576, 38 U.S.P.Q.2d 1665.
88 Id.
89 Id. at 1578, 38 U.S.P.Q.2d at 1666. An inadequate disclosure violates section 112, first paragraph, because the patent application fails to adequately teach a person of ordinary skill in the art how to make and practice the invention. Id. One purpose of the patent laws is to provide such a complete description that a reader can practice the invention without undue experimentation. Id.
90 Refac Int'l, 81 F.3d at 1578, 38 U.S.P.Q.2d at 1666.
91 Id.
92 Id. at 1578, 38 U.S.P.Q.2d at 1666-67.
93 Id. at 1578-79, 38 U.S.P.Q.2d at 1666-67.
94 Id.
95 Refac Int'l, 81 F.3d at 1579, 38 U.S.P.Q.2d at 1667.
96 Id. at 1579, 38 U.S.P.Q.2d at 1667-68. Landau and Pardo formed a company called Lapar and marketed the invention under the name, LANPAR. Id. at 1579, 38 U.S.P.Q.2d at 1667. Lapar assigned the patent to FRS Company, who then assigned part interest to Refac, who was obligated under the assignment agreement to use various computer software companies, including Lotus. Id.
97 Id.
98 Refac Int'l, 81 F.3d at 1579, 38 U.S.P.Q.2d at 1667.
99 Id.
100 Id. at 1579, 38 U.S.P.Q.2d at 1667-68.
101 Id., 38 U.S.P.Q.2d at 1668.
102 Id. at 1580, 38 U.S.P.Q.2d at 1668.
103 Refac Int'l, 81 F.3d at 1580, 38 U.S.P.Q.2d at 1669.
104 Id.
105 Id. at 1581, 38 U.S.P.Q.2d at 1669.
106 Id. at 1581-82, 38 U.S.P.Q.2d at 1669-70.
107 Id. at 1584, 38 U.S.P.Q.2d at 1671 ("Affidavits are inherently material, even if only cumulative.").
Relationship fraud occurs in medical inventions where the immediate relationship is not clear. For example, a company may hire a college professor to conduct some non-inventive research on one aspect of the invention. When the company runs into trouble with the application, the professor may submit an affidavit. To the Examiner, this affidavit appears to be from an unbiased professor who has no “stake” in the application. Unbeknownst to the Examiner is the fact that a prime source of funding for the professor comes from the applicant company. Surely the nexus between the professor and the company becomes a material bias.

C. Data is Presumed Material

Prosecuting a patent, particularly in various medical fields, often involves the initial disclosure or later submission of data based on experimental tests. The problems associated with experimentation are plain. First, some tests are successful while others are not. Second, interpretation of the test results or testing protocols is fraught with varying perspectives. The same data can be interpreted in many ways. In addition, experimental protocols and observations may have changed, but these changes, while reflected in laboratory notebooks, likely do not reveal the subjective motivation for the change. Accordingly, the interpretation of naked entries in the notebooks can be twisted to suit each litigant’s purposes. This is an area fruitful for finding material misstatements.

In addition, because medical applications contain examples, these examples may imply that actual tests were run and data collected, when in fact they were not. For example, an application may be written as “a sample of X was obtained and dissolved in a solvent. It was then heated and mixed with Y. The resulting mixture was then crystallized and the crystal was then subjected to X-ray crystallography. The results as shown in FIG. 1.” While it may be true that FIG. 1 does represent an X-ray crystallogram, this passage implies that the inventors performed this experiment using the process disclosed. It is definitely material if, in fact, no underlying experiments were done at all, or experiments were done differently than expressed, even if FIG. 1 accurately reflects the results.

Professor Chisum observed that because “the Patent and Trademark Office is without means to conduct such tests, it normally relies on the applicant’s data. It is not surprising, therefore, that this area breeds more problems with fraud and inequitable conduct than any other.” It is perfectly reasonable to believe that any testing data disclosed is truthful and accurate, and hence, material.

D. Failure to Provide Unfavorable Test Results is Inherently Material

As mentioned above, testing generally involves successful and unsuccessful results. It is quite tempting to fail to identify unsuccessful data. One area where unfavorable test results will make a difference is where the applicant is relying on unexpected results to overcome an obviousness rejection. The following scenario illustrates the point. Assume that the claimed invention refines or improves the efficiency of a product and calls for element X to be within a range of 100 to 1000. In the first Office Action, the Examiner cites the Smith ‘123 patent against the claims because the Smith reference teaches element X in the range of 50 to 1500. The Examiner rejects the claim and cites the standard rejection that the prior art discloses the claimed range and that it would have been obvious to a person of ordinary skill in the art to optimize the disclosed prior art range to come up with the narrower claimed range. That is, the narrower claimed range, in view of the disclosed larger range, is not patentable.

One way to overcome this rejection would be to show that the narrower range, while optimizing the disclosed range, in fact showed some unexpected results and that the narrower range had superior characteristics over the prior art. Therefore, the applicant may submit some testing data that shows that the narrower range had these superior properties. If the Examiner, therefore, failed to disclose the poor test results leads to an issued patent. The applicant, therefore, failed to disclose potentially damaging test results in which the Examiner would have questioned whether the narrower claimed range was, in fact, superior.

The failure to provide unfavorable test results is repeatedly held by courts to be a sufficient basis to find materiality. For example, in Gregco, Inc. v. Kewanee Industries, Inc., the district court emphasized the heightened duty of reporting experimental test results:

This court and the Third Circuit have therefore been particularly vigilant in requiring patent applicants to disclose all pertinent test results. . . . Gregco does not contend that simply because the test results were learned after the filing of the patent application, they need not be disclosed. Such a rule would be contrary to the requirement of high standards of conduct in proceedings before the PTO.

As another court summarized:

[Inequitable conduct exists where inconsistent or contradictory representations in prior related patent applications are coupled with submission of an affidavit directed to “testing” that created the misleading inference that it constituted a “complete and accurate analysis of all the testing, instead of an edited version thereof.” Thus, there is a duty to disclose or even go so far as to “red flag” contradictory information with regard to test results, where results appear to be in sharp contrast with what the applicant is telling the Patent Office, since the Patent Office is incapable of

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108 Hoffman-LaRoche, 323 F.3d at 1364-65 (stating that Example VI was written in the past tense as if it was performed as written, but was simply a combination of two other examples that were performed).


110 Id. at 867, 870 (emphasis added).
verifying comparative tests and has to rely upon the candor of the parties submitting those test results. Test results that are contradictory to those of an earlier application should be disclosed to the Examiner.113

Upjohn v. Mova Pharmaceutical Corp.114 illustrates the potential perils of failing to disclose adverse results.115 In Upjohn, the trial court ruled that Mova’s product did not infringe and that Upjohn committed inequitable conduct. The Federal Circuit affirmed the non-infringement ruling but reversed the inequitable conduct ruling.116 Upjohn sued Mova for patent infringement based on Mova’s abbreviated new drug application (“ANDA”) that it submitted to the FDA.117 In defending the suit, Mova alleged inequitable conduct based on Upjohn’s submissions to the Patent Office during prosecution.118 The invention concerned an anti-diabetic drug that claimed “spray dried lactose” in a particular percentage of the excipient.119 Apparently, the amount of lactose excipient is critical in the ease of industrial-scale manufacturing and likely assists in the in vivo drug delivery.120

Mova argued that Upjohn committed misconduct during prosecution when it submitted the experiments run by Dr. Ni.121 In the first declaration, Dr. Ni showed experimental results obtained by showing flow rates through an hourglass of various formulations.122 The Examiner rejected this declaration because Dr. Ni did not adequately describe the ingredients and amounts used.123 The comparisons were made using non-spray dried lactose plus the active drug ingredient.124 In response, Upjohn submitted another declaration that showed the laboratory notebooks, which indicated that the drug was not used in the experiments and a placebo was substituted.125 In addition, although the prior declaration stated non-spray dried lactose was used, the notebooks showed that spray-dried lactose was used.126 That is, the claims were to spray-dried lactose plus the active ingredient drug but the flow-rate experiments used spray-dried lactose plus a placebo. Although the Examiner rejected the second declaration, the Board reversed and the patent issued.127

Mova argued that Upjohn intentionally misrepresented in the first declaration that the drug was in the experimental formulations and that the second declaration and notebook pages could not cure that first defect.128 The Federal Circuit, however, ruled that there was no intent to deceive because the Examiner had rejected both the claims before and after the declarations and that the notebook made clear that the placebo was used.129

Mova then argued that Upjohn deliberately withheld the fact that it had carried out tests three years earlier using a large dose of the active ingredient drug, albeit that the later issued patent claimed a dosage substantially less.130 In particular, Upjohn determined that the prior tests showed adverse flow rates and later reformulated the dosage to the now claimed dose.131 Mova therefore argued that the disclosure of the test results and the poor flow rates would have been fatal to the patentability.132 But the Federal Circuit stated that there was no intent to deceive the Office because the dosages in the withheld tests were well beyond what was eventually claimed and Upjohn abandoned any high dosage forms, thus rendering them irrelevant.133 Upjohn was lucky.

E. Failure to Provide Accurate Descriptions of Test Conditions is a Material Misstatement

Related to the failure to provide unfavorable data is the consistent concern of the courts and the PTO that patent applicants provide an accurate comparison of the “conditions” of their experiments, data, and comparisons with the prior art. Courts have held that failure to provide an accurate statement of conditions is a material misrepresentation.134 As one court noted, many patents have been held unenforceable when affidavits submitted by an applicant provided “misleading information as to test conditions.”135

115 Id. (reversing trial judge’s ruling of inequitable conduct and holding that there was no intent to deceive in failing to disclose adverse test results, failing to describe the proper testing conditions, and failing to inform newly added inventors of the duty to disclose information).
116 Id. at 1308, 56 U.S.P.Q.2d at 1287.
118 Upjohn, 225 F.3d at 1308, 56 U.S.P.Q.2d at 1287.
119 Id.
120 Id. at 1309, 56 U.S.P.Q.2d at 1289.
121 Id. at 1312-13, 56 U.S.P.Q.2d at 1291.
122 Id. at 1313, 56 U.S.P.Q.2d at 1291.
123 Upjohn, 225 F.3d at 1313, 56 U.S.P.Q.2d at 1291.
124 Id.
125 Id.
126 Id.
127 Id.
128 Id.
129 Id.
130 Id.
131 Id.
132 Id.
133 Id.
134 Upjohn, 225 F.3d at 1314, 56 U.S.P.Q. at 1293.
135 See Rhone-Poulenc Agro SA v. DeKalb Genetics Corp., 272 F.3d 1335, 1356, 60 U.S.P.Q.2d 1769, 1783 (Fed. Cir. 2001) (holding that omission of test comparison was not material because that test failed to actually make a proper basis of comparison; that is, even if it was submitted, it was an improper comparison to make); see also Hoffmann-LaRoche, 323 F.3d 1354, 66 U.S.P.Q.2d 1385.
Glaxo Inc. v. Novopharm Ltd.,\(^{136}\) is an example where inaccurate test conditions and the subsequent affidavit filed called into question the validity of the patent. In this case, Glaxo filed two applications directed to Form 2 of its blockbuster anti-ulcer medication.\(^{137}\) The Examiner rejected the second Form 2 application based on Glaxo’s first application that purportedly disclosed both Form 1 and Form 2 of the drug.\(^{138}\) In response, Glaxo submitted an affidavit that compared Form 1 and Form 2, “showing” that Form 2 was chemically different from Form 1 and, thus, the first application’s disclosure of Form 1 and Form 2 did not anticipate.\(^{139}\)

During the litigation, the truth about the circumstances underlying the affidavit became clear. Glaxo admitted that Form 1, used to run the affidavit-based tests, was not the same Form 1 as taught in the first patent.\(^{140}\) Accordingly, when Glaxo compared Form 2 to Form 1 to show that the first application did not anticipate the second one, the basis for comparison was improper because the comparison did not actually compare the first application’s Form 1. Rather, it compared a Form 1 prepared under different conditions.\(^{141}\) The district court ruled that although the affidavit was material, there was no proven intent to deceive.\(^{142}\) Although the Form 1 affidavit data was generated using a different source of Form 1, the chemical properties of Form 1 were the same irrespective of the underlying method of manufacture.\(^{143}\) To this end, the comparison of Form 2 with the independent obtained Form 1 would have been the same as if the comparison was with the first patent derived Form 1.\(^{144}\) The Federal Circuit called the question of intent “debatable,” but affirmed the district court’s ruling of no inequitable conduct.\(^{145}\)

F. Failure To Comply With the Requirements of Section 112, First Paragraph, Is Always a Material Misstatement

There are three requirements under section 112, first paragraph: best mode, enablement, and written description.\(^{146}\) As often occurs in the field, there may be many ways to perform or make the claimed invention. The best mode requirement protects the public from the inventor who only discloses the second best way for making the invention while reserving the best way for himself.\(^{147}\) For example, a method of creating an invention may require heating a substance

where one may heat the substance via a Bunsen burner, oil bath, or water bath. Each heating modality offers its own benefits and detriments. The best mode requirement would require an inventor to disclose which heating modality is the best way to heat. In diagnostic inventions, it may require an inventor to disclose which type of assay, probes, or reagents to use.\(^{148}\) While schools of thought differ in terms of how much disclosure is necessary, it would appear that a material misstatement about which mode is best would be fatal. “Because disclosure of the best mode is statutorily required, failure to disclose the best mode is inherently material and . . . reaches the minimum level of materiality necessary for a finding of inequitable conduct.”\(^{149}\)

A two-prong test is required to determine if the best mode requirement is violated. First, the fact finder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention.\(^{150}\) This prong is highly subjective and focuses on the inventor’s state of mind as of the date of filing the application.\(^{151}\) Then, if the inventor subjectively considered one mode to be preferred over all others, then

[i]he second inquiry is whether the inventor’s disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention. This inquiry is objective and depends upon the scope of the claimed invention and the level of skill in the relevant art.\(^{152}\)

It is important to recognize that the best mode requirement does not extend to production details\(^{153}\) including commercial considerations such as equipment on


\(^{138}\) Eli Lilly, 251 F.3d at 963, 58 U.S.P.Q.2d at 1874.


\(^{140}\) Id. at 1318 (citing Great N. Corp. v. Henry Molded Prods., 94 F.3d 1569, 1572 (Fed. Cir. 1996) (citing Transpro Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 560, 32 U.S.P.Q.2d 1077, 1084 (Fed. Cir. 1994)); Wahl Instruments, Inc. v. Avionics, Inc., 950 F.2d 1575, 1579-80, 21 U.S.P.Q.2d 1123, 1127 (Fed. Cir. 1991)). In Eli Lilly, the Federal Circuit stated: the extent of the information that an inventor must disclose depends on the scope of the claimed invention. . . [T]he best mode requirement does not extend to production details or routine details. . . Production details, which do not concern the quality or nature of the claimed invention, relate to commercial and manufacturing considerations such as equipment on hand, certain available materials, prior relationships with suppliers, expected volume of production, and costs. Routine details, on the other hand, implicate the quality and nature of the invention, but their disclosure is unnecessary because they are readily apparent to one of ordinary skill in the art. 251 F.3d at 963 (internal citations omitted).
hand, availability of materials, relationships with suppliers, or customer requirements. Further, the best mode requirement does not extend to "routine details" apparent to one of ordinary skill in the art because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention. Furthermore, the specification ought not to be a catalogue of the existing technology and preferably omits that which is well known.

The primary difference between a failure to disclose the best mode and inequitable conduct in failing to disclose the best mode is that the former requires no "intent to mislead." Only "evidence of 'concealment,' whether accidental or intentional, is considered. An applicant who intentionally conceals the best mode commits inequitable conduct.

The same applies to the enablement requirement. "Enablement" is defined as the ability to teach one of ordinary skill in the art how to make and use the claimed invention. That is, does the specification provide meaningful instructions on how to make and use the invention? As with the best mode requirement, the enablement requirement does not require such a detailed catalog of the technologies to make or use the invention. Rather, the public may be required to experiment to make and use the invention in the context of the specification. The standard for enablement is whether any experimentation is undue. There are several medical cases in which the court found the claims

not enabled. It is important to recall that merely because a claim is not enabled does not mean that the inventor committed inequitable conduct. Culpable conduct is still required.

The Bristol-Myers Squibb v. Rhone-Poulenc Rorer decision highlights how inequitable conduct applies to enablement issues. Stripped to its bare facts, the inventors were in the midst of publishing a technical article. In that article, the inventors stated that certain chemicals would not work or would not work well in the scientific process. The inventors submitted a draft of the article to their French patent attorney who then prepared a French patent application. The French patent application included the chemicals and stated that they would work. He named other chemicals that would also work. After the inventors' review, the French application was timely filed, the article was sent for publication, the counterpart U.S. patent application was filed, and then the article was published. The U.S. patent attorney hired to prepare the U.S. patent application based on the French patent application did not have a copy of the article. To this end, the article, once published, was never sent to the U.S. Patent Office during the application process. A U.S. patent issued. But due to some concerns over claim scope, the inventors filed a reissue application. The U.S. patent attorney hired to handle the reissue application received a copy of the article, opined that it was largely irrelevant, but still submitted the article to the Office during that application process. A reissue patent still issued.

The district court ruled, and the Federal Circuit affirmed, that inequitable conduct occurred. The courts were not persuaded that any good faith absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).


Indeed, failure to meet a requirement of patentability, such as enablement, does not of itself establish the intent element of inequitable conduct. Engel Indus., Inc. v. Lockheed Corp., 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). It is necessary that the failure be based on affirmative material withholding for the purpose of misleading or deceiving the patent Examiner.

In re Bristol-Myers Squibb, 226 F.3d at 1226, 66 U.S.P.Q.2d 1481.

Id. at 1230. Id.

Id. at 1231. Id.

Id. 326 F.3d at 1231. Bristol-Myers, 326 F.3d at 1231.

Id. Id.

Id. Id.

Id.

Id.

Id. at 1232-33. Bristol-Myers, 326 F.3d at 1232.

Id. at 1233.

Id. at 1229.
existed. That is, a reasonable examiner would have objectively thought that the article was important because it included exemplary working chemicals that the inventors themselves had said would not work in the article. Accordingly, the issue "of whether a reference would be considered important by a reasonable examiner in determining whether a patent application is allowable, including whether the invention is enabled, is a separate issue from whether the invention is actually enabled." 165

Finally, the written description requirement concerns whether the inventor invented what he is now claiming. "The purpose is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" Although rarely occurring, written description issues may give rise to inequitable conduct. For example, often times for biotechnology-related inventions, cell lines or cell cultures are deposited with approved depositories. In these cases, the application essentially states that this depository contains biological material useful for practicing the invention and that the reader is informed. Inequitable conduct in these situations may occur when the patentee intentionally: (a) misidentifies the depository; (b) deposits the wrong biological sample; (c) deposits a correct but defective sample; or (d) otherwise fails to comply with the deposit rules and written description requirement. 169

The best mode, written description, and enablement requirements work jointly and severally to ensure that the inventor discloses all the important details about the invention. Accordingly, important details in medical inventions would include building instructions; biocompatibility (e.g. sterility, antipyrogenicity) issues; testing conditions; purification techniques; spectrophotometric results; formulae; and examples of experiments run, if any. Material information standards would require disclosure of the necessary scientific and technical information so that the ordinary artisan could fully practice the invention without having to unduly experiment with the manufacture.

G. Summary of Materiality

In summary, the materiality standard requires a disclosure of information that an Examiner would consider as impacting the patentability of the invention versus whether that information actually impacts patentability. The materiality prong is extremely important because the data submitted, omitted, or falsified is the type of evidentiary proof that an Examiner would receive but could not confirm its authenticity. This data, therefore, is very persuasive because it is unconfirmable. As shown, affidavit practice, a staple of the medical patent application process, is an area ripe for materiality chicanery.

IV. INTENT - DEFINED

Having determined materiality, one then proceeds to the intent prong. "To satisfy the intent to deceive element of inequitable conduct, 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" But it is important to remember that if the infringer fails to prove the minimum threshold of intent to deceive, then the burden of showing good faith does not shift to the patentee because the burden remains on the infringer to prove intent to deceive. Proof of intent is derived from an examination of the "totality of the circumstances." Intent "is most often proven by a showing of acts, the most natural consequences of which are presumably intended by the actor." Culpable intent may, therefore, be inferred from the facts and circumstances surrounding the applicant's conduct. With regard to the intent to deceive, the law recognizes that "intent need not, and rarely can, be proven by direct evidence." [P]roof of the actual state of mind of the applicant or

165 Id. at 1241.
166 Bristol-Myers, 326 F.3d at 1238-39.
167 Id.
168 Id. at 1238-39.
169 Amgen, 314 F.3d at 1330, 65 U.S.P.Q.2d at 1397.
171 Id.
persons associated with or representing an applicant is not required. But it must be remembered that intent still must be proved to the minimum threshold and not as some matter of strict liability because:

A patentee’s oversights are easily magnified out of proportion by one accused of infringement. . . . Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required. As this statement shows, infringers are so quick to accuse patent prosecutors or inventors of inequitable conduct that it seems that any action or inaction undertaken can be grounds for inequitable conduct charges. To this end, some patent prosecutors advise clients that “everything is relevant and material” and thus will disclose everything that is marginally relevant and marginally material.

Fiskars v. Hunt Manufacturing reaffirmed that the applicant cannot be guilty of inequitable conduct if the PTO had the prior art but the applicant did not purposefully stress the art’s importance. In particular that court stated that, the infringement defendant failed to show that the plaintiff withheld, with deceptive intent, disclosure of the prior art device during prosecution of patent in suit, since the prosecution history showed that the plaintiff submitted a brochure describing the device to the PTO, and though the Examiner did not consider it, the plaintiff was under no obligation to stress the relevance of the device, and since [an] applicant cannot be guilty of inequitable conduct if the reference was cited to the [Examiner], whether or not it was a ground of rejection by the examiner. . . . And [an] applicant is not required to tell the PTO twice about the same prior art, on pain of loss of patent for inequitable conduct.

As will be seen later, an infringer argues quite frequently about withholding references, intentionally misleading the Examiner, or intentionally mischaracterizing. The above statement shows that one major benefit to submitting prior art to the Examiner is that it becomes easier to defend against a charge of inequitable conduct.

at 1686 (noting that “[i]ntent need not, and rarely can, be proven by direct evidence. It is most often proven by a ‘showing of acts the natural consequence of which are presumably intended by the actor.’”) 159 Rohm & Haas Co., 772 F.2d at 1571, 220 U.S.P.Q. at 301.
161 But see infra notes 357-367 discussing “burying” references. Therefore, as the Federal Circuit suggested, one should inquire into the “facts and circumstances facing the actor at the time of the prosecution.” Akzo N.V. v. E.I. DuPont de Nemours, 635 F. Supp. 1336, 1356, 230 U.S.P.Q. 263, 278 (E.D. Va. 1986).

A. Gross Negligence Is Not An Intent To Deceive

There are four levels of actions (or inactions) in the law of tort that are applicable to an inequitable conduct finding — actions that are intentional, reckless, negligent, and grossly negligent. Each level of action may be taken into account by the court in establishing legally sufficient “deceptive intent” for inequitable conduct. Gross negligence though, which generally uses the “knew or should have known” standard, is not enough. In 1988, the Federal Circuit ruled en banc in Kingsdown Medical that gross negligence alone does not mandate a finding of intent to deceive. Thus, the standard of “knew or should have known” is not the proper standard. The Federal Circuit has reversed district courts decisions that used the negligence standard. The Federal Circuit has tried to be consistent in overturning negligence based inequitable conduct.

Other recent cases, however, seem to resurrect this gross negligence standard. As a result, the defendant should be very careful to argue that the patent is unenforceable under the Kingsdown Medical standard, and not the gross negligence standard. This is because Kingsdown Medical was an en banc decision and these later cases cannot overrule prior en banc precedent. Thus, it is dangerous to rely on the “knew or should have known” standard, even though this standard assists the defendant.

Consequently, it is clear that gross negligence alone will not compel an inference of intent to deceive, but it is not clear whether the en banc Federal Circuit meant that gross negligence can never support the inference of intent. The Federal Circuit has also noted that many people can differ as to what is


The should have known standard presents serious problems for the Federal Circuit as well as the federal district courts — problems that were recognized in the cases leading up to Kingsdown. Any defendant could dig through the plaintiff’s files in discovery, find something that might be considered material under the liberal “reasonable examiner” standard, and have a shot at rendering the patent unenforceable — a complete defense.

Id.

204 Kimberly-Clark Corp. v. Fort Howard Paper Co., 772 F.2d 860, 863, 227 U.S.P.Q. 36, 37 (Fed. Cir. 1985) (“Counsel is apparently unaware that a panel of this court is bound by prior precedent decisions unless and until overturned in banc.”).
material, and thus has given the benefit of the doubt to the patentee if the patentee has showed some good faith.\textsuperscript{206}

B. The Totality of the Circumstances Standard Requires a Court To Consider Negligent Acts, Grossly Negligent Acts and Reckless Acts as a Basis For Finding Deceptive Intent

In \textit{Kingsdown}, the Federal Circuit held that, "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive."\textsuperscript{207} The words of \textit{Kingsdown} make it clear that a single finding of gross negligence would not, in and of itself, be sufficient for a finding of deceptive intent.\textsuperscript{208} \textit{Kingsdown} implies that if there are other circumstances, including the circumstances surrounding the gross negligence, then the grossly negligent acts may be considered sufficient to establish deceptive intent. The conduct of the patent applicant must be viewed in its entirety and where the totality of the patentee's conduct "manifests a sufficiently culpable state of mind," a determination of intent to deceive is warranted.\textsuperscript{209} Federal courts have followed the Federal Circuit's lead and held that gross negligence, as a part of the totality of circumstances, is sufficient to establish an intent to mislead.\textsuperscript{210} While negligent and grossly negligent acts are part of the totality of circumstances to be considered in establishing culpable intent, a "reckless" act is sufficient, standing alone, to establish intent. This principle was made clear in \textit{Modine Manufacturing}, in which the Northern District of California subsequent to the \textit{Kingsdown} decision, noted:

\begin{quote}
It is apparent to this Court that Kingsdown eliminates gross negligence as a sufficiently culpable state of mind to support a finding of inequitable conduct. To the extent that prior law held a finding of gross negligence sufficient to support a finding of inequitable conduct, that law is reversed by Kingsdown. After Kingsdown, a person prosecuting a patent application, owing a duty of candor to the Patent Office, who is grossly negligent in misrepresenting or omitting to disclose a material fact to the Patent Office is not guilty of inequitable conduct. Culpable conduct must be accompanied by a state of mind, on the continuum from accident to intent, that is higher than gross negligence. In the opinion of this Court, Kingsdown does not limit that state of mind to a specific intent to deceive, but rather reaches a state of mind that is equivalent to intentional conduct by recognizing that conduct which indicates "sufficient culpability to require a finding of intent to deceive" may support a finding of inequitable conduct. In traditional analysis, recklessness is seen as the equivalent of intent where an equivalent is recognized. This Court therefore concludes that after Kingsdown the requisite state of mind is either intent or recklessness, and that gross negligence is not sufficient.\textsuperscript{211}

In sum, the \textit{Kingsdown} standard — "sufficient culpability to require a finding of intent to deceive" — may be met by direct evidence of intent, circumstantial evidence of intent, or evidence of recklessness.\textsuperscript{212} That same Kingsdown standard may be met by an examination of the totality of circumstances which necessarily includes examination of negligent and grossly negligent acts. A review of negligent and grossly negligent acts, in light of all the circumstances may, and often does, ultimately compel a finding of deceptive intent and inequitable conduct.

C. Mere Denial is Never Enough to Overcome an Inference of Intent

The patentee invariably denies wrongdoing. Such denials are never enough; much more is required to demonstrate good faith. As the Federal Circuit noted, "[a] mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances."\textsuperscript{213}

D. Intent and the Duty to Search for Prior Art

It should be noted, though, once the reference is in front of the Examiner, the Examiner is presumed to have looked at it.\textsuperscript{214} Even if the Examiner did not actually use a highly material reference in his rejection, the applicant is not under any duty to reemphasize the reference's importance.\textsuperscript{15} Accordingly, even if the applicant argues the art in a mischaracterizing manner, the Examiner is free to disregard the applicant's interpretations and independently assess the art in

\begin{footnotes}
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\item B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1584, 37 U.S.P.Q.2d 1314 (Fed. Cir. 1996); see also \textit{Allied Colloids}, 64 F.3d at 1578, 35 U.S.P.Q.2d at 1846 ("It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability.").
\item \textit{Kingsdown Med.}, 863 F.2d at 876, 9 U.S.P.Q.2d at 1392 (emphasis added).
\item \textit{Id.}
\item \textit{Consol. Aluminum Corp.}, 910 F.2d at 809.
\item See, e.g., \textit{Baxter Diagnostics, Inc. v. AVL Scientific Corp.}, 924 F. Supp. 994, 1002 (C.D. Cal. 1996) ("Proof of gross negligence can be circumstantial evidence of an intent to mislead."); \textit{Hoffman-La Roche}, 906 F.2d at 688.
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\item 206 \textit{B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.}, 72 F.3d 1577, 1584, 37 U.S.P.Q.2d 1314 (Fed. Cir. 1996); see also \textit{Allied Colloids}, 64 F.3d at 1578, 35 U.S.P.Q.2d at 1846 ("It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability.").
\item 207 \textit{Kingsdown Med.}, 863 F.2d at 876, 9 U.S.P.Q.2d at 1392 (emphasis added).
\item 208 \textit{Id.}
\item 209 \textit{Consol. Aluminum Corp.}, 910 F.2d at 809.
\item 210 See, e.g., \textit{Baxter Diagnostics, Inc. v. AVL Scientific Corp.}, 924 F. Supp. 994, 1002 (C.D. Cal. 1996) ("Proof of gross negligence can be circumstantial evidence of an intent to mislead."); \textit{Hoffman-La Roche}, 906 F.2d at 688.
\item 212 \textit{Kingsdown Med.}, 863 F.2d at 876.
\item 213 \textit{GFI}, 265 F.3d at 1275, 60 U.S.P.Q.2d at 1144-45 ("Beyond its arguments . . . which we have rejected, GFI does little more than deny any intent to deceive the Patent and Trademark Office."); \textit{Mobile Oil Corp.}, 869 F. Supp. 251, aff'd and vacated, 92 F.3d 1203 (3rd Cir. 1996) ("Although subjective good faith may prevent the inference of intent, if an undisclosed reference was material and the applicant knew or should have known that the reference was material, a mere denial of bad faith is insufficient.") (citing \textit{FMC}, 835 F.2d at 1416); see also \textit{Crichton}, 120 F.3d at 1257; \textit{Labounty Mfg.}, 958 F.2d at 1076.
\item 215 \textit{Fiskars, Inc.}, 221 F.3d at 1327, 55 U.S.P.Q.2d at 1577 (sanctioning defendant for frivolous arguments that four references were withheld even though they were submitted and holding that patentee need not re-emphasize importance of references to Examiner; Federal Circuit affirmed that applicant is not under any duty to tell the Office twice about the same prior art).
\end{enumerate}
\end{footnotes}
relation to the claims.216 This situation occurred in Life Technologies v. Clontech Laboratories,217 in which the district court held the patents unenforceable. The Life Technologies inventors researched gene sequences that had beneficial properties.218 In doing so, the inventors, who were working in one direction, read an article by Johnson that pointed them in another direction.219 That direction was against the knowledge and teachings of the time.220 To debunk the Johnson article, the inventors performed testing using Johnson's teachings, but were surprised to learn that Johnson was indeed correct.221 Sometime later, one inventor learned that another researcher had presented somewhat of the same subject matter at a conference.222 At that point, the inventors filed for a patent and submitted the Johnson article to the Patent Office.223 The Examiner rejected the claims in view of Johnson but the inventors overcame those rejections.224 The inventors' patent attorney advised against disclosing the other researcher's conference presentation.225 The first patent issued.226 During prosecution of the second patent application, the inventors submitted the other researcher's work, but the Examiner did not consider that information relevant or material.227 The second patent application issued thereafter.228

The district court held that the patents were unenforceable for inequitable conduct because the inventors had allegedly omitted a discussion about the Johnson article and its relevance to how the inventors used Johnson to arrive at their invention; that any discussion of Johnson was misleading; and that the inventors failed to disclose the other researcher's work in the first patent application.229 The Federal Circuit reversed on all three grounds because: (a) the Johnson article was before the Examiner and the inventors were not obligated to discuss its relevance or how Johnson motivated the inventors to work in a particular direction;230 (b) any statements made about submitted prior art were not misleading because the Examiner could have read the reference for himself and come to his own conclusions;231 and (c) that the inventors only had vague

non-specific knowledge of the other researcher's work but did not have full and disclosable information.232

Applicants do not have a duty to hunt and search for prior art.233 Otherwise, every infringer will allege that every patentee has somehow violated a putative "reasonableness of the search" duty. Searching also poses an interesting jurisprudential dilemma, which may be explained by way of example. If a patentee performs a search for prior art, the infringer will argue that in some circumstances the patentee may have found relevant and material art but failed to submit it. This may occur when the patentee searches the USPTO databases using class and subclass search parameters.234 Now, when sued, an infringer may argue that when the patentee performed the search, he ought to have found the alleged piece of relevant and material prior art and submitted. Thus, the infringer attempts to create a presumption that where the patentee searches in a class/subclass, he is presumed to have at least examined each piece of art in that class and thus imputes the knowledge of the art in those classes/subclasses to the patentee. To this end, the failure to submit this presumed prior art is inequitable conduct. This sounds appealing but an analogy can be drawn to Examiner searches.

During prosecution, the Examiner will also search classes/subclasses for prior art. The Examiner, upon finding reams of prior art, may choose only a few of them to make of record in the prosecution. In a lawsuit, the infringer may proffer a piece of prior art from that same class/subclass and proffer it for invalidity.235 The patentee will argue that because the search parameters were the same between the patent-in-suit and the putative prior art, the patentee asserts that the Examiner, in the routine performance of his job, will have seen that prior art and issued the patent over that prior art. Thus, the patentee argues that because the Examiner is presumed to have seen it, the infringer will have a difficult time proving by clear and convincing evidence that the prior art invalidates the patent.

218 Id. at 1322, 56 U.S.P.Q.2d at 1187.
219 Id. at 1323, 56 U.S.P.Q.2d at 1188.
220 Id. at 1322, 56 U.S.P.Q.2d at 1188.
221 Id.
222 Life Techs., Inc., 224 F.3d at 1322-23, 56 U.S.P.Q.2d at 1188.
223 Id. at 1323, 56 U.S.P.Q.2d at 1188.
224 Id.
225 Id.
226 Id.
227 Life Techs., Inc., 224 F.3d at 1323, 56 U.S.P.Q.2d at 1188.
228 Id.
229 Id. at 1323-24, 56 U.S.P.Q.2d at 1188-89.
230 Id. at 1325, 56 U.S.P.Q.2d at 1189-90.
231 Id. at 1326, 56 U.S.P.Q.2d at 1190-91.
233 As a general rule, there is no duty to conduct a prior art search. Thus, there can be no inequitable conduct in failing to disclose prior art or information of which one was not aware. FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6, 5 U.S.P.Q.2d 1272, 1275 n.6 (Fed. Cir. 1987); FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d 1112, 1115 (Fed. Cir. 1987). In Nordberg, Inc. v. Telesmith, Inc., there was no duty to search all files the patentee had and thus did not commit inequitable conduct. 82 F.3d 394, 38 U.S.P.Q.2d 1593. The court reenphasized that the patent applicant must have "actual" knowledge of the existence of the alleged prior art and that the applicant must have actual knowledge of its materiality. Id. at 397, 38 U.S.P.Q.2d 1595-96.
234 All U.S. patents are classified into various classes and subclasses. Accordingly, "like" patents may be found within the same class/subclass. For instance, "games" may be a class and the subclass may be "puzzles" such that a patentee searching in "puzzles" will likely find all the prior art related to puzzles.
235 For example, the prior art may anticipate (under section 102) or render obvious (under section 103) the claims.
As appealing as the argument is, the courts are not persuaded. For example, in Chore-Time Equipment, Inc. v. Cumberland Corp., the court held that even though the patentee may argue that the Examiner found that prior art and still issued the patent over it, the burden of proof still rests on the infringer to prove invalidity, by clear and convincing evidence, and can assert any prior art — even art considered by the Examiner — to invalidate the claims if the infringer satisfies the burden of proof. Returning now to the prior example, it stands to reason that if no presumption exists for the Examiner to have examined the prior art, then a patentee who searches the prior art is not presumed to have found and withheld the prior art unless it can be proven that the patentee actually found and withheld it with an intent to deceive. That is, the patentee had actual knowledge of the art and withheld it with the requisite intent to deceive.

Although the courts may suggest that there is no duty to search, one may find this duty if the circumstances so warrant. Brasser v. Carafoli, is an example where the facts imposed a duty on the attorney to investigate the circumstances surrounding a potential on-sale bar. In this case, a law firm partner ordered an associate to draft and file a patent application before a potential on-sale bar date. It was undisputed that during the two days it took to draft the application, the law firm did not investigate any on-sale issues. The district court found inequitable conduct based on the following:

- the attorneys had notice that the potential on-sale activity had occurred;

236 See J.P. Stevens & Co., 747 F.2d at 1563, 223 U.S.P.Q. at 1095-96 (regarding applicant who argued unsuccessfully that the patent examiner was the same person who examined the non-disclosed reference; the Federal Circuit held that the record showed that it was possible for the Examiner to know of the reference but mere possibilities are not enough); see also FMC Corp. v. Hennsey, 836 F.2d 251, 257, 5 U.S.P.Q.2d 1272, 1274 (Fed. Cir. 1987) (regarding patentee who unsuccessfully argued that a reference was immaterial because the Examiner had cited it in an unrelated case and thus ought to have remembered it; the Federal Circuit stated that the duty of candor required more than an assumption that the Examiner remembered art cited in related cases).


239 Brasser, 267 F.3d 1370, 60 U.S.P.Q.2d 1482. This case is also an example of a case in which patent invalidity was affirmed in a prior decision, but the current appeal was predicated on the award of attorney fees due to inequitable conduct. See id. Attorney fees are awarded to the prevailing party under 35 U.S.C. § 285 when the case is “exceptional.” Exceptional cases may involve inequitable conduct, litigation misconduct, vexatious or unjustified litigation, bad faith litigation, frivolous suits, or willful infringement. See Hoffman-La Roche, 213 F.3d at 1365, 54 U.S.P.Q.2d at 1850; Seminole, Inc. v. Aerocon Corp., 81 F.3d 1566, 1574, 35 U.S.P.Q.2d 1551, 1557-58 (Fed. Cir. 1996) (finding litigation misconduct and unprofessional behavior are relevant to award of fees and may suffice on their own to make a case exceptional); Cambridge Prods. Ltd. v. Penn Nutrients, Inc., 962 F.2d 1048, 1059-51, 22 U.S.P.Q.2d 1577, 1579-80 (Fed. Cir. 1992).

240 Brasser, 267 F.3d at 1374, 60 U.S.P.Q.2d at 1483.

241 Id.

242 Id.

The Federal Circuit affirmed, stating that the attorney’s knowledge of the potential on-sale bar, the lack of any rational basis to support the putative bar date, the failure to investigate the details at any time before or after the application filing, and the failure to poll the inventors about potential bar dates contributed to the inequitable conduct. The court reiterated that there is normally no duty to investigate when there is no notice of the existence of relevant and material information. Even a mere possibility that such information may exist does not give rise to the duty to investigate. By inference, therefore, when the patentee or his attorney becomes aware that the “mere possibility” has become a “real probability,” then the duty to investigate exists. Accordingly, the Federal Circuit affirmed the district court’s summary judgment that Brasser committed inequitable conduct.

E. Intent is Found Where There is a Pattern of Misrepresentations or Omissions

Courts have held that where a pattern of misrepresentations or omissions exists, the intent of the actors to make those misrepresentations or omissions is presumed. “While the making of a single material misrepresentation or the withholding of a single piece of material information may alone suffice to establish inequitable conduct, a pattern of such actions or omissions clearly argues against honest mistake and provides strong support for a ruling of...”
inequitable conduct.247 Indeed, just two acts have been held sufficient to establish a "pattern."248

Often it is possible to review an omission of information or to review the now known information and, in light of that information, recognize immediately the falsity of statements actually made to the Patent Office. Where such full disclosure of all the information would have made it difficult or impossible for the applicant to make the argument that was made, the courts infer the original act -- misrepresentation or omission -- was intentional. The argument, as made, could not have been made had all the information been available. In LaBounty, the evidence amply supported the inference that LaBounty "acted with culpable intent to mislead or deceive the PTO by withholding its own known prior art devices and by making an argument for patentability which could not have been made had the art been disclosed."249

In GFI, Inc. v. Franklin Corp.,250 the GFI patent applicant filed an application directed to a type of sectional sofa.251 During prosecution, the applicant visited a competitor furniture designer, noted that the competitor also designed a type of sectional loveseat, and noted that he had also filed a patent application on that design a few months before the GFI applicant did.252 The GFI inventor also saw a model of the loveseat and obtained the competitor's own patent application.253 Apparently, each learned that the other had filed patent applications on their respective sofas or loveseats and, to this end, the competitor offered his conception and reduction to practice information to the GFI inventor, presumptively to settle any priority contest as to who invented first.254 GFI refused this mutual information exchange and, after the patent issued, sued a number of other manufacturers, who defended on the ground that GFI committed inequitable conduct in failing to disclose the competitor's patent application and brochures.255

In affirming the district court's ruling of inequitable conduct, the Federal Circuit noted that GFI possessed a lot of information about the competitor's invention.256 The court was not persuaded by GFI's argument that GFI believed that the competitor's activities were not prior art.257 GFI argued that its invention was patentable over the prior art, an argument it was not entitled to make given the questionable nature of whether the competitor's activities were prior art or not.258 Accordingly, the applicant failed to disclose the competitor's pending application and the competitor's brochures even though the precise nature of the discussion between the applicant and competitor was to determine which application had priority.259 This priority contest argument could not have been made if GFI had disclosed the competitor's activities.260

F. Cultivated Ignorance Can Prove Intent

The Federal Circuit has warned against "studied ignorance." In FMC Corp. v. Hennessy Industries, Inc.,261 the court stated that "one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art."262 In effect, the theory of cultivated ignorance prohibits an applicant from hiding behind from that which is plainly before him.

In LNP Engineering Plastics, Inc. v. Miller Waste Mills,263 however, the Federal Circuit affirmed the district court's finding of no inequitable conduct. In this case, there were three patents in suit.264 The patentee was aware of Japanese publication #1 but did not submit it to the U.S. Examiner during prosecution of any of the three patents in suit.265 The foreign prosecution in Japan of patent #2 resulted in a Japanese publication #2 being used to reject the claims of patent #2.266 The patentee, though, did not submit Japanese publication #2 to the U.S. Examiner either.267 The patentee had a portion of Japanese publication #2 translated and determined that it was simply cumulative of unsubmitted Japanese publication #1.268 The trial court, however, found that the Japanese publication #2 was not cumulative and was material because that publication was being used to reject the co-pending Japanese application.269 Thus, presuming the claims

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248 Paragon Podiatry Lab., Inc., 984 F.2d at 1193; see also Critikon, 120 F.3d at 1259, 43 USPQ 2d at 1671 (reversing district court finding of no intent stating, "Given the materiality and the failure at any point to offer a good faith explanation of the pattern of nondisclosure, an intent to mislead may be inferred.").
249 LaBounty Mfg., 958 F.2d at 1076-77.
250 265 F.3d 1268, 60 USPQ 2d 1141.
251 Id. at 1272, 60 USPQ 2d at 1142.
252 Id.
253 Id. at 1274-75, 60 USPQ 2d at 1144.
254 Id. at 1272, 60 USPQ 2d at 1142.
255 GFI, 265 F.3d at 1272, 60 USPQ 2d at 1142.
256 Id. at 1274-75, 60 USPQ 2d at 1144.
257 Id. at 1275, 60 USPQ 2d at 1144.
258 Id. at 1275, 60 USPQ 2d at 1146.
259 Id. at 1275, 60 USPQ 2d at 1142.
260 266 GFI, 265 F.3d at 1274, 60 USPQ 2d at 1144.
261 836 F.2d 521, 5 USPQ 2d 1272 (Fed. Cir. 1987).
262 Id. at 526 n.6, 5 USPQ 2d at 1275-76 n.6; see Enico, supra note 83, at 353 n.89.
263 275 F.3d 1347, 1361, 61 USPQ 2d 1193, 1203 (Fed. Cir. 2001).
264 Id. at 1350, 61 USPQ 2d at 1194.
265 Id. at 1360, 61 USPQ 2d at 1202.
266 Id.
267 Id.
268 266 LNP Eng'y, 275 F.3d at 1360, 61 USPQ 2d at 1202.
269 Id.
were the same, the Japanese publication #2 that was used to reject the Japanese application was material to the U.S. case that contained the same claims. The district court also criticized the patentee’s decision to forego translating the entire publication when he knew that the reference as a whole was being used to reject the claims. But the district court, when evaluating all the circumstances and balancing the credibility of the patent attorney, determined that there was no intent to deceive. The Federal Circuit likewise determined that the unsubmitted publication #2 was material and not cumulative. The court relied on MPEP section 2001.06(a), which requires applicants to submit prior art found in foreign prosecution, especially if that prior art is used to reject foreign claims that are similar to the co-pending U.S. application. Exercising some restraint, the Federal Circuit relied on its standard of review to defer to the district court’s decision that there was no inequitable conduct. The court was not convinced that the district court committed clear error.

Cultivated ignorance may also occur in areas where incomplete submissions are made. For example, a situation may occur when part of a scientific journal article is submitted. Here the applicant possessed the entire reference but only submitted parts thereof. Because the rule requiring an applicant to err on the side of disclosure, the applicant ought to have submitted the entire reference.

A closer call occurs when the entire reference is voluminous. For example, if the relevant section is a chapter of a book, then is there a duty to submit the entire book? Because the rules no longer require a pinpoint citation, the Examiner would be left with reading an entire book without any guidance as to what chapter is relevant. Surely an applicant who submits only a chapter would be accused of withholding the book, and an applicant who submits the book would be accused of “burying” the relevant chapter in the book. If the applicant submits the book with an identification of the relevant chapter, the applicant would be accused of not identifying other relevant chapters.

In Hemstreet v. Burroughs Corp., the district court rejected the plaintiff’s argument that it brought a reference to the attention of the Examiner by mentioning a part of it. The plaintiff mentioned page seventeen of a very long document. However, the plaintiff then argued that it also put pages 271-72 into the record also. The court rejected the argument that “by this mention of

276 id. at 1360-61, 61 U.S.P.Q.2d at 1202-03.
277 id. at 1360-61, 61 U.S.P.Q.2d at 1202.
278 id. at 1360, 61 U.S.P.Q.2d at 1202.
279 LNP Eng’g, 275 F.3d at 1361, 61 U.S.P.Q.2d at 1203.
280 id.
281 id.
282 id.
283 id.
284 id.
285 LaBonte v. MPL Sys., 958 F.3d at 1076, 22 U.S.P.Q.2d at 1033.
286 See infra notes 357-367 regarding “burying” a reference.
288 id. at 1125, 6 U.S.P.Q.2d at 1974.
289 id.
290 id.
291 id.
292 id.
293 id. at 1125, 6 U.S.P.Q.2d at 1974.
294 id.
295 id.
296 id. at 1373, 54 U.S.P.Q.2d at 1006.
297 id. at 1374, 54 U.S.P.Q.2d at 1005.
298 id. at 1372, 54 U.S.P.Q.2d at 1003.
299 id. at 1374, 54 U.S.P.Q.2d at 1005.
300 id.
301 id.
302 id.
303 id.
304 id.
305 id.
306 id.
307 id.
308 id.
309 id.
310 id.
311 id.
312 id.
313 id. at 1374, 54 U.S.P.Q.2d at 1006.
314 id. at 1375, 54 U.S.P.Q.2d at 1006.
315 id. at 1378, 54 U.S.P.Q.2d at 1008.
316 id. at 1376, 54 U.S.P.Q.2d at 1006.
317 id.
318 id.
319 id.
320 id.
321 id.
322 id.
323 id.
G. Related Applications and Injunctive Unenforceability

Because related applications have an impact on each other, examining related applications and determining what was said can reveal inequitable conduct. For example, in *Li v. Second Family Ltd. Partnership v. Toshiba Corp.*, the district court, as affirmed by the Federal Circuit, found the patent unenforceable because *Li* failed to tell the Examiner that the claims were not entitled to earlier filing date priority. In this case, there were two sibling patents each claiming priority to a long lineage of earlier patents. During prosecution of sibling 2, the Board of Patent Appeals ruled that the claims of sibling 2 were not entitled to priority up the chain. *Li* failed to disclose this Board’s opinion to the Examiner in sibling 1. *Li* did, however, submit a lineage chart that identified sibling 2. The Board opinion was highly material because the ability to claim priority to an earlier filing date means that the universe of prior art that can be used to reject the claims is smaller. Accordingly, intervening prior art that could have been available was not applied because the Examiner believed, wrongfully, that the sibling 1 was entitled to claims for earlier priority. The courts did not agree with *Li’s* arguments that the patents were still patentable over any intervening prior art. Rather the courts held that a patent may be still valid, that is patentable, over the prior art but may still be held unenforceable due to inequitable conduct.

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296 Id. at 1377, 54 U.S.P.Q.2d at 1007-08.
297 Id. at 1377-78, 54 U.S.P.Q.2d at 1007-1008; see also *Gambro Lundia*, 110 F.3d 1573, 1580, 42 U.S.P.Q.2d 1378, 1385.
300 Id. at 1376-77, 56 U.S.P.Q.2d at 1683.
301 Id. at 1375-76, 56 U.S.P.Q.2d at 1682-83.
302 Id. at 1376, 56 U.S.P.Q.2d at 1684.
303 Id. at 1378, 56 U.S.P.Q.2d at 1685.
305 Id. at 1379-80, 56 U.S.P.Q.2d at 1686.
306 Id. at 1380, 56 U.S.P.Q.2d at 1686.
307 Id. at 1380-81, 56 U.S.P.Q.2d at 1687. Similarly, the applicant need not disclose to the PTO advantages, improvements, or modifications discovered after the filing date since these characteristics were not material to the invention as originally filed. *Engel Indus.*, 946 F.2d at 1534; 20 U.S.P.Q.2d at 1304. A reference that is material only to withdrawn claims cannot be the basis of a holding of inequitable conduct. *Kimberly-Clark Corp. v. Johnson & Johnson Co.*, 745 F.2d 1437, 1457, 223 U.S.P.Q. 603, 616-17 (Fed. Cir. 1984). But see *Fox Indus.*, 922 F.2d at 804, 17 U.S.P.Q.2d at 1581 ("Finch had an obligation to disclose the brochure to the PTO notwithstanding the fact that those of the claims issued in the form in which he drafted them. A fortuitous rejection does not cure a breach of the duty of candor. *Driscoll*, 731 F.2d at 885, 221 U.S.P.Q. at 751. Nothing in *Kimberly-Clark* requires the contrary.").
308 Id. at 534, 48 U.S.P.Q.2d 1321 (Fed. Cir. 1998).
309 Id. at 547, 48 U.S.P.Q.2d at 1330.
310 Id.
311 Id.
312 Id.
313 *ATD*, 159 F.3d at 547, 48 U.S.P.Q.2d at 1330.
314 Id. The author notes, actually, that MPEP section states that the information need not be submitted from the parent into a later "continuing" application unless the applicant so desires. A "continuing" application actually comprises three types of applications: (i) a "continuing" application; (ii) a divisional application; and (iii) a continuation-in-part application. 37 C.F.R. § 1.53(b) (2001). Most confusion occurs because the term "continuing" is too often interchanged with "continuation" application, which is not totally accurate. Accordingly, the plain language of MPEP § 609 expressly states that even continuations and continuations in part may benefit from the considered art in the parent application because that section uses the term "continuing" application versus just "continuation." MPEP § 609 (2003).
contain information material to patentability if they contain closer prior art than that which was before the United States Examiner, it is the reference itself, not the information generated in prosecuting foreign counterparts, that is material to prosecution in the United States.\(^{316}\)

The Federal Circuit stated that the “details of foreign prosecution are not an additional category of material information.”\(^{317}\) The Federal Circuit affirmed, stating that “because the Sendzimir reference was of record in the parent ‘743 application, and because MPEP § 609 states that the information need not be resubmitted, there was not clear and convincing evidence of material withholding with intent to deceive.”\(^{318}\) Furthermore, MPEP section 707.05(a) states, “In the rare instance where no art is cited in a continuation application, all the references cited during the prosecution of the parent application will be listed at allowance for printing in the patent.”\(^{319}\)

In *Nintendo of America, Inc. v. Magnavox Co.*,\(^{320}\) regarding the alleged failure to cite prior art relied upon by one Examiner in rejecting claims in a parent application to a new Examiner of a continuation application, the court stated,

\[\text{[there is no doubt that it is good practice for a patent applicant with a divisional application to inform the new patent Examiner of all prior art that was before the first patent Examiner. However, the PTO rules require a patent Examiner to search the patent application file for prior art himself.]}\(^{321}\)

In *Akron Polymer Container Corp. v. Excel Container, Inc.*,\(^{322}\) the Federal Circuit court stated,

\[\text{[the district court’s findings of fact enumerate the many occasions during the prosecution of the Katz application when disclosure of the Venus application could have been, but was not, made to the Examiner. From the facts taken as a whole, the district court concluded that Container’s failure to disclose the Venus application arose from deceitful intent.]}\(^{323}\)

The Federal Circuit further elaborated:

The district court noted, but gave no weight, to the fact that Container did disclose the existence of the Katz application to the Venus application’s examiner, and thus put the PTO on notice of the codependency of the two applications. This undisputed fact sponsors Excel’s main argument as to why the judgment of unenforceability is incorrect. Excel contends, we think convincingly, that it hardly could be seeking to deceive the PTO as to the existence of copending applications when it actually disclosed the fact of copendency to the Venus examiner.

As we have noted before, the facts in inequitable conduct cases rarely, if ever, include direct evidence of admitted deceitful conduct. The intent element of the offense is thus in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred. But for the fact that Container actually disclosed the fact of copendency of the two applications to the PTO, while still failing to disclose the Venus application to the Katz application’s examiner, it could be argued that the other facts in this case are sufficient to support a threshold finding of deceitful intent by clear and convincing evidence. Our confidence in such a conclusion is undermined, however, when we afford weight to the inference running contrary to deceitful intent that must be drawn from Container’s disclosure of the Katz application to the Venus application’s examiner.

The clear error in this case is the absence of the requisite weight that must be given to Container’s disclosure of the Katz application, and of the fact of the copendency of the two applications, to the PTO through the Venus application’s Examiner. This fact points away from an intent to deceive. When examining intent to deceive, a court must weigh all the evidence, including evidence of good faith. Thus, when we measure the facts of record, we conclude that a threshold level of deceitful intent has not been shown.\(^{324}\)

In addition to the above examples of misconduct in related applications, false claims to priority in related applications may rise to the level of inequitable conduct. In *Purdue Pharma L.P. v. Boehringer Ingelheim*,\(^{325}\) the Federal Circuit upheld the preliminary injunction sought by Purdue against Boehringer by concluding that Boehringer had failed to prove inequitable conduct in a priority claim.\(^{326}\) In this case, Purdue amended its specification during prosecution to

\[\text{Id. at 1383, 47 U.S.P.Q.2d at 1535.}\]

\[\text{Id. at 1383-84, 47 U.S.P.Q.2d at 1535-36 (internal citations omitted).}\]

\[\text{237 F.3d 1359, 57 U.S.P.Q.2d 1647.}\]

\[\text{Id. at 1363-64, 57 U.S.P.Q.2d at 1649. Because the grant of a preliminary injunction relies, in part, on the likelihood of success of proving infringement, part of the injunction analysis wades into}\]
include a claim for priority to a parent application because the Examiner suggested that Purdue do just that.\textsuperscript{327} In the amendment, Purdue categorically stated that the amendment and the claim for priority was to inform everyone that the application was indeed a continuation in part application ("CIP") of the parent.\textsuperscript{328} The Examiner noted that the claims in the CIP were not entirely entitled to priority to the parent, as the claims were also based on additional matter unique to the CIP.\textsuperscript{329} Roxane, a Boehringer business unit, argued that Purdue intended to dupe the Examiner into believing that the parent was not prior art against the later CIP.\textsuperscript{330} This is because in a CIP application, the "old" matter, that is, matter that is common to the parent application, is entitled to the parent's filing date; whereas "new" matter, that is, matter that is unique to the CIP application, is entitled only to the CIP filing date.\textsuperscript{331} Accordingly, Roxane argued that Purdue

the patent invalidity/enforceability fields because if the patent is likely to be found invalid or unenforceable, then it is likely that the patentee will not succeed in the infringement case.\textsuperscript{332}

\textsuperscript{327}Id. at 1366-67, 57 U.S.P.Q.2d at 1652.

\textsuperscript{328}Id. at 1367, 57 U.S.P.Q.2d at 1652.

\textsuperscript{329}Id.

\textsuperscript{330}Purdue Pharma, 237 F.3d at 1366-67, 57 U.S.P.Q.2d at 1652-53.

\textsuperscript{331}See generally 35 U.S.C. § 120 (2003) (regarding the universe of prior art available depends on the filing dates). A practical example may benefit the reader. Suppose on Date 1, the applicant files a parent application that disclosing subject matter A, B, and C. But for some reason, the parent application claims A and B, but not C. Later on Date 2, the applicant files another patent application disclosing subject matter A, B, C, D, and E. We can assume that D and E are improvements that make the invention better and was "new" matter. Under the new matter rule, 35 U.S.C. § 132 in combination with 35 U.S.C. § 120, this later application would be called a "CIP," a continuation-in-part, because it partly continues the previous application. Because subjects A, B, and C are common to both applications, this subject matter would be given the parent filing date of Date 1. The new matter D and E, however, would be given the new filing date of Date 2. The CIP application need not claim any of the new subject matter as the CIP may claim A, B, and C only -- subject matter that was totally disclosed in the parent but not claimed. In reality the CIP would likely claim some part of the new matter, such as A, B, and D/E; or A, B, C, and D/E. If the CIP only claimed A, B, and C, then this claim would be entirely afforded the parent filing date (Date 1) and the Examiner would have to find prior art that precedes this date to reject the claim. On the other hand, if the CIP claimed A, B, and E, then only A and B would be afforded the parent filing date and the Examiner needs to concentrate on the 2 filing dates to reject the claim. Thus, claims for priority are useful for an applicant so that the applicant can backdate an application and reduce the size of the universe of prior art. But the additional benefit of including claims for priority is that section 102(e) "backdater" issued patents to the earliest filing date. This means that the above CIP could be used as prior art against someone else; that is, the CIP would be used offensively against someone to preclude them from getting a patent. Thus, when a CIP includes the claim for priority, it is given two effective section 102(e) dates; subject matter A, B, and C is given Date 1 and subject matter D and E is given Date 2. Thus, the CIP can play havoc against someone else because it would require that later applicant, if confronted with the CIP patent as prior art, to digest the applications to determine exactly what subject matter was disclosed and when. This can be quite a tedious chore, not to mention expensive. See Purdue Pharma, 237 F.3d at 1367, 57 U.S.P.Q.2d at 1653 ("As pointed out . . . a claim to priority to an earlier patent strengthens the offensive value of later patent.").

\textsuperscript{332}Purdue Pharma, 237 F.3d at 1367, 57 U.S.P.Q.2d at 1352-53.

\textsuperscript{333}Id.

\textsuperscript{334}Id. at 1367-68, 57 U.S.P.Q.2d at 1652-53; see also 35 U.S.C. § 120.

\textsuperscript{335}Id. at 1367, 57 U.S.P.Q.2d at 1652-53.

\textsuperscript{336}See Molina, 48 F.3d at 1182, 33 U.S.P.Q.2d at 1830.

\textsuperscript{337}149 F.3d 1317, 47 U.S.P.Q.2d 1225.

\textsuperscript{338}Id. at 1332, 47 U.S.P.Q.2d at 1232.

\textsuperscript{339}MPEP § 708.02 (2003).

\textsuperscript{340}Id. (Identifying twelve circumstances in which Make Special petitions may be granted, such as the old age or poor health of an inventor, inventions that have great public purpose, such as HIV/AIDS drugs or energy conservation, or counter-terrorism); see also 37 C.F.R. § 1.102 (2003).

\textsuperscript{341}MPEP §§ 708.02(I)(D), (II)(C), 708.02(VIII)(C).

intended to mislead the Examiner into believing the "new" matter disclosed and claimed only in the CIP was actually entitled to an earlier filing date.\textsuperscript{332}

The Federal Circuit held otherwise. The court noted that the Examiner himself was under no illusion that the claims of the CIP were not entitled to priority of the parent's filing date.\textsuperscript{333} Because making a claim for priority means that the old matter gets the old date, this was a benefit to Purdue as its CIP-issued patent would become prior art at an earlier date against someone else.\textsuperscript{334} Accordingly, this was a bona fide reason to make a claim for priority to the parent even though the CIP claims would not be entitled to the earlier date.\textsuperscript{335}

The theory of infectious unenforceability arises in related applications. As a general rule, inequitable conduct in a parent can be imputed to other related cases on the theory that the later applications relied on the first.\textsuperscript{376} This can be "cured" though. In Baxter International, Inc. v. McGaw, Inc.,\textsuperscript{377} the inequitable conduct in the parent did not affect the child because the child claims were not related to the omitted art and the claims had been divided into a new application.\textsuperscript{378} An unexplored issue is whether this cure is effective if the claims are related to the tainted parent claims. It stands to reason through, the related claims in the parent are tainted and this, likewise, taints the related claims in the children, unless the taint is "cured."" The above situations illustrate the more classical ways in which inequitable conduct can be shown. Most are related to intentionally withholding information known to the applicant. Patent procurement, however, may involve other situations related to obtaining the patent faster or examining the form in which information is submitted. Accordingly, it is fruitful to examine other non-classical situations in which inequitable conduct can rear its ugly head.

H. Fraudulent Petition to Make Special to Advance Examination Out of Normal Order

Because applications are normally examined on a first-submitted basis, an applicant can file a "Petition to Make Special" that basically petitions the Patent Office to examine the applications out of turn.\textsuperscript{399} There are several bases for these petitions.\textsuperscript{340} One basis exists when the applicant certifies that it has "made or caused to be made a careful and thorough search of the prior art, or has a good knowledge of the pertinent prior art."\textsuperscript{341} In effect, by so certifying, the applicant
is "helping" the Examiner find the prior art. The Federal Circuit in General Electric Music Corp. v. Samick Music Corp. stated that the required search must be more than just a casual search, more than just looking in one's files, more than just talking to one's colleagues, and more than just staying within one's internal sources. Here, the Petition succeeded in achieving expedited examination of the application. Accordingly, the jury finding of inequitable conduct was not unreasonable because the patentee was caught making inconsistent statements about the one reference that it did find in the "search."345

I. Misleading Petitions to Revive Abandoned Patent Applications

An application remains pending until it is issued or becomes abandoned. Abandonment is intentional or unintentional. An applicant may intentionally abandon a pending application if the applicant intentionally fails to respond to some Office Action communication. That is, the applicant simply ignores the outstanding Office Action and the application is deemed abandoned for want of prosecution as of the due date for response. In addition, applicants may intentionally abandon the application by filing a notice of express abandonment in the U.S. Patent and Trademark Office.

More often though, an application becomes abandoned unintentionally. Some common instances include failure to receive an Office Action (e.g., it was mailed to the wrong address), a mistake by the attorney in docketing correct due dates, the file is lost, or just simple inadvertence by the attorney or applicant. In these situations, the Notice of Abandonment sent by the Office is usually the applicant's first indication of the abandonment. To cure the abandonment, the applicant may file a "Petition to Revive" the application and pay a fee. A Petition to Revive must include enough information to satisfy the petition officer that the abandonment was unintentional or unavoidable. As with any document submitted to the Office, there is an express statutory mandate that the submitter not supply false or misleading information to the Office. Therefore, a situation for fraud may arise when the applicant has unintentionally abandoned the application but has no satisfactory reason why that abandonment occurred.

To this end, the applicant may falsify the facts in the petition to make it more favorable. Furthermore, if substantial patent rights are at stake (e.g., blockbuster drugs) then revival becomes so important that falsification is the only way out. Finally, where abandonment is the attorney's fault, the threat of malpractice precipitates a desire to falsify.

In Lumentype International Corp. v. Cable Lite Corp., the Federal Circuit affirmed the district court's findings that the petition for unintentional abandonment constituted inequitable conduct because the record demonstrated that the application was intentionally abandoned after the patent attorney advised that issuance was unlikely.

J. "Burying" References

As previously mentioned, an applicant has the duty to disclose relevant and material information to the Examiner. It is also axiomatic that in close calls of relevance and materiality, the applicant should err on the side of disclosure. The other benefit for submitting prior art is that the Examiner is deemed to have considered that piece of art and decided to allow the claims over the prior art. Courts have declined to find inequitable conduct based on alleged mischaracterizations of references supplied to an Examiner, because PTO Examiners are free to reach their own conclusions regarding the prior art and should not thoughtlessly accept an applicant's interpretation.

Accordingly, during invalidity litigation, the infringer will rarely try to invalidate the patent based solely on the prior art already before the Examiner because the Examiner, a presumed expert in the prior art, issued the patent over that art. The problem for the applicant, therefore, is submitting very relevant and very material prior art voluntarily but then risk not having the patent issue over that art. Some applicants resort to "burying" prior art amongst tens or hundreds of other references. The hope is that the Examiner will not find that art and/or will not spend the time securing the art during examination. In effect, the applicant seeks to "slip one by" the Examiner.

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345 See In re Medgest, 17 U.S.P.Q.2d 1455, 1458 (Comm'r of Patents 1990) (stating if the attorney conceals the mistake, this cannot be charged to his client); Link v. Wabash R.R., 370 U.S. 626, 633-34 n.10 (1962) (stating that attorney's negligence does not excuse client as client's recourse is malpractice against the attorney).
347 See id. at *3.
348 MPEP § 707.05.
349 See Molina, 48 F.3d at 1179-80, 33 U.S.P.Q.2d at 1827.
350 See Gembrow Limited, 110 F.3d at 1580, 42 U.S.P.Q.2d at 1384-85; Akzo N.V. 808 F.2d at 1482, 1 U.S.P.Q.2d at 1247.
351 See, e.g., Bristol-Myers, 326 F.3d at 1236 (quoting Rohm & Haas Co., 722 F.2d at 1572-73, 220 U.S.P.Q. at 302) (stating that "a presumption that an examiner was able to find, with his expertise and adequate time, the critical data when he was presented with a 'mountain of largely irrelevant data' ignores the real world conditions under which examiners work").
The courts generally dislike burying material prior art among a long list of prior art, especially if the other art is marginal, immaterial, or cumulative. In the "old days" an applicant had to comment on the relevance of each piece of prior art. The new MPEP does not require such commentary if the prior art is in English. Non-English documents still require some commentary. Nothing prohibits the applicant, though, from commenting on the relevance of each piece of prior art submitted. The problem then becomes how those comments can later be used against the applicant. First, prosecution history can be used in construing the scope of the claims and, thus, such statements may unduly limit claim scope. Secondly, the prosecution history may estop the applicant from alleging infringement under the Doctrine of Equivalents. In practice, the applicant ought to use some organized method to submit the art. For example, the prior art can simply be listed on the PTO Form 1449 in numerical, chronological, or alphabetical order. This way, there is no intent to "bury" the relevant art among the listed art because the applicant had no control over where each reference would appear in the stack so the most relevant reference could just as likely be in the beginning, middle or end.

K. Failure to Disclose Prior Art, Especially References Cited by Foreign Patent Offices

As with any U.S. patent application, the applicant may also choose to file the same application in a foreign country because each country controls its own patent law. To this end, most countries also engage in an examination process to determine patentability. During prosecution of the foreign application, prior art may be found by the foreign patent Examiner. That patent Examiner may find very material and relevant art that is either in English or non-English. Thus, during prosecution of the U.S. application, the applicant may become aware of prior art found by another Examiner. Of course if the foreign-found prior art is identical to that art presented to the USPTO Examiner, then the foreign art is simply cumulative. On the other hand, if the art is different, then it should be submitted.

In addition, during foreign prosecution, foreign Examiners may issue written opinions detailing how the prior art applies to the claims. This is especially evident in the Patent Cooperation Treaty ("PCT") regime. During the PCT process, a search Examiner will search out prior art and issue an International Search Report ("ISR"). That ISR will also have a code that characterizes the prior art and how that prior art affects the claims. For example, "X" art means that the prior art is considered to defeat the novelty of the claim; "Y" art means that the prior art is considered to defeat the inventive step (obviousness) of the claim. Other codes may indicate if the prior art is relevant to the scope of the disclosure. Similarly, if the PCT application later undergoes substantive examination, a Written Opinion will be issued that is, for all intents and purposes, akin to a USPTO Office Action. Accordingly, there will be details the Rule 56 duty). To put the reference for consideration before the examiner, the applicant must follow the procedures described in MPEP § 608 and hence, only submission by the prescribed routes, such as PTO Form 1449 listing, will suffice. Here the district court further criticized the applicant for attempting to "bury" the reference as number forty-nine in a list of ninety-four other references. Id. at *62-*63.

Assume that the claims being prosecuted in the U.S. case are identical or substantially similar to those being prosecuted in the foreign applications.

Patents or other printed publications as prior art need not be in English to qualify as prior art as 35 U.S.C. § 102(a) and (b) are not limited to English language prior art and, thus, any foreign language prior art is still valid prior art for the USPTO's purposes. See SEL, supra note 284-297.

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Foreign patent attorneys representing applicants for U.S. patents through local counsel surely must be held to the same standards of conduct which apply to their American counterparts; a double standard of accountability would allow foreign attorneys and their clients to escape responsibility for fraud or inequitable conduct merely by withholding from the local correspondent information unfavourable to patentability and claiming ignorance of United States disclosure requirements.
of the prior art and how that applies to the claims. Furthermore, because a U.S. applicant may choose to have the European Patent Office ("EPO") undertake the search and examination and EPO Examiners can search in multiple languages, the EPO Examiner may find more prior art in the various languages than what was found by the U.S. Examiner, who presumably searches in English only. Accordingly, because the ISR and Written Opinion may reveal undisclosed prior art, the U.S. applicant should submit the ISR and Written Opinion to the U.S. Examiner.\(^{371}\) In Molins v. Textron, Inc,\(^{372}\) the court specifically stated that the, 

"[I]t failure to cite to the PTO a material reference cited elsewhere in the world justices a strong inference that the withholding was intentional.\(^{373}\)

For example, Appendices I and II show different search reports. Appendix I shows two PCT Search Reports (from serial no. PCT/US98/27198 and PCT/US01/05198) where the USPTO was the Search Authority (see bottom left box indicating "ISA/US"). In the 27198 report, the U.S. Examiner found Wallace as "X" art against the novelty of claims 1-8, 10, and 12-37. Similarly, he found the Gray "X" art against the other claims. In the 05198 report, the Examiner found the "Y" art (obviously prior art) against various claims. According to these Search Reports, if similar claims exist in a copending or related U.S. cases, then the prior art found in the Reports would be considered to destroy the novelty or nonobviousness of those claims as well.

In Appendix II, a Search Report (from serial no. PCT/IB99/00078) generated by the EPO is shown. In the 00078 Search Report, it shows "X" art that destroys the novelty of various claims and shows "A" art. "A" is identified as being relevant to the state of the art but not to the claims. The EPO Searcher also made detailed comparisons between the cited art and the precise claims involved. This search report would likely be indispensable to the U.S. Examiner because of the detailed search and comparison analysis. To this end, aside from the cited references being meaningful, the Search Report would also be meaningful because of the analyses presented.

L. Submission of False or Misleading Affidavits

Affidavits are used to place evidence, both fact and opinion, before an Examiner for the purpose of establishing patentability. However, statements made in affidavits can have detrimental effects in litigation, particularly with respect to the inequitable conduct defense. The Federal Circuit treats affidavits with an elevated degree of scrutiny with regard to both elements of the defense. As to intent, the court has observed that "[t]he interference [of an intent to mislead] arises not simply from the materiality of the affidavits, but from the affirmative acts of submitting them, their misleading character, and the inability of the examiner to investigate the facts."\(^{374}\) Furthermore, the Federal Circuit has recently held that "[a]ffidavits are inherently material, even if only cumulative."\(^{375}\) Consequently, a patentee was precluded from arguing that the submission of two affidavits which independently established patentability negated the materiality of a third, misleading affidavit.\(^{376}\) A patent practitioner must, accordingly, be particularly careful when submitting affidavits to ensure that the information submitted is neither deceptive nor misleading.

As described above, affidavit practice is a ripe area for inequitable conduct claims. Affidavit issues can arise from alteration of exhibits,\(^{377}\) failure to disclose known, material facts,\(^{378}\) omission of relevant (unfavorable) test data,\(^{379}\) misleading evidence of commercial success,\(^{380}\) failure to test the closest prior art,\(^{381}\) misrepresentations regarding the state of the art or technical information,\(^{382}\) and nondisclosure/misrepresentations regarding the relationship between the affiant and the applicant.\(^{383}\)

Avco v. PPG Industries\(^{384}\) is an example of how affidavit practice can haunt the patentee in subsequent litigation. PPG wanted to produce a fire retardant product that competed with Avco's "Chartek 59," so it obtained the Avco product for reverse engineering purposes.\(^{385}\) The PPG inventor found, during a

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373 Id. at 1182, 33 U.S.P.Q.2d at 1829.
375 Id. at 1583, 38 U.S.P.Q.2d at 1670.
376 Id. at 1582-83, 38 U.S.P.Q.2d at 1669-70; see also Rohm & Haas Co., 722 F.2d at 1571, 220 U.S.P.Q. at 301 ("in contrast to cases where allegations of fraud are based on the withholding of prior art, there is no room to argue that submission of false affidavits is not material."). But see Litton Sys., 87 F.3d at 1570-71, 39 U.S.P.Q.2d at 1328-29 (stating the trial court found materiality because the affiant's statement "convined the Examiner to reverse his rejection of the application"); however, the Federal Circuit reversed finding that on the ground that the declaration was only one of four on which the Examiner based allowance).
379 See, e.g., Rohm & Haas Co., 722 F.2d at 1556.
382 See B.F. Goodrich, 72 F.3d at 1585, 37 U.S.P.Q.2d at 1320 (stating even truthful statements may amount to inequitable conduct if "crafted in a misleading manner through the intentional omission of particular relevant facts"); see also Chiron Corp. v. Abbott Lab., 902 F. Supp. 1103 (N.D. Cal. 1995).
383 See Refac Int'l, 81 F.3d at 1581; Paragon Podiatry Lab., Inc., 984 F.2d at 1190-91.
384 867 F. Supp. 84, 34 U.S.P.Q.2d 1026, appeal dismissed, 1994 WL 745644 (Fed. Cir. 1994) (dismissing appeal due to Avco's failure to file appeal brief). As the appeal was dismissed, the case is procedurally persuasive insofar as any other district court opinion.
385 Id. at 87-88, 33 U.S.P.Q.2d at 1027-28.
patent search, that the "Sawko" patent disclosed using zinc in the retardant.\(^{386}\) In
addition, during the product development, the inventor repeatedly conducted
comparative experiments using the Chartek product as a control that finally
culminated in a product that met strict UL standards.\(^{387}\) After applying for the
patent, the inventors submitted information about the prior art and casually
mentioned the Chartek product in the submission.\(^{388}\) The Examiner rejected
the claims over various prior art patents but did not reject it specifically over the
Sawko patent.\(^{389}\) To overcome these references, the inventors devised new
comparative tests that compared the invention to the prior art retardants, but not
against the Chartek product, and the patent issued thereafter.\(^{390}\) Among other
things, Avco alleged that the patent was unenforceable because PPG withheld
the Sawko reference from the Office and submitted testing data via affidavits
that compared only the prior art patents to the closely related Chartek product.\(^{391}\)

In reviewing the then-standards of inequitable conduct, the district court
found the Sawko patent was not material because the judge presumed that the
Examiner found it and allowed the patent in spite of over the Sawko patent.\(^{392}\)
As such, once the court held the patent immaterial, the intent to withhold
was irrelevant and there could be no inequitable conduct as a matter of law.\(^{393}\) With
respect to the failure to disclose the Chartek commercial product itself to the
Examiner, the judge found it to be material because it was the very product
around which PPG was designing.\(^{394}\) Despite finding that the product was
material, the judge found that there was no evidence that PPG inventors were
aware that the Chartek product was the closest prior art even though the court
later determined that it was.\(^{395}\)

With respect to the pre-patent control tests that compared the PPG
prototype with the Chartek product, which was not disclosed but very material,
the judge held the tests material.\(^{396}\) The judge reasoned that because it would
have been "apparent to any fair-minded observer that PPG's earlier tests in
developing" the PPG product and the comparison tests with the Chartek product
were very material to the very claims that PPG were presenting to the Patent
Office.\(^{397}\) In addition, the judge was disturbed that PPG failed to submit any

\(^{386}\) Id. at 87, 34 U.S.P.Q.2d at 1028.
\(^{387}\) Id. at 87-88, 34 U.S.P.Q.2d at 1027-28.
\(^{388}\) Id. at 88, 34 U.S.P.Q.2d at 1028.
\(^{389}\) Avco, 867 F. Supp. at 88 n.3, 34 U.S.P.Q.2d at 1029 n.3. The district court presumed that the
Examiner found and reviewed the Sawko patent because the Examiner searched the same
categories and subclasses in which Sawko was classified.
\(^{390}\) Id. at 88, 34 U.S.P.Q.2d at 1028.
\(^{391}\) Id.
\(^{392}\) Id. at 91, 34 U.S.P.Q.2d at 1031.
\(^{393}\) See, e.g., Advanced Cardiovascular Sys. v. Medtronic, Inc., 265 F.3d 1294, 1306, 60 U.S.P.Q.2d 1161, 1171 (Fed. Cir. 2001) (affirming summary judgment of no inequitable conduct in holding
that once the alleged conduct was deemed immaterial, then the intent prong need not be analyzed).
\(^{394}\) Avco, 867 F. Supp. at 91, 34 U.S.P.Q.2d at 1031.
\(^{395}\) Id.
\(^{396}\) Id. at 93, 34 U.S.P.Q.2d at 1032.
\(^{397}\) Id.
contributions of L, M, and N to the USPTO as to avoid any of Y’s ownership interest in the patent.

In PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., the inventions in the three patents-in-suit related to high-speed chromatography used to separate biological materials.405 Through a series of district court opinions and intervening Federal Circuit cases related to inventorship qualifications, the district court ultimately determined that PerSeptive committed inequitable conduct via its “persistent course of material misrepresentations, omissions, and half-truths to the PTO” regarding inventorship.407 In this case, the district court determined that the three named inventors failed to disclose that three omitted individuals could have been inventors.408 The district court did not find inequitable conduct based on the dispute over joint inventorship, which is normally correctable if the omitted inventors did not have deceptive intent in their omission.409

Rather, the district court held and Federal Circuit affirmed the pattern of keeping the names of the omitted inventors from the Examiner was inequitable conduct.410 In particular, the courts found that: (1) one named inventor falsely stated that he conceived of the invention and only used an omitted inventor to reduce part of the invention to practice even though another named inventor flatly contradicted this in a writing; (2) the named inventors falsely asserted that they were the only inventors and that they solely developed important aspects of the invention; (3) one named inventor intentionally failed to disclose his extensive and documented collaboration with an unnamed inventor; (4) the

406 Id. at 1317, 56 U.S.P.Q.2d at 1002.
407 Id. at 1330, 56 U.S.P.Q.2d at 1005.
408 Id. at 1320, 56 U.S.P.Q.2d at 1003-04.
409 35 U.S.C. § 256 (2003); see also Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1556, 45 U.S.P.Q.2d 1321, 1325 (Fed. Cir. 1997) (clarifying that when the issue is of joint invention and whether a patent that omits an inventor can be corrected, the Federal Circuit held that the deceptive intent must be by the omitted inventor and that the originally named inventor’s state of mind is not relevant). Quite frankly, this makes no sense to the author because more often than not the named inventor is the one who deceptively intends to omit the other inventors. It should be recalled that named inventors have ownership interests and, therefore, all inventors have an incentive to be named. In contrast, it behooves named inventors to omit others so that the others will not share in the patent. This act completely violates the statutory provision that all inventors be named, that the named inventors disclose all the inventors, and disclose any relevant and material information about the prior art.

An example of when an omitted inventor may want to be intentionally omitted is where the omitted inventor has created a statutory prior art bar (e.g., created a public use bar) and has conspired with the named inventors to be omitted so that the prior art bar need not be disclosed. This, of course, presumes some financial interest in obtaining the patent and that those finances will be shared. But see Frank’s Casing Crew & Rental Tools, Inc. v. PMR Techs. Ltd., 292 F.3d 1363, 1376, 63 U.S.P.Q.2d 1065, 1074-75 (Fed. Cir. 2002) (sustaining the district court’s holding that the named inventors’ misconduct in deliberately failing to name another inventor constituted a pattern of “intentional conduct designed to deceive the attorneys and patent office as to who the true inventors were” and rendered the patent unenforceable).

410 See PerSeptive Biosystems, 225 F.3d at 1320, 56 U.S.P.Q.2d at 1004.
statements or omitting particularly relevant facts cannot cure this conduct by making truthful statements.\textsuperscript{423} If the applicant tries to cancel or amend the claims that are subject to the omitted reference, this too may not cure the inequitable conduct.\textsuperscript{424} This is because, as the court in Baxter noted, in determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. "Claims are not born, and do not live, in isolation. Each is related to the other claims, to the specification, and drawings...[and] to earlier or later versions of itself in light of amendments made to it."\textsuperscript{425}

Thus, the inequitable conduct relevant to certain claims may "taint" or "infect" all other claims and thus render the entire patent unenforceable. Withholding information from the Patent and Trademark Office may "soil the patentee's hands" so as to render all patents-in-suit unenforceable.\textsuperscript{426} In some circumstances though, an applicant can "cure" some forms of inequitable conduct by making a full, clear, and truthful disclosure to the Patent Office, including pointing out specifically where the prior misstatement or untruth occurred.\textsuperscript{427}

The Gambro Lundia v. Baxter Healthcare Corp.\textsuperscript{428} case is one example of this situation. Gambro sued Baxter for infringement of the '552 patent and Baxter defended on many grounds, including inequitable conduct.\textsuperscript{429} Repgreen, a British company, developed ultrafiltrate calculation technology but went bankrupt before exploiting it fully.\textsuperscript{430} Gambro purchased Repgreen's technology, developed it further, and then began filing patents -- first in Sweden and then in the United States.\textsuperscript{431} Gambro used Repgreen's in-house Swedish counsel for the Swedish application and used Repgreen's U.S. patent attorney for its USPTO application.\textsuperscript{432} The USPTO Examiner rejected the U.S. application for anticitation in view of the published German '756 patent application.\textsuperscript{433} Because the German '756 prior art was in German, Gambro's Swedish patent attorney, who was fluent in German, prepared the response on behalf of the U.S. patent attorney to file in the USPTO.\textsuperscript{434} The Response also included a full copy of the German '756 application.\textsuperscript{435} Based on the response, the Gambro '552 patent issued.\textsuperscript{436}

Baxter argued that Gambro mislead the Examiner in determining whether the German '756 patent application taught a specific fluid path.\textsuperscript{437} Gambro used terms such as, "[part 9 of the German '756 patent] is at all times influenced by another part and fluid path," and the district court believed that this was misleading because the German '756 did show that the part and fluid path was "not" at all times fixed.\textsuperscript{438} Accordingly, the district court believed that because the German '756 showed a variable fluid path, that Gambro's statement that the German '756 showed a fixed fluid path was plainly wrong and misleading.\textsuperscript{439}

The Federal Circuit reversed, stating that "at all times" was not as material and deadly as the trial court believed.\textsuperscript{440} The Federal Circuit noted that Gambro submitted a British patent that corresponded to the German '756.\textsuperscript{441} Accordingly, the U.S. Examiner had before it, not only the German language prior art, but also an English language version and that when examining the totality of the circumstances, the Examiner could have read the Gambro response arguments, looked at the German '756 prior art for confirmation, and then examine the British patent too to re-confirm the truth or accuracy of the Gambro statements.\textsuperscript{442} Thus, there were no material misstatements to clarify or explain away.\textsuperscript{443}

V. CONCLUSION

In sum, inequitable conduct poses a serious problem for patentees in the medical field. Because a tremendous amount of medical literature exists in non-patent medical journals, these journals present a valuable source for prior art. Because tremendous pressures exist for medical professionals to publish results, quite plainly relevant and material prior art may exist in these journals. Although it is quite common for medical practitioners to perform tests, re-tests, submit affidavits, and the like, the applicants must take great care in characterizing these activities. It goes without saying that an applicant ought to be upstanding, honorable, and not deceive the Patent Office in any way. As the above discussion shows, almost no activity is immune from a charge of fraudulent intent. In addition, because of the complexities inherent in the patent practice

\textsuperscript{423} BF Goodrich, 72 F.3d at 1585, 37 U.S.P.Q.2d at 1320.
\textsuperscript{424} Baxter In't'l, 149 F.3d at 1331; see also Fox Indus., 922 F.2d at 804, 17 U.S.P.Q.2d at 1581.
\textsuperscript{425} Baxter In't'l, 149 F.3d at 1331.
\textsuperscript{426} Consol. Aluminum Corp., 910 F.2d at 812; Precision Instrument, 324 U.S. at 818-19.
\textsuperscript{427} Rohm & Haas Co., 722 F.2d at 1572-73, 220 U.S.P.Q. at 301-02; see also Neupak v. Ideal Mfg., 41 Fed. Appx. 435, 441-42 (Fed. Cir. 2002) (stating that memoranda regarding subsequent reexamination declaration back and forth between patent attorney and inventors did not evidence an intent to deceive).
\textsuperscript{428} 110 F.3d 1573, 42 U.S.P.Q.2d 1378.
\textsuperscript{429} Id. at 1576, 42 U.S.P.Q.2d at 1380-81.
\textsuperscript{430} Id. at 1575, 42 U.S.P.Q.2d at 1380.
\textsuperscript{431} Id.
\textsuperscript{432} Id.
\textsuperscript{433} Gambror Lundia, 110 F.3d at 1575, 42 U.S.P.Q.2d at 1380.
\textsuperscript{434} Id.
\textsuperscript{435} Id. Although the opinion indicates that Gambro "provided the examiner with a German language copy of the '756," the opinion later states that, "Although the patent examiner relied on Gambro's translations..." Id. at 1575, 1581-82, 42 U.S.P.Q.2d at 1380, 1386 (internal citation omitted). This indicates that Gambro submitted an English language translation, not a German language copy as previously indicated.
\textsuperscript{436} Gambror Lundia, 110 F.3d at 1575, 42 U.S.P.Q.2d at 1380.
\textsuperscript{437} Id. at 1580-81.
\textsuperscript{438} Id. at 1581.
\textsuperscript{439} Id. at 1581, 42 U.S.P.Q.2d at 1385-86.
\textsuperscript{440} Id.
\textsuperscript{441} Gambror Lundia, 110 F.3d at 1580.
\textsuperscript{442} Id. at 1581.
\textsuperscript{443} Id.
and procedures, there are many areas in which an applicant may manipulate the system. But as shown above, an Examiner will discover any chicanery and expose the patentee.

A stricter construction of the inequitable conduct rules that forces disclosure of a reference or the truth has several distinct advantages. First, it provides an applicant with the ability to obtain higher quality claims because relevant and material information was before the Examiner. Second, for art submitted, the applicant enjoys a de facto presumption that the Examiner issued the claims over that art. Third, in most circumstances, a court will not find an applicant liable for inequitable conduct because the Examiner had the references and was able to read the reference for himself and come to his own conclusions. Fourth, submission (absent any mischaracterizations) is antithetical to withholding so it is very difficult to establish intent. Fifth, quite simply the rules of ethics require submission. Sixth, good faith submission may eliminate a charge of Walker Process fraud and/or antitrust concerns. These concerns may result in enhanced damages, costs, and fees. Seventh, although not explored here, 18 U.S.C. § 1001 criminalizes false statements made to the Patent Office. Accordingly, while the author is not aware of any cases in which the government arrested a patentee for false statements, this does not mean that it could not punish the patentee with a fine and/or imprisonment.44

45 18 U.S.C. § 1001. Section 1001, entitled “Statements or entries generally,” provides:
(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully --
(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
(2) makes any materially false, fictitious, or fraudulent statement or representation;
or
(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;
shall be fined under this title or imprisoned not more than 5 years, or both.

TABLE I

This compilation represents a twelve-year survey of Federal Circuit cases in which inequitable conducts has been an issue in patent infringement litigation. Cases of inequitable conduct on appeal from the Board to the Federal Circuit are omitted. Also omitted are cases that, even though involving inequitable conduct in litigation, the Federal Circuit made no express opinion on the matter.

A. Federal Circuit Affirms Inequitable Conduct Finding

Brasseler v. Stryker, 267 F.3d 1370, 60 U.S.P.Q.2d 1482 (Fed. Cir. 2001) (stating that given extreme short notice to file patent application due to potential on-sale bar, attorneys failed to conduct even minimal investigation pre- and post-filing to determine when sales occurred, summary judgment of inequitable conduct affirmed).

Bristol-Myers Squibb v. Rhone-Poulenc Rorer, 326 F.3d 1226, 66 U.S.P.Q.2d 1481 (Fed. Cir. 2003) (affirming an intent to deceive when inventors’ publication was not presented in parent application but was presented in later reissue; publication was material because it described examples that would not work yet patent described them as working).


GFI v. Franklin Corp., 265 F.3d 1268, 60 U.S.P.Q.2d 1141 (Fed. Cir. 2001) (stating applicant failed to disclose competitor’s earlier filed pending application and competitor’s brochures even though precise nature of discussion between applicant and competitor was to determine which application had priority).

Hoffmann-LaRoche v. Promega, 323 F.3d 1354, 66 U.S.P.Q.2d 1385 (Fed. Cir. 2003) (affirming two out of the three grounds of inequitable conduct: remedying, requesting further explanation on third ground; conduct concerned comparisons between claimed enzyme and prior art, false misrepresentation that experiments were run when they were not, and comparative examples).
Vague non-specific knowledge of another researcher rather than full and disclosable information).


Newell Window Furnishings, Inc. v. Springs Window Fashions Div., 15 Fed. Appx. 836 (Fed. Cir. 2001) (reversing district court’s ruling because failure to submit previously litigated settlement agreement and prior judge’s denial of preliminary injunction order that raised the spectre of patent invalidity, did not indicate an intent to deceive because every patentee has motive to settle lawsuits and get consent agreements of patent validity).

N. Am. Oil Co., Inc. v. Star Brite Distrib., Inc., 46 Fed. Appx. 629 (Fed. Cir. 2002) (vacating district court’s holding that patent was unenforceable due to inequitable conduct because it did not meet the threshold).


Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 64 U.S.P.Q.2d 1676 (Fed. Cir. 2002) (reversing trial court’s ruling of no inequitable conduct for further consideration because district court did not make any findings on inequitable conduct).


Upjohn Co. v. MOVA Pharm. Corp., 225 F.3d 1306, 56 U.S.P.Q.2d 1286 (Fed. Cir. 2000) (reversing holding that there was no intent to deceive in failing to disclose adverse test results, failing to describe the proper testing conditions, and failing to inform newly added inventors of the duty to disclose information).

C. Federal Circuit Affirms No Inequitable Conduct


B. Federal Circuit Reverses Finding of Inequitable Conduct


Juicy Whip v. Orange Bang, 292 F.3d 728, 63 U.S.P.Q.2d 1251 (Fed. Cir. 2002) (reversing jury finding and holding that declarations submitted regarding long-felt need and problems in the art were not false or only slightly misleading).


Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 56 U.S.P.Q.2d 1186 (Fed. Cir. 2000) (holding that district court erred in requiring a discussion of the relevance of submitted prior art, finding statements made about submitted prior art were not misleading because Examiner could have read reference himself and come to his own conclusions, and finding that the inventors only had
Abbott Labs v. Torpharm, 300 F.3d 1367, 63 U.S.P.Q.2d 1929 (Fed. Cir. 2002) (affirming summary judgment ruling that a single omission to submit x-ray diffraction study was not inequitable conduct).

Advanced Cardiovascular Sys. v. Medtronic, Inc., 265 F.3d 1294, 60 U.S.P.Q.2d 1161 (Fed. Cir. 2001) (affirming summary judgment of no inequitable conduct because no clear evidence that ACS's settlement agreement and attempt to stop possible interference was inequitable conduct).

Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 56 U.S.P.Q.2d 1332 (Fed. Cir. 2000) (finding no intent to deceive when Russian inventors permitted another person to sign the oath because Russian inventors were unfamiliar with technicalities of U.S. patent laws).


Allen Eng’g Corp. v. Bartell Indus., 299 F.3d 1336, 63 U.S.P.Q.2d 1769 (Fed. Cir. 2002).


Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 65 U.S.P.Q.2d 1385 (Fed. Cir. 2003) (affirming district court’s determination that none of the patents were unenforceable because no intent showed).


Catalina Lighting v. Lamps Plus, 295 F.3d 1277, 63 U.S.P.Q.2d 1545 (Fed. Cir. 2002) (affirming jury decision that “omitted” art was simply cumulative and that no intent to deceive was proven).


Duro Last v. Custom Seal, 321 F.3d 1098, 66 U.S.P.Q.2d 1025 (Fed. Cir. 2005) (stating omitted prior art was marginally relevant at best).

Eaton v. Rockwell Int’l, 323 F.3d 1332 (Fed. Cir. 2003) (affirming that alleged evidence of an intent to deceive was actually evidence of good faith).


Fiskars v. Hunt Mfg. Co., 221 F.3d 1318, 55 U.S.P.Q.2d 1569 (Fed. Cir. 2000) (sanctioning defendant for frivolous arguments that four references were withheld even though they were submitted and that patentee to re-emphasize importance of references to and affirming that an applicant is not under any duty to tell the Office twice about the same prior art).


Gliaxco, Inc. v. Novopharm, 52 F.3d 1043, 34 U.S.P.Q.2d 1565 (Fed. Cir. 1995) (affirming no inequitable conduct even though the affidavits comparing drug products were misleading, no intent to deceive shown).


Interactive Techs., Inc. v. Pittway Corp., No. 98-1464 1999 U.S. App. LEXIS 11166 (Fed. Cir. June 1, 1999) (affirming no inequitable conduct because allegedly withheld reference’s subject matter was actually submitted in the patent application text).

Jazz Photo v. Int’l Trade Comm., 264 F.3d 1094, 59 U.S.P.Q.2d 1907 (Fed. Cir. 2001) (holding that allegedly withheld prior art was simply cumulative art and thus was not inequitable conduct).


LNP Eng’g Plastics v. Miller Waste Mills, 275 F.3d 1347, 61 U.S.P.Q.2d 1193 (Fed. Cir. 2001) (holding even though no clear evidence of an intent to deceive when patent attorney only had portion of foreign prior art translated to determine its materiality, prior art cited in foreign prosecution was material and not cumulative).


Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 57 U.S.P.Q.2d 1699 (Fed. Cir. 2001) (finding no requisite intent to deceive shown, despite finding that the three incidents at issue were highly material).


Purdue Pharma L.P. v. Boehringer Ingelheim, 237 F.3d 1359, 57 U.S.P.Q.2d 1647 (Fed. Cir. 2001) (holding in the context of a preliminary injunction, Purdue was entitled to the injunction because Roxane Labs, a Boehringer company, did not sustain its burden of proving potential invalidity due to inequitable conduct).


D. Federal Circuit Finds Inequitable Conduct Even Though Lower Court Did Not


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APPENDIX I

INTERNATIONAL SEARCH REPORT

International application No. PCT/US94/21579

A. CLASSIFICATION OF SUBJECT MATTER

IPC1: G06P 3/00
US CL: 407/256

B. FIELD SEARCHES

Malicious documentation searched (classification system followed by classification symbols)

U.S. 3929901, 306, 310, 66105

Documents searched other than malicious documentation so that each document is included in the fields searched

Documents searched during the international search (name of data base used, where predictable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Date of the actual completion of the international search: 27 FEBRUARY 1999

Date of mailing of the international search report: 2.2 MAR 1999

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks

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