



A White Paper

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A CURRENT APPLICATION OF THE DOCTRINE OF INEQUITABLE CONDUCT BY THE FEDERAL CIRCUIT AND TIPS FOR THE PRACTITIONER

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This paper has been prepared by the Intellectual Property Owners Association Pharmaceutical Issues and Patent Law (U.S.) Committees to provide background to IPO members regarding the doctrine of inequitable conduct. It should not be construed as providing legal advice or as representing the views of IPO.

Inequitable conduct remains prominent in many patent disputes. It is a doctrine that is problematic and fraught with uncertainties that occasionally trip up even the most skilled patent practitioners. In this paper, we attempt to provide assistance to the patent practitioner by (1) discussing the current application of the doctrine of inequitable conduct by the Federal Circuit, including the standard of review and a split in the panel decisions by the court that has developed concerning the threshold level of intent required; and (2) providing useful Tips for the Practitioner for consideration during their practice of how to avoid, as best possible, frivolous allegations of inequitable conduct.

Doctrine of Inequitable Conduct

The Federal Circuit tried to settle the law on inequitable conduct in its *en banc* decision in *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (*en banc*). Since *Kingsdown*, the court has developed two conflicting lines of cases on inequitable conduct.

One line of cases applies a lower standard of inferred intent to deceive if it is determined that (1) highly material information is withheld, (2) applicant knew of the information and knew or should have known of its materiality, and (3) applicant gave no credible explanation for omission. *See, e.g., Ferring v. Barr Labs*, 437 F.3d 1181 (Fed. Cir. 2006).

A second line of cases applies a stricter standard that requires a “threshold level” of deceptive intent. *Star Sci. v. R.J. Reynolds*, 537 F.3d 1357 (Fed. Cir. 2008).

By comparison, the Supreme Court has required overt fraud in three inequitable conduct cases, as noted in Judge Linn’s concurring opinion in *Larson Mfg. Co. v. Aluminart Products Ltd.*, 559 F.3d 1317, (Fed. Cir. 2009) and in the certiorari petition for *Aventis Pharma v. Amphastar Pharms.*, 525 F.3d 1334 (Fed. Cir. 2008), *cert. denied*, 129 S.Ct. 2053, __ U.S. __ (2009). *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 809, 819 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 240, 243 (1944); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243 (1933).

Kingsdown

In *Kingsdown*, a panel of Chief Judge Markey and Circuit Judges Smith and Archer reversed a district court’s finding of inequitable conduct finding that the patentee’s actions did not support an inference of intent to deceive. *Kingsdown*, 863 F.2d at 873-874. The panel based its reversal on a finding that the facts did not amount to gross negligence. *Id.* More importantly, the entirety of

the Federal Circuit determined that gross negligence alone cannot justify an inference of intent to deceive. *Id.* at 876.

Kingsdown presented the Federal Circuit with an issue of first impression – whether the incorrect inclusion in a continuation application of a claim that contained allowable subject matter, but failed to meet the requirement of 35 U.S.C. § 112, ¶ 2 supported a holding of unenforceability due to inequitable conduct. *Id.* at 872. During the six-and-a-half year patent prosecution, the applicant received numerous rejections and filed numerous amendments. *Id.* at 869. In one Office Action, the Examiner stated that pending claim 50 recited allowable subject matter, but utilized terms that render the claim indefinite. *Id.* at 870. The applicant amended the claim, and the Examiner subsequently noted its allowability. *Id.* Since the Examiner had not allowed all of the claims proposed by the applicant, the applicant appealed the decision.

While the appeal was pending, the applicant filed a continuation application to include claims that covered a product of a competitor. *Id.* at 870. The new application included several previously approved claims along with new claims. Inadvertently, the applicant stated that new claim 43 corresponded to allowable claim 50. It did not. Instead, it corresponded to the earlier claim 50 that the Examiner had rejected as indefinite. The district court found that this error rendered the patent unenforceable. The district court inferred intent because the submission amounted to gross negligence and the inclusion of earlier claim 50 provided the applicant a better chance of proving infringement against the competitor. *Id.* at 871-872.

A three judge panel reversed the district court's finding stating that it would have been easy for the applicant to make this ministerial mistake and so it did not amount to gross negligence. Further, the panel rejected the district court's second basis finding that the district court did not consider the presence of other claims that may have provided a basis for the infringement allegation. *Id.* at 875.

Recognizing Federal Circuit precedent exists supporting the gross negligence standard applied by the district court, the Federal Circuit addressed four issues: (1) whether gross negligence compels a finding of intent to deceive; (2) whether inequitable conduct is a question of law; (3) the standard of review applied by the Federal Circuit; and (4) whether a finding of inequitable conduct renders all claims unenforceable. *Id.* at 876-877. Firstly, the Federal Circuit held that "gross negligence" does not itself support an inference of intent to deceive. All of the evidence, including evidence of good faith, "must indicate sufficient

culpability to require a finding of intent to deceive.” *Id.* at 876. Secondly, the Court held that the question of whether inequitable conduct occurred is equitable – and not legal – in nature. *Id.* Thirdly, the Federal Circuit held that it will apply an abuse of discretion standard during its review of lower court findings. Finally, the Federal Circuit held that inequitable conduct as to a single claim renders the entire patent unenforceable. *Id.*

Following, we address in more detail several of the issues discussed above, including the Federal Circuit’s standard of review and its application of the different threshold levels of intent.

Standard of Review

Since the standard of review that the Federal Circuit applies in reviewing a lower court’s holdings dictates the ultimate outcome of the appeal in many instances, we thought it worthwhile to discuss it further. The standard of review on appeal is deferential on all three determinations involved in inequitable conduct, putting the appellant at a disadvantage.

First, the threshold issues of materiality and intent are considered questions of fact. As such, these are subject to highly deferential review for substantial evidence (jury verdict) or clear error (bench trial). Under both standards, the reviewing court must affirm even if it disagrees with the factual finding, provided the reviewing court does not have a definite and firm conviction that a mistake was made (clear error), *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1543 (Fed. Cir. 1987), or some supporting evidence exists (substantial evidence). Substantial evidence exists when there is more than a “mere scintilla” of relevant evidence, such that “a reasonable mind might accept as adequate.” *Henkel Corp. v. Procter & Gamble Co.*, 560 F.3d 1286, 1288 (Fed. Cir. 2009).

Second, the ultimate determination of inequitable conduct is reviewed for abuse of discretion, as an equitable issue. This standard generally allows for reversal only if the decision is arbitrary or capricious, is based on legal error, or is based on clearly erroneous or unsubstantiated factual findings. *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1022 (Fed. Cir. 1986). In *Kingsdown*, 863 F.2d at 877 (citations omitted) the Federal Circuit expressed the standard as follows:

As an equitable issue, inequitable conduct is committed to the discretion of the trial court and is

reviewed by this court under an abuse of discretion standard. We, accordingly, will not simply substitute our judgment for that of the trial court in relation to inequitable conduct. “To overturn a discretionary ruling of a district court, the appellant must establish that the ruling is based upon clearly erroneous findings of fact or a misapplication or misinterpretation of applicable law or that the ruling evidences a clear error of judgment on the part of the district court.”

Lower Threshold Of Intent

Several recent Federal Circuit opinions appear to apply a lower threshold for determining intent to deceive than other recent opinions. These cases include *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008), *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007), *Aventis Pharma v. Amphastar Pharms.*, 525 F.3d 1334 (Fed. Cir. 2008), *cert. denied*, 556 U.S. ____ (U.S. Apr. 27, 2009) (No. 08-937) and *Ferring v. Barr Labs*, 437 F.3d 1181 (Fed. Cir. 2006).

In *Praxair*, a partially split panel of Circuit Judges Dyk, Bryson and Lourie affirmed a district court’s finding of inequitable conduct with respect to one patent and reversed with respect to a second. *Praxair*, 543 F.3d at 1310. Judge Dyk authored the opinion to which Judge Lourie concurred-in-part and dissented-in-part. The defendant based its inequitable conduct defense on the failure of the applicant to cite certain prior art, including the Max Light devices, a US patent and the existence of products containing Restricted Air Flow Orifices (“RFO”). To support its inequitable conduct finding, the district court focused on certain statements made during the prosecution that, in the district court’s view, the applicant could not have made had the USPTO known of the RFO art. *Id.* at 1312. Further, the district court noted that the patentee failed to provide testimony explaining its failure to disclose the prior art. *Id.* at 1313.

The panel opinion started by noting that the materiality and intent prong of inequitable conduct are separate and a finding of materiality alone does not give rise to a presumption of intent. *Id.* at 1313. The majority, however, continued its analysis by stating that an inference of intent to deceive is appropriate when: (1) highly material information is withheld; (2) the applicant knew of the information and knew or should have known of the materiality; (3) and the applicant fails to provide a credible explanation for withholding the

information. *Id.* Based on this methodology, the majority held that intent to deceive could be inferred from the failure to disclose the RFO art. *Id.* at 1315.

Judge Lourie dissented to the inequitable conduct finding concerning the RFO art. *Id.* at 1329. Judge Lourie argued that the majority's opinion failed to recite any evidence of intent to deceive. *Id.* Instead, the majority merely justified its inference based on that fact that the RFO art was well known. In Lourie's view, the district court conflated the intent with materiality.

In *Nilssen*, a panel of Circuit Judges Mayer and Lourie and District Court Judge Linares (sitting by designation), in a decision authored by Judge Lourie, affirmed a district court's finding of inequitable conduct with respect to fifteen patents related to electrical lighting products.¹ *Nilssen*, 504 F.3d at 1226. The fifteen patents included eleven patents that were part of the litigation and four patents that plaintiff had withdrawn shortly before trial. *Id.* The district court based its findings on a litany of mistakes that had occurred during the prosecution.² The errors identified by the district court include: (1) failure to disclose professional association between patentee and a declarant and a financial interest of the declarant; (2) failure to change "small entity status" after executing licensing agreement with larger entity; (3) intentional misclaiming of an effective filing date; (4) failure to disclose an ongoing litigation; and (5) failure to identify relevant prior art. *Id.* at 1227-1228.

The Federal Circuit panel held that although individually these mistakes may not rise to the level to support unenforceability, these numerous incidents, where the only explanation is inadvertency, may collectively support a finding of inequitable conduct. *Id.* at 1235. Citing *Ferring v. Barr*, the panel held that the relationships between a declarant and an applicant is material to the credibility and content of the affidavit. *Id.* at 1230. Thus, the district court had not erred with respect to its first basis. Further, the panel reiterated the proposition that infectious inequitable conduct can render related patents unenforceable. *Id.* As such, the panel held it was not an abuse of discretion for the district court to render a decision concerning the enforceability of the four patents that plaintiff withdrew from the case at a late stage.

¹ The Court laid out the standard under which it reviews lower court inequitable conduct findings. *Id.* at 1229. It appears this standard played a substantial part in the panel's ultimate determination.

² Initially, a patent attorney prosecuted the patents, but plaintiff began prosecuting the patents *pro se* during the later part of prosecution. *Id.*

In considering the remaining issues supporting the district court's analysis, the panel affirmed the district court. The panel refused to override the district court's credibility determination when considering intent with respect to the payment of a small entity fee. *Id.* at 1231-1232. Also, the panel stated that it is not necessary that an examiner rely on a claim for priority or that entitlement to an earlier priority be expressly argued in order to overcome prior art to support a finding of inequitable conduct. *Id.* at 1233. A claim of priority is inherently material as it may affect validity determinations by the USPTO or later district courts. Furthermore, the language of the MPEP shows that the existence of a litigation concerning a related patent is material. *Id.* at 1233-1234. Lastly, the fact that the withheld prior art references came before the applicant on numerous occasions supports the inference that the applicant intended to deceive the USPTO rather than a mere oversight on behalf of the applicant. *Id.* at 1235.

In *Aventis Pharma*, a split panel with Circuit Judge Prost authoring the panel decision that Circuit Judge Moore joined and Circuit Judge Rader dissented affirmed a district court's finding of intent to deceive. *Aventis Pharma*, 525 F.3d at 1337. An earlier panel had affirmed a finding that the withheld information was material. Thus, the majority affirmed the inequitable conduct finding. The withheld information concerned dosage data for certain examples in the patent and the prior art.

During the prosecution, Plaintiff submitted two declarations of a non-inventor employee that discussed the half-life comparison between the claim product and the prior art. *Id.* at 1339-1340. The second declaration argued that unexpected results supported patentability because the half-life of the claimed product was statistically significantly better than the prior art. *Id.* at 1340. Neither declaration mentioned that the comparison was made between different doses of the claimed compound and the prior art compound.

During the lower court proceedings, Plaintiff espoused several theories to counter the intent prong. Plaintiff argued that: (1) it was proper to use different dosages, because one should use the "clinically relevant dose" to determine therapeutic properties as opposed to composition properties; (2) that the half-life is independent of dose; and (3) that the omission was inadvertent. *Id.* at 1342. The district court rejected the first two positions as contradicted by the evidence. *Id.* at 1342-1343. The district court rejected the third as not credible considering the declarant's scientific qualifications. *Id.* at 1343.

As an initial matter, the majority noted that it reviews a district court's finding of intent to deceive for clear error. *Id.* at 1343. This standard requires that the appellate court must have a definite and firm conviction that a mistake has been made. The majority found that the district court had not clearly erred with its determination concerning the clinically relevant dosage argument and the half-life is dosage independent argument. *Id.* at 1347-1348. The majority upheld the district court's rejection of the testimony put forth by the declarant. Finally, the majority rejected the inadvertence argument because sufficient evidence of concealment existed to warrant the finding that the applicant intentionally withheld the information.

Circuit Judge Rader dissented because the record did not show clear and convincing evidence of intent. *Id.* at 1349. In his view, Federal Circuit case law restricts inequitable conduct findings "to only the most extreme cases of fraud and deceptive intent." *Id.* Judge Rader invited the entire Federal Circuit to revisit *Kingsdown*, "[i]n light of the rejuvenation of the inequitable conduct tactic." *Id.* at 1350. Judge Rader opined that a review is warranted because recently "the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct. Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic." *Id.* Judge Rader found the declarant's omissions, although negligent, did not rise to the level necessary to show intent. *Id.* at 1351-1352.

In *Ferring*, Circuit Judges Dyk and Mayer affirmed a district court's grant of summary judgment on unenforceability. *Ferring B.V.*, 437 F.3d at 1183. Circuit Judge Newman dissented in a strongly worded decision. *Id.* at 1195. The district court based its holding on the failure of the applicant to inform the USPTO that several declarants had previous dealings with the plaintiff before filing the declarations in question.

During the prosecution of the patent-in-suit, the USPTO "suggested that applicants obtain evidence from a non-inventor" to support the applicant's understanding of a particular claim term. *Id.* at 1184. Over the course of several years, the applicant submitted declarations from four knowledgeable scientists, which ultimately resulted in the issuance of the patent. *Id.* at 1185. The district court found intent because the applicant failed to inform the USPTO that the declarants had various past relationships with Ferring. More specifically, one declarant received research funding from 1985-1986 to conduct a clinical study, but that declarant was not receiving funding when he submitted the declaration.

A few years before submitting the declaration, one of the declarants had been Ferring's pre-clinical research director and a paid consultant after he left Ferring. A third declarant had worked on several projects funded by Ferring in the years before he submitted his declaration. Lastly, several declarants did not include a CV with their declarations.

The majority agreed with the district court that the declarations were highly material and that the past relationships were significant. *Id.* at 1190. With respect to intent, the majority stated that summary judgment is appropriate where the record establishes (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding of the information. *Id.* at 1191. In the majority's view, the fact that the USPTO asked for "non-inventors" evidence put the applicants on notice that the USPTO was seeking disinterested declarants. *Id.* at 1192.

In her dissent, Judge Newman argued that the majority returned inequitable conduct jurisprudence to the pre-*Kingsdown* days by rejecting the objectivity that *Kingsdown* sought to bring to inequitable conduct determinations. *Id.* at 1196. In her view, the majority imposed "a positive inference of wrongdoing, replacing the need for evidence with a 'should have known' standard of materiality from which deceptive intent is inferred, even in the total absence of evidence." *Id.*

Higher Threshold Of Intent

Another line of cases applies a stricter standard that does not allow inferring intent absent evidence thereof; instead, this line of cases requires a "threshold level" of deceptive intent. *Star Sci. v. R.J. Reynolds*, 537 F.3d 1357 (Fed. Cir. 2008).

The Federal Circuit directly contradicted the *Praxair* line of cases in *Star Sci. v. R.J. Reynolds*, 537 F.3d 1357 (Fed. Cir. 2008) by stating the patentee "need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive . . ." The court further noted that inference of intent must be "the single most reasonable inference able to be drawn from the evidence". The Federal Circuit reversed the district court's ruling of inequitable conduct, because "RJR cannot carry its burden simply because Star failed to prove a credible alternative explanation." And, while a court can infer intent from indirect evidence, "no inference can be drawn if there is no evidence, direct or indirect, that can support the inference."

At issue were a patent and its continuation-in-part (CIP) application on a tobacco curing method to reduce carcinogenic nitrosamines. Defendants argued intent to deceive the PTO, because the applicants never disclosed in the patent or CIP a letter from a consultant commenting on old tobacco curing technology in China. The applicants switched law firms in mid-stream and used a third law firm to mediate the transfer. The district court found not credible Star's testimony that it switched firms for performance reasons.

In reversing inequitable conduct on the parent patent, the Federal Circuit did not discuss materiality. But the court apparently could have reversed on both patents for lack of materiality. The Federal Circuit reversed inequitable conduct on the CIP by finding the omitted letter cumulative and not material. The opinion quotes a single claim as representative for both patents, and the CIP differed from its parent only in a revised statement in the specification about nitrosamines.

In *Ariad Pharm. v. Eli Lilly*, 560 F.3d 1366 (Fed. Cir. 2009), the Federal Circuit held that a district court must make "independent findings of both materiality and intent." The court reasoned that "Lilly cannot prove deceptive intent by clear and convincing evidence simply by relying on the materiality of the errors. Rather, there must be clear and convincing evidence of 'culpable' conduct."

The claims at issue in *Ariad* were methods for regulating gene expression. The patentee failed to disclose that a Figure in the specification, which was relied upon by an attorney in a subsequent response during prosecution, was an incomplete gene sequence. Also, the patentee failed to disclose to the PTO four references that were not prior art, but were relevant to support an inherency argument. Here, the scientist familiar with the four references testified that he did not want to inundate the USPTO. The Federal Circuit noted that Lilly failed to show that the scientist understood the relevance of the four references. Despite the reliance on an incomplete Figure and a failure to submit references relative to inherent anticipation, the Federal Circuit nonetheless affirmed the district court ruling of no unenforceability.

In *Astrazeneca v. Teva*, 583 F.3d 766 (Fed. Cir. 2009), the Federal Circuit affirmed the lower court's grant of summary judgment denying inequitable conduct because there was not enough evidence to show a material withholding with an intent to deceive. *Id* at 769. The patent at issue was directed to quetiapine, the active ingredient in the atypical antipsychotic SEROQUEL™. The challenger's main assertion for its inequitable conduct allegation was that

the patentee who had submitted an initial IDS consisting of several compounds failed to include internal test data for those compounds and later deliberately misled the examiner when submitting a declaration by the inventor containing the test data directed towards a different set of compounds. *Id.* at 770-773.

The patentee countered the assertion and explained that the comparison data from different compounds in the IDS provided in the declaration was in direct response to the examiner for more structurally similar compounds, as requested in an Office Action. *Id.* at 773-774. The Federal Circuit affirmed that the patentee properly addressed the closest prior art, and that the omitted test data was not material because the compounds were not the structurally closest compounds.

The court further noted the only evidence of intent offered by the challenger was the failure of the patentee to include internal test data for the compounds identified in the IDS. *Id.* 776-777. No other evidence was offered of deceptive intent. Judge Newman sitting with Judges Rader and Prost stated, “[t]he law is clear that ‘inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.’” *Id.* (citing to *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003)). The court further stated that “[a]n applicant would not know how much of its research effort must be filed with the PTO, although of no interest to the examiner, or run the risk of accusation of wrongdoing no matter where the line is drawn.” *Id.*

Finally, and most recently, in *Exergen Corporation v. Wal-Mart Stores, Inc. and S.A.A.T.*, 575 F.3d 1312 (Fed. Cir. 2009), where the asserted patents are directed toward infrared thermometers that measure human body temperature, the Federal Circuit affirmed the lower court’s denial of SAAT’s motion to amend its pleading to include an allegation of inequitable conduct because of the failure by SAAT to satisfy the heightened pleading requirement under Federal Rule of Civil Procedure 9(b). *Id.* at 1316.

Exergen filed the suit on July 27, 2001 alleging infringement of two patents – the ‘813 and ‘205. *Id.* at 1317. The ‘685 patent issued about two months later and was subsequently added to the suit on October 2, 2001. *Id.* On September 6, 2002, SAAT filed a motion to amend its answer to add inequitable conduct as an affirmative defense against the ‘685 and ‘813 patents. *Id.*

Specifically, SAAT stated in its pleadings that Exergen was aware of several prior art patents, including one that had already been cited during the prosecution of the '205 patent which is one of the three patents in suit, but failed to cite them prior to issuance of the '685 patent. *Id.* at 1325-1326. It also stated that Exergen made knowingly inconsistent arguments to the patent office during the prosecution of the '685 patent. *Id.* at 1326. Based on these facts, SAAT argued that it had met the threshold of Rule 9(b) under the First Circuit's "time, place, and content" test for pleadings. *Id.*

The Federal Circuit in its discussion of the inequitable conduct initially pointed out that the law to be applied to determine whether such pleading satisfies the particularity standard under Rule 9(b) is its own law, not the regional circuit's threshold. *Id.* In this case, this standard is notably different than the standard adopted by the First Circuit. Specifically, the court stated:

In sum, to plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although 'knowledge' and 'intent' may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Id. at 1328-1329.

The Federal Circuit found that allegations in SAAT's pleading were deficient on two accounts: (1) particularity of the facts alleged; and (2) reasonableness of the inference of scienter. *Id.* at 1329.

With regards to the first deficiency, i.e., the failure to allege the facts, the court pointed out the pleading generally refers to "Exergen, its agents and/or attorneys," but does not mention a specific individual – the "who." *Id.* It also indicated that the pleading failed to state which claims and claim limitations the

withheld references were relevant to and where in the withheld references the material is found – the “what” and “where.” *Id.* Lastly, the court stated the pleading did not identify those claim limitations that were allegedly absent from the information of record to show why such withheld references are not cumulative and how an examiner would have used such references in assessing the patentability of the claims – the “why” and “how.” *Id. at 1329-1330.*

As to the second deficiency, the court held that the pleading does not provide a “factual basis to infer that any specific individual, who owed a duty of disclosure in prosecuting the ‘685 patent, knew of the specific information in the [allegedly withheld references] that is alleged to be material to the claims of the ‘685 patent.” *Id. at 1330.* The court further noted that a reference can consist of numerous pages whereby “its various teachings may be relevant to different applications for different reasons. Thus, one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material *information* contained in that reference.” *Id. at 1330.* (emphasis in original) (citation omitted).

SAAT’s assertion that the failure to cite these prior art references in related applications can give rise to inferring deceptive intent was rejected by the court. *Id. at 1331.*

The mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct. Indeed, SAAT’s pleading does not contain specific factual allegations to show that the individual who had previously cited the [allegedly withheld patent] knew of the specific information that is alleged to be material to the ‘685 patent and then decided to deliberately withhold it from the relevant examiner.

Id.

Tips for the Practitioner

The uncertainty surrounding the different threshold levels of intent applied by the courts combined with the unique nature of each set of facts in a

particular case make it nearly impossible for a patent practitioner to act in a predictable and “equitable” manner during the prosecution of a patent application.

To assist the patent practitioner in avoiding later allegations of inequitable conduct, facts relating to either the materiality and/or intent from numerous cases decided recently by the Federal Circuit involving allegations of inequitable conduct, regardless of the Court’s ultimate finding on inequitable conduct, were considered and used to develop useful practice tips. The practice tips below, although derived from pharmaceutical-specific cases, are general tips for any practitioner.

Practice Tip: Establish a policy or, at a minimum, a consistent pattern, that is implemented for all patents and patent applications within your practice or company, which provides guidance for making decisions when disclosing references to the USPTO.

Teva argued Pfizer committed inequitable conduct by failing to disclose two prior art references that Pfizer was aware of and in possession during the prosecution of the applications which led to the patents-in-suit. These prior references disclosed chemical compounds that had a different heterocyclic core than the claimed invention. Pfizer argued these references were not material because of this difference. Not only was this a significant distinction as explained by Pfizer and one of the co-inventors, but Pfizer also “presented evidence of its own highly consistent pattern of disclosing references having the same heterocyclic core in the prosecution of hundreds of its other patent applications.” In fact, Pfizer had disclosed the prior art reference in the prosecution of an application having the same heterocyclic core. The Federal Circuit recognized the district court’s weight given to this “highly consistent pattern” as strong evidence supporting Pfizer’s reason for not disclosing this reference and affirmed the lower court finding that Teva failed to show materiality and intent. *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc*, 518 F.3d 1353, 1367 (Fed. Cir. 2008)(Dyk*, Michel, Kennelly)

Practice Tip: Ask your declarant prior to submitting a declaration if he or she has made any conflicting statements in the past, such as prior articles, to avoid any misleading statements. If so, or even if it is questionable, also submit the reference to the Patent Office.

Par argued Pharmacia filed a declaration with an intent to deceive the Patent Office on a point of material significance. Pharmacia in response to an

obviousness rejection submitted a declaration which consisted of a statement that conflicted with an article co-authored by the declarant. The article was not submitted to the Patent Office. Specifically, the statement in the declaration indicated that “even at dosages of 45 µg the 20-ethyl compound does not cause statistically significant decrease in IOP.” Meanwhile, the article stated that “[t]opical application of [45 µg the 20-ethyl compound] causes a statistically significant IOP reduction....” The lower court found that the declarant “knew or should have known [that the declaration] was inaccurate and misleading” and the declaration was crucial, and therefore material, to overcoming the rejection. The lower court inferred intent from the circumstances and found inequitable conduct. The Federal Circuit affirmed. *Pharmacia Corporation v. Par Pharmaceutical, Inc.* 417 F.3d 1369 (Fed. Cir 2005)(Rader*, Schall, Linn)

Practice Tip: Avoid repeatedly relying on or arguing to the Patent Office “results” which were not performed but only obtained through insight, without informing the Patent Office.

Purdue made repeated representations to the Patent Office, without any proof at the time the assertions were made or prior to the issuance of the patent that “it had discovered its controlled release oxycodone formulation controlled pain over a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids.” In addition, Purdue also during prosecution referred to the four-fold dosage range as a “result” on several occasions and emphasized the “clinical significance” of its discovery. While it may be irrelevant if an invention was discovered by insight or experiment, the Federal Circuit found the omission to the Patent Office was material not because of a failure to inform the Patent Office whether a “surprising discovery” is based on insight or experiment, but rather because Purdue’s arguments in addition to their reliance on the discovery used language that suggested clinical trials had been performed to support the reduced dosage range. The Federal Circuit, upon panel rehearing; however, vacated the lower court’s finding of inequitable conduct and remanded it to assess intent and re-assess level of materiality, which the Federal Circuit, contrary to the lower court, stated is low. *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006)(Plager*, Gajarsa, Linn)

Practice Tip: Avoid the use of past tense to describe Examples and Results if specified steps were not actually performed. If past tense is mistakenly used, correct immediately, and certainly if the Examiner relies on it, to prevent any misunderstanding.

Novo used past tense in an Example, which the Examiner relied upon for enablement, and therefore was considered material, although Novo never successfully performed the entire experiment. Specifically, Novo indicated in Example 1 that a fusion product “was purified” from an extract, that it “was evaluated” and “was then treated” with an enzyme. Applicant also submitted expert testimony related to the steps described in Example 1, upon which the Board relied upon in a further interference proceeding, further suggesting its materiality. In addition, the lower court found intent because “Novo nine years after it first submitted Example 1 to the PTO knew or should have known that the examiner would have considered” Example 1 as important to an enablement inquiry. Federal Circuit affirmed lower court’s finding of inequitable conduct. *Novo Nordisk v. Bio-Technology*, 424 F.3d 1347 (2005)(Schall*, Archer, Bryson)

Practice Tip: Submit English language translations of complete references instead of only the Abstract if there is any question about the remainder or specifics of the reference.

Hercon argued Key had committed inequitable conduct when it only submitted to the Patent Office the English-language abstract of a Japanese patent application instead of submitting the complete translated application. It was noted the abstract describes, in general, terms an adhesive transdermal formulation containing a polymer, cross-linking agent and drug. The abstract however never mentioned any specific drug. But, the application disclosed nitroglycerin, which is the subject of claims at issue, as a suitable drug. The Federal Circuit affirmed the district court’s finding of no inequitable conduct, relying primarily on the lack of intent. Despite its holding, however, the Federal Circuit noted the issue was a “close one” and found the district court’s finding of no materiality “problematic.” *Key Pharmaceuticals v. Hercon Laboratories, Inc.*, 161 F.3d 709 (Fed. Cir. 1998)(Plager*, Mayer, Clevenger)

Practice Tip: Partial disclosure of comparative test results is not necessarily inappropriate; however, err on the side of submission of full comparative results to avoid a finding of minimum level of materiality.

Impax asserted Aventis submitted only certain comparisons while it withheld comparative testing data relating to several compounds that were part of the same testing, where some of these withheld compounds gave better results with at least one of the two parameters being considered for effective treatment. The district court found the withheld test data was not material because of several reasons, including “none of the []compounds from the withheld tests produced results significant in both parameters” and that results for the

compounds were not inconsistent with the representation made to the Examiner. The district court however hinted that “even if it did find a ‘minimal level of materiality’ there was an absence of intent to deceive.” The Federal Circuit affirmed the district court’s finding of no inequitable conduct. *Impax Laboratories, Inc., v. Aventis Pharmaceuticals, Inc.*, 468 F.3d 1366, 1376-77 (Fed. Cir. 2006)(Schall*, Rader, Prost)

Practice Tip: Review closely and consider ways to avoid blurring distinctions between different subject matter, such as dogs and humans, e.g., use separate paragraphs, explicitly refer to materials relied upon, when preparing a declaration so the Examiner is not misled.

Dr. Reddy’s argued Lilly committed inequitable conduct by intentionally making misleading material statements in a declaration. Specifically, it was argued that the declaration created a false impression that improved cholesterol findings from a dog study could be extrapolated to humans. The district court disagreed. In fact, the declarant (physician) separated his discussion concerning the study in dogs and benefits in humans into different paragraphs. The declarant also expressly relied on declarations from others (pharmacologist and statistician) for the basis of his clinical statements regarding the dog studies. The Federal Circuit affirmed the district court’s finding of no inequitable conduct. *Eli Lilly and Company v. Zenith Goldline Pharmaceuticals, Inc.* 471 F.3d 1369 (Fed. Cir. 2006)(Rader*, Schall, Gajarsa)

Practice Tip: Avoid leaving out comparison data in a declaration even if it shows conflicting results.

Syntex submitted a declaration that contained data purporting to show the unexpected superiority of claimed surfactant compound (octoxynol 40) in comparison to similar compounds (octoxynols). The declaration excluded data showing octoxynol 12.5 which was capable of similar results as claimed compound. The district court did not find this data to be material, and therefore did not find inequitable conduct, because it found the purpose of the declaration was to show that not all octoxynols work, not to show that octoxynol 40 was the only octoxynol that worked. The Federal Circuit affirmed the lower court’s decision finding no inequitable conduct but not because of both lack of materiality and intent, as the district court held, but only lack of intent (based on credible testimony from inventors). The Federal Circuit found the withheld data to be material to the general statement in the declaration, just not sufficiently

material to overcome lack of intent. *Syntex (USA) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005)(Gajarsa*, Prost, Clevenger)

Practice Tip: Describe the constituent makeup of any demonstrations or experiments discussed in a declaration, and submit a follow up declaration if necessary. Also, it is not necessary to include failed experiments if the amount or range of a constituent is outside of the claim scope.

Mova argued Upjohn committed inequitable conduct by intentionally misrepresenting facts in its declaration. Specifically, Upjohn submitted a declaration that showed a comparison between two formulations. The Examiner had indicated the ingredients and amounts used were absent. Upjohn submitted a second declaration that stated the constituents of the formulations. Mova asserted that Upjohn intentionally misrepresented that an ingredient was present in the formulation. The Federal Circuit sided with Upjohn finding that among other things the second declaration remedied any ambiguity in the first declaration.

Also, Mova argued Upjohn failed to submit tests it had performed from several years prior to its declaration. Particularly, Upjohn ran tests having a high concentration of an ingredient that were unsuccessful. Upjohn argued the concentration used in the failed tests was outside of the scope of the claims. Despite an ultimate finding of inequitable conduct by the district court, the Federal Circuit reversed. *Upjohn Company v. Mova Pharmaceutical Corp.*, 225 F.3d 1306 (Fed. Cir. 2000)(Newman*, Skelton, Archer)

Practice Tip: Unless you are sure it is irrelevant, disclose dosage information in prior art comparisons, even if not specifically requested.

Teva argued Aventis committed inequitable conduct by failing to disclose dosages involved in comparisons with prior art during prosecution. During prosecution Aventis submitted an inventor declaration and results from a statistical analysis showing that the claimed low molecular weight heparins exhibited significantly longer half-life than formulations prepared in the prior art. The district court agreed with Teva, holding that the representation by Aventis was material to patentability and a strong inference of intent existed because Aventis provided no credible explanation for comparing half-lives at different doses and because comparisons of half-lives at the same dose showed little difference in half-live. On appeal, Aventis argued that the district court erred in finding materiality because the examiner had not requested dosage

information and thus it could not have been material to patentability. The Federal Circuit affirmed the district court's finding of inequitable conduct holding that the dosage information was material to patentability and Aventis did not disclose the information to the Examiner, or did so in a misleading way. *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d. 1334 (Fed. Cir. 2008)(Michel*, Clevenger, Schall)

Practice Tip: Conduct specific inquiries and searches for articles related to patentability that were published by named inventors and disclose them.

Rhone-Poulenc failed to disclose an article published by the inventors relating to the synthesis of taxol during prosecution of a patent on synthesis of taxol. The article was found to be material notwithstanding the fact that it did not lead an examiner in reissue proceedings, during which the article was disclosed, to reject the claims. In rejecting Rhone-Poulenc's arguments regarding materiality the Federal Circuit focused on the "reasonable patent examiner" standard and found testimony of Rhone-Poulenc's witness to be unpersuasive because it was self-serving and not supported by either objective evidence or by the testimony of an independent expert. The Court further relied heavily on the district court's intent findings and the fact that the accused patent agent did not appear at the intent hearing. *Bristol-Myers Squibb Company v. Rhone-Poulec Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003)(Prost*, Clevenger, Schall)

Practice Tip: Disclose search reports and prior art from related foreign patent applications, especially if references are identified as particularly relevant.

Following a district court finding of unenforceability for failure to disclose a referenced cited in corresponding EPO application's search report, Cordis appealed to the Federal Circuit. The Federal Circuit agreed that the reference cited by EPO, and identified as "particularly relevant if combined with another", was material and vacated and remanded for further findings on intent element of inequitable conduct. *Cordis Corporation v. Boston Scientific Corporation*, 188 Fed. Appx. 984 (Fed. Cir. 2006)(Mayer, Bryson*, Prost)

Practice Tip: Search for and disclose copending applications, including rejections and prior art cited, when claims are closely related.

Teva and Dr. Reddy argued that Eisai committed inequitable conduct by intentionally withholding a related copending application, rejections from that copending application and a prior art reference cited during the prosecution of

the Eisai's rabeprazole application. The district court held that while the copending application claimed the ethyl homolog of rabeprazole, Eisai's scientists never referred to the compound by that name or related it to rabeprazole in any way. The Federal Circuit affirmed the district court's finding of no inequitable conduct holding that Teva and Dr. Reddy presented no direct evidence of deceptive intent nor any evidence to support an inference of materiality.

Interestingly, defendants had argued that had the copending application been disclosed, the Examiner in the rabeprazole application might have made a provisional double patenting rejection – a rejection that the Court recognized had little consequence and could be easily overcome. *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008)(Rader*, Linn, Prost)

Practice Tip: Disclose relationships between patentee and declarants, even if not specifically requested by Examiner. If possible, use disinterested declarants.

In response to the Examiners' request for evidence from a non-inventor, the patentee submitted numerous declarations to support their interpretation of the term "peroral". Barr argued that failure to disclose the relationship between the patentee and declarants after PTO asked for "evidence from a non-inventor" constituted inequitable conduct. The Federal Circuit affirmed summary judgment of inequitable conduct finding that it was important for Examiner to know that the declarants were not connected with patentee in any way in order to determine to what extent he should rely on those declarations. The court found that the relationships were not isolated or confined to distant past and the declarants clearly had ongoing and mutually beneficial relationships with patentee. The court also recognized that a declarant's prior relationship with the patent applicant may be material and nondisclosure of such interest had previously been grounds for inequitable conduct. *Ferring B.V. and Aventis Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006)(Newman, Mayer, Dyk*)