

Legal Updates & News

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The Opportunities and Challenges Presented by the Revitalized Defense of Inequitable Conduct to Patent Infringement: Thoughts for Patent Litigators and Prosecutors

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by [Jose L. Patiño](#), [James J. Mullen](#)

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As we have previously chronicled,^[1] the defense of inequitable conduct has been reinvigorated by recent Federal Circuit case law bringing a new vitality to an affirmative defense it previously discouraged as a “plague.”^[2] In the latest development on this front, *McKesson Info. Solutions, Inc. v. Bridge Medical Inc.*,^[3] the Federal Circuit underscored that this sea change in approach is comprehensive, broadly applicable to all aspects of the duty of candor owed to the PTO, and is not contingent on when the conduct at issue occurred. The apparent new regime regarding unenforceability counsels patent litigators and practitioners alike to conform their practices to a more creative outlook on the duty of disclosure.

The *McKesson* case concerned the concurrent prosecution of a series of co-pending applications in the mid-1980s, pertaining to an interactive, bar coding-based system for use in hospitals to ensure that the right patient, receives the right medication, at the right dosage, for the right ailment, and at the right time.^[4] Only one of the patents that issued from these co-pending cases, the '716 patent,^[5] was asserted in the litigation. The plaintiff, McKesson Information Solutions, was not involved in the prosecution of the '716 patent, and owned that patent only by virtue of a merger with another company. The defendant, Bridge Medical, asserted the affirmative defense of inequitable conduct, and charged that the patent prosecutor, who had never been retained or supervised by McKesson, had withheld (1) prior art made of record in the related co-pending applications from the '716 Examiner; (2) two rejections made by another examiner in a co-pending case; and (3) an allowance made by the '716 Examiner in another co-pending application under review by the same Examiner.^[6] In response, the patent prosecutor argued that he could not recall why he did what he did more than seventeen years before when these patents were prosecuted, that the art withheld from the examiner in the '716 case was cumulative, and that it was not the practice of his or any other law firm to cite office actions in the 1980s.^[7]

The *McKesson* court affirmed the district court's finding that the '716 patent was unenforceable for inequitable conduct because the patent prosecutor had withheld these three categories of information under circumstances giving rise to an inference of an intent to deceive.^[8] In so holding, the Federal Circuit clarified some of its recent decisions to underscore the breadth of the disclosure obligation and the diversity of the circumstantial evidence upon which a finding of inequitable conduct can be made. It revisited its decision in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*,^[9] where it had held that selectively withholding prior art from the PTO while disclosing it to another Federal agency (in that case, the FDA), supports an inference of an intent to deceive.^[10] The *McKesson* court held that *Bruno* applied to material information selectively withheld *within* the PTO, that is, to withhold material art made of record before one examiner while withholding it from another can serve as circumstantial evidence of deceptive intent.^[11] It was no defense, moreover, that the patent prosecutor had disclosed the existence of the co-pending applications to the '716 Examiner where the withheld prior art could be found. The court explained that notwithstanding its ruling in *Akron Polymer Container Corp. v. Exxel Container, Inc.*,^[12] which had found disclosure of co-pending applications to be inconsistent with an intent to deceive,^[13] the district court did not clearly err when it considered that disclosure but found it to be outweighed by the failure to provide a credible explanation for failing to also co-cite the withheld art.^[14]

The *McKesson* court also expounded on its decision in *Dayco Prods., Inc. v. Total Containment, Inc.*,^[15] where it held, among other things, that an office action containing the “contrary decision of another examiner reviewing a *substantially similar* claim in a co-pending case” is material information subject to disclosure.^[16] It explained that it did not intend to suggest in *Dayco* that substantial similarity was required for office actions to be material in a co-pending case. As long as the evidence shows clearly and convincingly that the contrary decision would have been important to the examiner’s consideration of patentability in the co-pending case, the district court may find a rejection issued in a co-pending case subject to the duty of disclosure without regard to substantial similarity.^[17]

Continuing its guidance with respect to the disclosure of office actions, the *McKesson* court also addressed notices of allowance. It held that the patent prosecutor breached his duty by failing to make of record in the '716 case the allowance of a co-pending application by the same examiner.^[18] Because the allowance in the related case “plainly gives rise to a conceivable double patenting rejection,” it was material and subject to disclosure.^[19] Further, that it was the same examiner who allowed the co-pending case was not of consequence to the duty of disclosure. Adopting the reasoning of the Manual of Patent Examining Procedure (the “MPEP”), and the Seventh Circuit’s 1972 decision in *Armour & Co. v. Swift & Co.*,^[20] the Federal Circuit held that the patent prosecutor was not entitled to assume that a busy examiner “would recall his decision to grant the claims” in the co-pending case.^[21]

And there is much more to take note of in the *McKesson* court’s treatment of inequitable conduct. For example, the patent prosecutor offered certain explanations for his conduct, although he could not specifically recall the prosecution seventeen years before. Those explanations were deemed to lack credibility, and hence supportive of an intent to deceive under the law,^[22] in part because there was no written evidence.^[23] The court held that the district court did not clearly err in its finding that the prosecutor’s argument that he must have believed the prior art withheld from the '716 prosecution was cumulative was not credible, because there were no notes or other documentation from the prosecution file offered to corroborate the prosecutor as is recommended by the MPEP.^[24] Notably, this is the first point of law from *McKesson* that has been cited in support of a finding of inequitable conduct in a subsequent case.^[25]

In addition, the *McKesson* prosecutor contested the charge that he must have known of the materiality of the withheld prior art because he cancelled certain claims in the co-pending prosecution in light of that art, noting that it was “legitimate and acceptable practice” to cancel claims for later prosecution to position the remaining claims for allowance, and noting that he “explicitly stated that he was not acquiescing in the rejection but reserving the right to bring the claims in a further application.”^[26] The Federal Circuit held that cancellation of the claims was still evidence that the rejection in the co-pending case “could not be easily overcome” because of the withheld art, and as a consequence, “whether it is characterized as ‘acquiescence’ or ‘legitimate and acceptable practice’ [it] is evidence of materiality.”^[27] Further rejecting the notion that a customary patent prosecution practice is a defense to inequitable conduct, the court also observed that where a prosecutor either knows or should have known, based on the MPEP or otherwise, that a common practice may breach the duty of candor in a particular instance, it is “untenable” to rely on that practice in response to the charge of inequitable conduct.^[28]

The evolution of the case law offers the patent litigator a number of strategic approaches for the advancement and defense of inequitable conduct cases. When assessing the response to an assertion of patent infringement, the question of unenforceability now deserves the same “deep dive” that is commonplace for invalidity. The file history must be assessed with care, not only to determine what the inventors and the patent prosecutors knew, but also to determine what they should have known that was either not disclosed or disclosed in a misleading fashion. The early assistance of a patent law expert may now be vital. Special attention is deserved by patents emerging from co-pending cases to determine whether selective disclosure has occurred, and to consider whether office actions containing important information relating to the patentability of the patent at issue were disclosed as required.

For those litigators on the defense side of the issue, the guiding principle is now that all claims of inequitable conduct are to be taken seriously, even those apparently innocuous acts or decisions the patent bar may call “standard practice.” The duty of candor as codified at 37 C.F.R. § 1.56 makes no such distinction, and the danger of relying on that concept is featured prominently in *McKesson*. Moreover, while developing a defense to the merits of the charge is an appropriate mission, consider whether an error or mistake should be conceded. It remains the law that even “gross negligence” will not support a finding of inequitable conduct.^[29] This is an unusual area of the law where pleading *nolo contendere* on the facts can set one free, but the impulse to contest must be battled to

find the way to plead it.

The holdings in *McKesson* also present patent prosecutors with an array of issues to address. Measures will have to be developed to mitigate the risk imposed by the greater threat of inequitable conduct charges that can stick. *McKesson*'s holding that all material prior art references must be disclosed to the Patent Office is certainly not news to a patent attorney. But the requirement that material office actions from related cases must be disclosed to meet the duty of candor may be new to some. Prosecutors should now review clients' patent estates to identify pending cases that could be characterized as containing overlapping subject matter and target those cases for the supplemental disclosure of office actions from related cases.

There may be a temptation to resist as an anachronism the holding of *McKesson* regarding the materiality of office actions in co-pending cases before the same examiner. During prosecution of the patents at issue in *McKesson*, a busy examiner would need to request a physical file and wait for some time for delivery in order to check matter in a co-pending case, where now it is electronically available instantly. But the *McKesson* court did not relegate this holding to the bygone era. Patent prosecutors must thus be sensitive to this requirement in the context of co-pending cases before the same examiner.

Patent prosecutors will also soon face an added degree of complexity in their effort to meet the duty of disclosure more clearly defined in *McKesson*. The PTO promulgated proposed rules in the summer of 2006, including an overhaul of the rules governing Information Disclosure Statement (IDS) practice.^[30] The proposed rules include a requirement to characterize disclosed references when more than twenty (20) references are submitted to the PTO. The characterization consists of applicants stating which portion of the reference is considered material and to which portion of the application the material relates.^[31] In the post-*McKesson* world, applicants prosecuting applications in families with multiple members will likely reach the twenty-reference threshold quickly and implicate characterization in most cases. Prosecutors should be prepared to spend more time on applications to adequately characterize the references.

To better position cases to address the forthcoming IDS rules and the impact of *McKesson*, prosecutors should consider adopting a comprehensive program for managing matter that may be subject to disclosure. A separate physical file should be established to maintain the art that presents itself during the prosecution of a patent application. The prosecutor should evaluate whether notes should be prepared regarding each reference reviewed, which *McKesson* identifies as a practice to be considered.

Going forward, prosecutors will need to be sensitive to the subject matter being pursued by a client across the entire scope of that client's patent portfolio. Heightened scrutiny of pending claims with an eye to how those claims overlap will need to be shown to identify patent families in which cross-disclosure is appropriate. This heightened level of scrutiny is particularly important for larger clients who use multiple outside patent prosecutors to handle their cases. This arrangement can easily produce a situation where references in one family are not cross-disclosed in another that contains overlapping subject matter because no single entity is sensitive to the relevant issues. If nothing else, careful supervision of the processes used to meet an applicant's duty of candor will go far to minimize a negative impact from *McKesson*.

The apparent new direction from the Federal Circuit on the viability of inequitable conduct claims will present more questions than answers in the near term. One thing is certain: allegations of inequitable conduct will take greater prominence in patent litigation. But as the *McKesson* teachings are digested by patent litigators and prosecutors, and incorporated into their practices, the heightened attention to disclosure requirements may very well produce more stable and defensible patents.

Footnotes:

[1] E. Wilson, "The Resurgence of Inequitable Conduct as a Defense to Patent Infringement (The Special Care Required When Submitting Affidavits to the PTO)," *Intellectual Property Quarterly*

Newsletter, Spring 2007.

[2] *E.g., Allied Colloids Inc. v. American Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995); *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

[3] 487 F.3d 897 (Fed. Cir. 2007). Morrison & Foerster was counsel of record for prevailing party, Bridge Medical, Inc., both at trial and on appeal.

[4] *See McKesson Info. Solutions*, 487 F.3d at 902.

[5] U.S. Patent No. 4,857,716.

[6] *See McKesson Info. Solutions*, 487 F.3d at 907-08.

[7] *See id.* at 908-12.

[8] *Id.* at 901-02.

[9] 394 F.3d 1348 (Fed. Cir. 2005).

[10] *Id.* at 1354-55.

[11] *McKesson Info. Solutions*, 487 F.3d at 916.

[12] 148 F.3d 1380 (Fed. Cir. 1998).

[13] *Id.* at 1384.

[14] *See McKesson Info. Solutions*, 487 F.3d at 917.

[15] 329 F.3d 1358 (Fed. Cir. 2003).

[16] *Id.* at 1368 (emphasis added).

[17] *McKesson Info. Solutions*, 487 F.3d at 920.

[18] *Id.* at 925-26.

[19] *Id.* at 925.

[20] 466 F.2d 767, 779 (7th Cir. 1972).

[21] *McKesson Info. Solutions*, 487 F.3d at 925-26.

[22] *E.g., Bruno*, 394 F.3d at 1354-55 (the lack of “a credible explanation for the nondisclosure” supports inferring an intent to deceive).

[23] *McKesson Info. Solutions*, 487 F.3d at 918.

[24] *Id.* (citing MPEP § 2004(18) (5th ed. rev. 3, 1986)).

[25] *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. MJG-01-1504, 2007 U.S. Dist. LEXIS 50311, * 54- * 56 (June 26, 2007 D. MD).

[26] *McKesson Info. Solutions*, 487 F.3d at 921-22.

[27] *Id.* at 922.

[28] *Id.* at 922-23.

[29] See *McKesson Info. Solutions*, 487 F.3d at 913 (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc* in relevant part)). This principle was inapplicable in *McKesson*: “this was not a case of mistake or negligence -- the prosecuting attorney testified that he would make all the same nondisclosure decisions again if prosecuting the same applications today.” *Id.* at 901.

[30] 71 *Fed. Reg.* 38808 (10 July 2006).

[31] See *id.*