

**August 8, 2009**

PATENT HAPPENINGS®

A publication by MATTHEWS PATENT-LAW CONSULTING on
judicial, legislative, and administrative developments in U.S. patent law

Special Report

Federal Circuit Tightens Requirements for Pleading Allegations of Inequitable Conduct

EXECUTIVE SUMMARY

In its most detailed opinion to date addressing the sufficiency of pleading allegations of inequitable conduct, the Federal Circuit in *Exergen Corp. v. Wal-Mart Stores, Inc.*, No. 2006-1491, 2007-1180, 2009 WL 2366535, *10-*15 (Fed. Cir. Aug. 4, 2009), held that “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.” *Id.* at *13. While district courts before *Exergen* often applied a “who, what, when, where and how” standard, as shown below, the Federal Circuit’s view of this standard demands a greater level of factual details in the pleading than the district courts have previously required.

Under *Exergen*, to plead sufficient facts showing the materiality of withheld information, an accused infringer must identify the exact information within a withheld prior art reference that it alleges is material, identify where that information can be found in the reference, identify the particular claim limitation or combination of claim limitations for which the withheld information is material, and then show how the prosecution record lacked that information. Clearly, this requires more than a one sentence

allegation that “reference X discloses Y, is non-cumulative of the art before the examiner, and therefore is material.” Additionally, the accused infringer must also plead *facts* that permit the court to draw a reasonable inference of intent to deceive, taking into account objective indications of good faith. Generalized conclusory allegations that “upon information and belief the patentee and/or its attorneys withheld reference X with the intent to deceive the PTO into issuing the patent” do not meet the *Exergen* pleading standard. Additionally, an accused infringer must name names in the pleadings. General allegations that a corporation, its inventors and its attorneys knew of the withheld information and failed to disclose it will not suffice.

Exergen does not alter the substantive law of inequitable conduct. But it does significantly increase the burdens for pleading inequitable conduct as an affirmative defense or as an unenforceability counterclaim. Undoubtedly, this opinion will have substantial and immediate impact on motion practice in patent litigation.

DISCUSSION

Public Policy Concerns

The Federal Circuit has long held the view that “unjustified accusations of inequitable conduct are

offensive and unprofessional.”¹ They “may deprive patentees of their earned property rights and impugn fellow professionals. They should be condemned.”² More recently, Judge Rader expressed his concern about the apparent runaway nature of inequitable conduct allegations in today’s patent litigation:

Although designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic. The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines.³

Judge Rader is not alone on the court in his concern and condemnation of unjustified inequitable conduct charges. Judge Newman has also spoken out on the evils of speculative charges of inequitable conduct:

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 ‘inequitable 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 grist 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.⁴

Perhaps as a judicial response to the present-day concern that allegations of inequitable conduct have

again risen to the level of being a “plague,”⁵ and do nothing but “spawn[] satellite litigation,”⁶ the Federal Circuit, in *Exergen*, substantially tightened the requirements to plead a defense or counterclaim of inequitable conduct.

The Pled Allegations in *Exergen*

In a proposed amended answer, the accused infringer in *Exergen* alleged that the patentee had committed inequitable conduct by not disclosing two of its own prior art patents to the PTO and by making statements to the PTO about the state of the art that appeared contradicted by statements the patentee had made on its website. As an example of the allegations regarding the withheld prior art, one paragraph of the proposed answer recited:

Prior to the filing of the ’685 patent application, Exergen filed a patent application that ultimately issued as U.S. Patent No. 4,566,808 (hereinafter referred to as “the ’808 patent”) on January 28, 1986. Thus, Exergen was aware of the ’808 patent well before the ’685 patent issued on September 18, 2001. The ’808 patent was material to the patentability of the ’685 patent because it discloses a technique of scanning a radiation detector across a target to measure the maximum emitted radiation, and it is not cumulative to the information already of record in the prosecution history of the ’685 patent.⁷

Exergen, 2009 WL 2366535 at *10.

¹ *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). See generally, Robert A. Matthews, Jr., ANNOTATED PATENT DIGEST § 27:126 Public Policy Perspectives of Baseless Inequitable Conduct Charges [hereinafter APD].

² *Id.*

³ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., *dissenting*).

⁴ *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., *dissenting*).

⁵ See *Dickson Indus., Inc. v. Patent Enforcement Team, LLC*, No. 2008-1372, 2009 WL 1393862, *5 (Fed. Cir. May 20, 2009) (*nonprecedential*) (“This court has long recognized that ‘the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.’”); see also *Burlington Industries, Inc. v. Dayco*, 849 F.2d 1418, 1422 (Fed. Cir. 1988); *Pfizer, Inc. v. Int’l Rectifier Corp.*, 538 F.2d 180, 196 (8th Cir. 1976).

⁶ *Multiform Desiccants, Inc., v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998) (“[T]he charge of inequitable conduct before the patent office had come to be attached to every patent prosecution, diverting the court from genuine issues and simply spawning satellite litigation.”).

⁷ The ’685 patent claims, inter alia, a method of detecting human body temperature based on laterally scanning a temperature detector across a forehead, *id.* at *7, and concerns a thermometer that detects radiation from the skin that covers the temporal artery in the temple region near the side of the forehead, *id.* at *1.

For intent to deceive, the accused infringer averred generally that it was “informed and believe[d]” that the patentee had an intent to deceive the PTO when it failed to disclose the prior art patents and made false statements to the PTO. Specifically, the complaint alleged:

Because Exergen was aware of the ’808 patent and the ’998 patent prior to the issuance of the ’685 patent, Exergen had an opportunity to disclose each of these patents to the PTO during the prosecution of the ’685 patent. Moreover, because the ’808 patent and the ’998 patent were material to the patentability of the ’685 patent, Exergen had an obligation to disclose each of these patents to the PTO. Nevertheless, Exergen failed to cite either of these patents to the PTO during the prosecution of the ’685 patent. SAAT is informed and believes, and therefore alleges, that Exergen, its agents and/or attorneys intentionally withheld the ’808 patent and the ’998 patent from the PTO with the intent to deceive the PTO to issue the ’685 patent.

Id.

Concluding that the allegations of inequitable conduct did not meet Rule 9(b)’s particularity requirements, the district court denied the accused infringer’s motion for leave to amend. The Federal Circuit affirmed.

The Federal Circuit’s Analysis

As a preliminary matter, the Federal Circuit reaffirmed that Federal Circuit law, and not the law of the regional circuit, applies to determine whether a pleading sufficiently pleads a defense or counterclaim of inequitable conduct. *Id.* at *11. The court also reaffirmed its earlier holdings, that Rule 9(b) of the Federal Rules of Civil Procedure applies to inequitable conduct allegations.⁸

⁸ See generally, APD § 39:13 Pleading Inequitable Conduct Under Rule 9(b).

Considering the particularity requirement of Rule 9(b),⁹ the court explained that “[a] pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” *Id.* Instead “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.” *Id.* at *13.

Examining the accused infringer’s proposed allegations, the Federal Circuit concluded that they failed to meet this standard. Focusing first on the requirement of pleading that an individual, owing a duty of candor to the PTO,¹⁰ had knowledge of the allegedly material information,¹¹ the Federal Circuit ruled that the proposed answer’s allegations fatally failed to identify by name the specific individual(s) who allegedly knew of the withheld prior art. The court explained that pleading a general reference to the “patentee and/or its representative and attorneys” does not adequately identify the “who” for showing that someone owing the duty of candor both knew of the material information and deliberately withheld or misrepresented it. *Id.* at *14.¹² As

“[T]o 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.”

⁹ Rule 9(b) provides: “In allegations fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” FED.R.CIV.P. 9(b) (2008).

¹⁰ See generally, APD § 27:9 Who Must Disclose.

¹¹ See generally, APD § 27:33 Actual Subjective Knowledge of the Existence of Information; see also APD § 27:32 Limited to Contemporaneously Held Knowledge; § 27:34 Reference in Assignee’s Files But Not Known by Inventor or Attorney; § 27:35 Duty to Investigate or Duty of Inquiry; and § 27:36 Objective Knowledge of Materiality.

¹² The court further instructed that “[b]ecause one of the purposes of Rule 9(b) is ‘to protect those whose reputation would be harmed as a result of being subject to fraud charges,’ a district court may require that filings be made under seal, require redaction of individuals’ names, and impose other safeguards ...” *Id.* at *13 n.6.

to the alleged misrepresentation to the PTO about the state of the art, and allegedly contradicted by statements on the patentee's web site, the court found that the pleading failed to plead facts showing that "at the time of the allegedly false statement [to the PTO], the individual who made this statement to the PTO was aware of an allegedly contradictory statement on Exergen's website." *Id.*

Considering the sufficiency of the allegations regarding materiality of the withheld references, the Federal Circuit rejected the contention that pleading a general conclusory statement that the reference taught certain scanning techniques pled sufficient facts to show the materiality of the withheld references. Specifically, the court faulted the accused infringer for not identifying in the pleading what specific claim limitations the "withheld references are relevant to, and where in those references the material information is found-i.e., the 'what' and 'where' of the material omissions." *Id.* The court also took issue with the conclusory allegation that the withheld information was not cumulative to the information already of record in the PTO record. It explained that the accused infringer should have "identif[ied] the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record," and then show where in the withheld references that information is present. *Id.* at *14. The court instructed that such detail in the allegations is "necessary to explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims." *Id.*

The Federal Circuit also found that the accused infringer's general allegation that the patentee and its agents knew of the withheld prior art failed to plead sufficient facts showing that someone owing the duty of candor knew that the withheld prior art patents contained information that was material. According to the Federal Circuit, knowledge of a reference does not automatically equate to knowledge of the

allegedly material information contained in that reference. And it is the latter that the law requires.

A reference may be many pages long, and 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. The pleading here does not allege facts that would support a reasonable inference that a relevant individual knew of the allegedly material information contained in the [withheld] '808 and '998 patents.

Id.

Regarding the allegations of "intent to deceive," the Federal Circuit explained that "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."¹³ *Id.* at *12. The court further explained that "[a] reasonable inference is one that is plausible and that flows logically from

the facts alleged, including any objective indications of candor and good faith." *Id.* at *13 n.5. The court expressly instructed that while a "reasonable"

The accused infringer should have "identif[ied] the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record," and then show where in the withheld prior art that information is present.

¹³ Although not cited in *Exergen*, the Federal Circuit's analysis of pleading "intent" appears consistent with the Supreme Court's recent pronouncement in *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1954 (2009) ("Rule 9 merely excuses a party from pleading discriminatory intent under an elevated pleading standard. It does not give him license to evade the less rigid-though still operative-strictures of Rule 8. And Rule 8 does not empower respondent to plead the bare elements of his cause of action, affix the label 'general allegation,' and expect his complaint to survive a motion to dismiss."). See also *Patent Happenings* June 2009 at pp.1-3 (discussing *Ashcroft* and its possible impact on pleading patent-related claims and defenses) (available at www.PatentHappenings.com).

inference of an intent to deceive suffices for testing the sufficiency of an inequitable conduct pleading, the holding of *Star Scientific* remains the law for *proving* inequitable conduct.¹⁴ *Id.* Hence, to actually prove intent to deceive based on inferences from circumstantial evidence, “the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the *single most reasonable* inference able to be drawn from the evidence to meet the clear and convincing standard.”¹⁵

Addressing the accused infringer’s allegation of intent to deceive based on “information and belief,” the court held the allegation did not present sufficient facts to support a reasonable inference of an intent to deceive. It explained that “[p]leading on ‘information and belief’ is permitted under Rule 9(b) when essential information lies uniquely within another party’s control, but only if the pleading sets forth the specific facts upon which the belief is reasonably based.” *Id.* at *15. In the case before, the accused infringer had alleged that “SAAT is informed and believes, and therefore alleges, that Exergen, its agents and/or attorneys intentionally withheld the ’808 patent and the ’98 patent from the PTO with the intent to deceive the PTO to issue the ’685 patent.” The Federal Circuit found that this allegation “provides neither the ‘information’ on which it relies nor any plausible reasons for its ‘belief.’” *Id.*

The accused infringer had further argued that, with respect to one of the withheld patents, intent to deceive should be inferred because the patentee had cited the withheld patent to the PTO during prosecution of another patent application. Rejecting this argument, the Federal Circuit explained that “[t]he 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.” *Id.* To make such a fact support a reasonable inference of intent to deceive, the pleading has to contain “specific factual allegations to show that the individual who had previously cited the ’998 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.* Thus,

[i]n the absence of such allegations, the district court was correct not to draw any permissive inference of deceptive intent with regard to the ’998 patent, lest inequitable conduct devolve into “a magic incantation to be asserted against every patentee” and its “allegation established upon a mere showing that art or information having some degree of materiality was not disclosed.

Id.

Likely Impact of Exergen

Exergen will have a significant impact in litigation. Patentees will likely file their Rule 12(b)(6) motions to dismiss inequitable conduct allegations with greater fervor than they already do. In view of Rule 15’s “futility” prong,¹⁶ accused infringers will face a tougher road in seeking leave to amend to add inequitable conduct allegations.¹⁷

More importantly, however, *Exergen*’s tougher pleading standards should help minimize instances of frivolous inequitable conduct charges. As shown above, pleading enough facts to show the “who, what, when, where, and how” now requires detailed factual allegations. To allege successfully the necessary facts, counsel for the accused infringer must complete

¹⁶ See generally, APD § 39:48 Futility; § 39:54 Denying Leave to Amend Based on Futility (collecting cases denying leave to add inequitable conduct defenses due to futility).

¹⁷ Given *Exergen*’s requirement of specificity in supporting factual allegations, it seems plausible that, as to the issue of “undue delay,” district courts may show more sympathy to accused infringers seeking leave to amend to add inequitable conduct allegations late in the discovery period, and even after a deadline to amend the pleadings has expired. Even before *Exergen*, district courts found good cause to permit late inequitable conduct allegations where the accused infringer had to depose fact witnesses to support the defense. *E.g., Probert v. The Clorox Co.*, 2009 WL 1011490, *2 (D. Utah Apr. 15, 2009) (accused infringer “appropriately waited until after taking Plaintiffs’ depositions” to file its motion for leave to amend to add inequitable conduct); *Cordance Corp. v. Amazon.com, Inc.*, 2009 WL 413121, *4-*6 (D. Del. Feb. 18, 2009) (“in light of the ‘pleading with particularity requirement of Rule 9(b),’ it was appropriate for Amazon to confirm the factual allegations through discovery”); see generally APD § 39:55 [Cases] Granting Motion to Amend to Assert Inequitable Conduct; see also APD § 39:46 Amendments Sought After Scheduling Order Deadline. *But cf.* APD § 39:53 Denying Motion to Amend to Assert Inequitable Conduct Based on Undue Delay.

¹⁴ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008).

¹⁵ *Star Scientific, Inc.*, 537 F.3d at 1366.

a thorough analysis of the withheld information, including determining who actually knew about the information, how that information applies to the claims and the PTO prosecution record, and what facts support a reasonable inference of an intent to deceive (taking into account evidence of good faith that the patentee may present). Conclusory allegations that an identified prior art reference is material, non-cumulative, and, on information and belief, was withheld with an intent to deceive the PTO, which sometimes passed muster before *Exergen*,¹⁸ will no longer be enough.

One should not overlook that litigation counsel for accused infringers must also meet their Rule 11 obligations when they plead facts necessary to satisfy the *Exergen* pleading standards. In the same manner that a patentee can face Rule 11 sanctions for failing to conduct an adequate pre-filing investigation,¹⁹ it seems plausible that an accused infringer might now face Rule 11 sanctions if it fails to conduct a sufficient pre-filing investigation that enables it to i) “identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record” in the prosecution history; ii) show where and how the withheld prior art contains that missing information; and iii) show how someone owing a duty to candor to the PTO knew that the withheld prior art contained that information.

ABOUT THE AUTHOR

Robert A. Matthews, Jr. provides patent-law consulting services to corporate counsel and trial counsel. Specifically, he helps counsel analyze and brief the myriad of substantive and procedural legal issues arising in patent infringement litigations. Matthews authors the ANNOTATED PATENT DIGEST,

¹⁸ See e.g. *Wilco AG v. Packaging Technologies & Inspection LLC.*, 615 F. Supp. 2d 320, 326-27 (D. Del. May 19, 2009); *UTStarcom, Inc. v. Starent Networks, Corp.*, No. 07 CV 2582, 2008 WL 5142194, *1 (N.D. Ill. Dec. 5, 2008); *Vita-Mix Corp. v. Basic Holdings, Inc.*, No. 1:06 CV 2622, 2007 WL 2816209, *5 (N.D. Ohio Sept. 27, 2007).

¹⁹ Under Rule 11, a patentee’s trial counsel generally must perform some form of an infringement analysis that compares the claims of the patent to the accused product, and must review the prosecution history. See generally, APD § 33:43 Rule 11 Requires Patentees Investigate Infringement Claims; § 33:44 Patent Attorney Must Independently Construe Claims; see also § 33:45 Evidentiary Support of Infringement Must Exist Before Filing Suit.

an eight-volume patent treatise published by West and available on Westlaw, the PATENT JURY INSTRUCTION HANDBOOK, and the monthly newsletter *Patent Happenings*®. Matthews has assisted clients with patent matters before the U.S. Supreme Court (*KSR* and *Bilski*), the Federal Circuit, the ITC and numerous federal district courts. Further information on the patent-law consulting services Matthews offers, plus a collection of patent litigation resources, can be found at www.MatthewsPatentLaw.com. Matthews can be reached at 434-525-1141 or by e-mail sent to ram@MatthewsPatentLaw.com.

All past issues of *Patent Happenings* are posted at www.PatentHappenings.com.

This newsletter is for informational purposes only and is a marketing publication of MATTHEWS PATENT-LAW CONSULTING. It is intended to alert the recipients to developments in the law and does not constitute legal advice or a legal opinion on any specific facts or circumstances. The contents are intended as general information only. This newsletter may be copied by and/or transmitted to others freely by its recipients, but only in its entirety so as to include proper recognition of the author. The information presented in this newsletter is, to the best of our knowledge, accurate as of the original publication. However, we take no responsibility for inaccuracies or other errors present in this newsletter. The information in this newsletter does not necessarily reflect the opinions of the firm or its clients. This newsletter may be considered ADVERTISING MATERIAL in some jurisdictions.