

Appeal No. 2008-1511, -1512, -1513, -1514, -1595

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)
and ABBOTT LABORATORIES

Plaintiffs-Appellants,

– v. –

BECTON, DICKINSON AND COMPANY,
and NOVA BIOMEDICAL CORPORATION

Defendants-Appellees,

and

BAYER HEALTHCARE LLC,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF CALIFORNIA, JUDGE WILLIAM H. ALSUP
En Banc

**BRIEF OF *AMICUS CURIAE* DOLBY LABORATORIES, INC.
IN SUPPORT OF NEITHER PARTY**

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June 30, 2010

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 26.1 and 47.4, counsel for *amicus curiae* Dolby Laboratories, Inc. certifies the following:

1. The full name of every party or *amicus* represented by us is:
Dolby Laboratories, Inc.
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is: Not applicable.
3. There is no parent corporation or any publicly held company that owns 10 percent or more of the stock of Dolby Laboratories, Inc.
4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by us in the trial court or agency or are expected to appear in this court are: Farella Braun + Martel LLP; John L. Cooper, Robert H. Sloss and Deepak Gupta.

June 30, 2010.

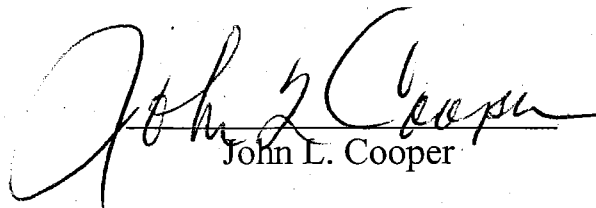

John L. Cooper

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

For more than four decades, Dolby Laboratories, Inc. (“Dolby”) has been an innovator in high-quality audio. In that time, its ubiquitous technologies have been incorporated in more than 3 billion licensed products for cinema, broadcast, home audio systems, cars, DVDs, headphones, games, televisions, and personal computers, among other things. Dolby’s innovation is well celebrated. For example, it or its employees have been honored by nine Academy Awards® from the Academy of Motion Picture Arts and Sciences, eight Emmy® Awards from the Academy of Television Arts & Sciences, and a Technical Grammy® from the Recording Academy. Dolby has over 1100 employees striving to continue its legacy of innovation, including technicians, engineers, researchers and scientists, all of whom are vital to Dolby’s patent process. For fiscal year 2008, Dolby spent more than \$62 million for research and development, and for fiscal year 2009 more than \$66 million.

As a result of its sustained commitment to innovation and research, today Dolby’s U.S. patent portfolio includes over 200 issued patents and over 300 pending applications, with foreign counterparts throughout the world. Dolby has earned billions of dollars in revenue through the licensing of its patents and related technology. As a technical innovator and

intellectual property leader, Dolby has a compelling and continuing interest in a clear and sensible judicial standard governing prosecution practice before the United States Patent & Trademark Office (“PTO”) and the assured enforceability of its patent rights.

Dolby respectfully submits this brief as *amicus curiae* in support of neither party.

STATEMENT OF THE ISSUE ADDRESSED BY *AMICUS CURIAE*

Dolby addresses solely question four presented by this Court in its April 26, 2010 order:

“4. Under what circumstances is it proper to infer intent from materiality? See Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) (en banc).”

SUMMARY OF ARGUMENT

A patent applicant who omits the disclosure of information contained in sources that the Manual of Patent Examining Procedure (“M.P.E.P.”) independently directs PTO examiners to consider cannot have specific intent to hide that information, regardless of how material it may be. The applicant cannot intend to hide that which is within the examiner's plain view. Thus, the current law's inference of intent to deceive based simply on the materiality of the particular undisclosed information, without regard for what the examiner is expected to independently obtain, is too broad and unfair to patentees. It is likely to result in a finding of intent to deceive – and, therefore, inequitable conduct – even though the patentee had no such specific intent. Dolby suggests that the Court adopt a more balanced rule that does not provide for an inference of intent from materiality where omitted information is contained within sources of which the PTO has notice and to which the M.P.E.P. expressly directs examiners.

The current law's inference of intent from materiality should be narrowed not just because it is unfair, but also because it is bad policy. This rule creates undesirable incentives for applicants to over-disclose prior art to the PTO. As the law presently stands, prudent applicants, to avoid the possibility of any future inequitable conduct issues, feel compelled to

disclose any and all information that they think a prospective adversary might later argue was somehow material to the prosecution. From related foreign applications, applicants may disclose every office action in every patent office in the world, and each reference cited therein. For patents in litigation, they may disclose all supposed prior art identified by an adversary in discovery. The amount of paper can be staggering. As a result of this tendency, truly pertinent art, that which the applicant (the person who most likely understands the technology best) genuinely believes to be most material, is being unfortunately obscured in a large volume of marginally material references simply to avoid litigation-created inequitable conduct issues. Rather than highlighting the best art, the duty of candor as implemented today, with its broad inference of intent from materiality, is instead causing that art to be obscured for examiners. Dolby's proposed standard would reverse this trend and restore the duty of candor to its purpose of improving patent quality.

ARGUMENT

I. IT IS IMPROPER TO INFER INTENT TO DECEIVE FROM MATERIALITY WHERE THE INFORMATION AT ISSUE IS CONTAINED IN SOURCES THAT THE M.P.E.P. INDEPENDENTLY DIRECTS EXAMINERS TO CONSIDER.

Under the current state of inequitable conduct law a court may infer intent to deceive when highly material information that the applicant knew or should have known about was not disclosed, in the absence of a credible explanation for non-disclosure. This sweeping inference applies even where the applicant would expect the examiner to independently identify and consider the omitted information.

The M.P.E.P. contains explicit instructions to examiners that they should review a number of sources and items as part of their review of an application. Public information to which the M.P.E.P. expressly directs examiners' attention stands in a different position from, for example, prior public use or on sale information, which resides uniquely in the knowledge of the patentee. While an applicant's withholding of the latter categories of information – those to which the examiner does not have independent access – might be consistent with an intent to hide, the omission of material information to which the M.P.E.P. directs examiners can evidence no such intent. Applicants who omit references they rightfully expect the examiner

to find and consider on his or her own cannot be regarded as intending to hide that information.

A. Precedents of This Court Wrongly Presume an Intent to Deceive Based on Omissions of Information in the Examiner’s “Plain View.”

This Court’s precedents permit a court to infer intent to deceive when highly material information that the applicant knew or should have known was not disclosed, in the absence of a credible explanation for non-disclosure. See, e.g., Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services., Ltd., 394 F.3d 1348, 1351, 1354-55 (Fed. Cir. 2005) (patentee’s withholding of material reference supported inference of intent despite claim of failure to appreciate materiality; no credible explanation of non-disclosure); Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1367-68 (Fed. Cir. 2007) (“[A] high degree of materiality, coupled with evidence that the applicant should have known of that materiality, creates a strong inference of an intent to deceive.”).

The current law applies this inference even to information within the examiner’s “plain view,” that is, information that an examiner operating under the M.P.E.P. is expected to consider. For example, in McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 926 (Fed. Cir. 2007), the Court declared unenforceable a patent based on a number of facts. In

prosecution the applicant had properly disclosed the existence of two co-pending related applications, one before the same examiner and one before a different examiner. Id. at 905, 912, 917. The applicant had erred, however, in two key respects. First, the applicant failed to disclose to the examiner that same examiner's own allowance of a related application, which was potentially material to a double patenting rejection. Id. at 925-26. Second, the applicant failed to disclose a specific prior art reference and specific claim rejections that came to light in the related application before the other examiner. Id. at 924-25. Based on these non-disclosures, even giving the applicant credit for disclosing the existence of the related applications, the Court affirmed the inference of an intent to deceive. Id. at 926. The Court ruled this way even though related file histories are readily accessible to all PTO examiners, the M.P.E.P. directs examiners to review related file histories, and the information at issue was all contained within the file histories. Relative to the double patenting issue, the M.P.E.P. also instructs examiners to do thorough inventor name searches. M.P.E.P. §§ 719.05, 804, 904.

The facts of McKesson spotlight the concern about the inference of intent from materiality for “plain view” information, because one of the key pieces of “omitted” information for the inequitable conduct finding was the

same examiner's own allowance of a related patent. In her dissent, Judge Newman argued that the majority wrongly and unfairly found deceptive intent as to references the same examiner had previously considered in connection with the related application:

It is not clear and convincing evidence of deceptive intent that the applicant did not inform the examiner of the examiner's grant of a related case of common parentage a few months earlier, a case that was examined by the same examiner and whose existence has previously been explicitly pointed out by the same applicant.

McKesson, 487 F.3d at 926. Judge Newman is correct on this issue. There can be no clear and convincing evidence of deceptive intent when the applicant has a right to expect the examiner to have knowledge of the allegedly withheld information, such as information in sources the M.P.E.P. instructs examiners to review.

B. The M.P.E.P. Directs Examiners to Conduct a Diligent Patentability Analysis By First Reviewing Routinely Used Search Locations.

The M.P.E.P., the PTO's internal policy manual that directs examiners on how to conduct the review of patent applications, instructs that "[t]he examiner, after having obtained a thorough understanding of the invention disclosed and claimed in the nonprovisional application, then searches the prior art as disclosed in patents and other published documents, i.e., nonpatent literature (NPL)." M.P.E.P. § 904. The M.P.E.P. states:

Technical literature, foreign patent documents, and reference and online searches available in [the Scientific and Technical Information Center] are all important resources for the patent examiner to utilize. These resources provide material which must be known or searched to determine whether claims of applications are directly anticipated and, therefore, unpatentable under the provisions of 35 U.S.C. 102.

M.P.E.P. § 901.06(a) (emphasis added); M.P.E.P. § 904.02 (requiring “thorough search”).¹

The M.P.E.P. directs examiners to consider, in particular, material that is genealogically linked to the application under examination:

- Inventor name searches for potential double patenting rejections (M.P.E.P. §§ 804, 904);²
- Patent family information, including foreign patent information (M.P.E.P. § 905.06);

¹ Beyond the direct subject matter of the claims, examiners are also instructed to search for equivalents (M.P.E.P. § 904.01(b)) and all non-analogous art (M.P.E.P. § 904.01(b)). They have access to all foreign patents, published applications, and any other published derivative material containing portions or summaries of the contents of published or unpublished patents (*e.g.*, abstracts) which have been disseminated to the public. (M.P.E.P. § 901.05). They have access to existing foreign translations and may specially request translations as well. (M.P.E.P. § 901.05(d)).

² *See also*, M.P.E.P. § 904; *Best Practices in Compact Prosecution*, 17 (“**ALWAYS, ALWAYS, ALWAYS** conduct an inventor name search to avoid missing a double patenting rejection.”) (emphasis in original) (visited May 26, 2010), <http://www.uspto.gov/patents/law/exam/compact_prosecution.pdf>.

- Art cited in parent applications (M.P.E.P. § 904);
- Art cited in related applications (M.P.E.P. § 719.05, Search Notes Box Entries (E));
- Art cited in international search reports for applications filed under 35 U.S.C. § 371 (M.P.E.P. § 904; M.P.E.P. § 609.03).

Because of the M.P.E.P.’s unambiguous directive that examiners independently review all of these materials, the PTO is on notice of all this information. Courts and applicants should be able to rely on the fact that examiners will, in fact, review these sources. Accordingly, the law should not infer an intent to deceive from the non-disclosure of this material.³

C. Non-Disclosure of Information Contained in the Search Sources Prescribed in the M.P.E.P. Evidences No Intent to Deceive Regardless of Its Materiality.

In view of the M.P.E.P.’s express examination directives, it is illogical to infer that applicants who omit references that the PTO acting in

³ Indeed it is essential to patent law’s presumption of validity that the PTO conducts itself with a high degree of care. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984) (attacker faces difficult burden in “overcoming the deference that is due to a qualified government agency presumed to have properly done its job”); see also, Superior Fireplace Co. v. Majestic Products Co., 270 F.3d 1358, 1367 & n.1 (Fed. Cir. 2001). Similarly, the M.P.E.P. instructs examiners to give “full faith and credit” to the patentability searches of prior examiners. M.P.E.P. § 704.01. The inequitable conduct analysis should proceed from this same premise of thoroughness. Accordingly, all interested parties – applicants included – are justified in presuming that PTO examiners execute their expressly prescribed duties as set forth in the M.P.E.P.

accordance with the M.P.E.P. should independently obtain can have the intent to hide those references and thus to deceive the PTO. This assumes that applicants intend to hide that which the PTO is expected to consider independently.

Applicants who do not disclose such “plain view” information should not be presumed to have the intent to act inequitably. It is a bedrock principle of inequitable conduct jurisprudence that “[t]o be guilty of inequitable conduct, one must have intended to act inequitably.” Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc) (gross negligence alone is insufficient to justify an inference of deceitful intent); 37 C.F.R. § 1.56. A finding of deceitful intent requires unambiguous proof of the applicant’s mental state. “Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.” See, Dayco Products, Inc., v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003). “[A] district court clearly errs in overlooking one inference in favor of an equally reasonable inference.” Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1367 (Fed. Cir. 2008). The elements of inequitable conduct must be proven by clear and convincing evidence. J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc., 747 F.2d 1553, 1559, (Fed. Cir. 1984), cert. denied,

474 U.S. 822 (1985). Such an exacting standard of proof is appropriate for the devastating remedy of unenforceability which accompanies a finding of inequitable conduct. Kingsdown, 863 F.2d at 877.

Where an applicant omits information that an examiner operating according to the M.P.E.P. should come to know independently, even a remote showing of intent is absent. There is certainly no “clear and convincing” showing of culpable intent where one withholds that which they know to be in the other’s plain view. The more reasonable explanation of such omissions is that the applicant was relying in good faith – as they should be entitled to do – on a thorough search of the sources identified in the M.P.E.P, and they opted not to inundate the examiner with redundant lists of references the examiner would presumably consider on their own. Yet the current law’s broad inference of intent from materiality requires overlooking this explanation in favor of the less reasonable and largely speculative inference that there was intent to deceive.⁴

⁴ By extension, this Court’s inverse “sliding scale” standard of materiality and intent for inequitable conduct is equally improper. Where highly material information is contained within M.P.E.P.-prescribed search sources, its high degree of materiality strengthens an inference of a *lack* of intent to deceive. The more material the information contained within M.P.E.P.-prescribed sources, the more reasonable it is for the applicant to presume that the examiner will identify and consider it on his or her own.

D. Dolby's Proposal Comports with Akron and Dayco: There Is No Intent to Deceive Where the PTO is "On Notice" of Material Information.

Eliminating the inference of intent to deceive for information in the plain view of the examiner comports with this Court's precedents establishing that where the PTO is "on notice" of material information the applicant does not have an intent to deceive. In Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380 (Fed. Cir. 1998), an applicant was prosecuting two quite similar applications. Id. at 1381-82. He informed one examiner of the co-pendency, but failed to promptly inform the other. Id. The Court reversed the district court finding of inequitable conduct because the applicant "hardly could be seeking to deceive the PTO as to the existence of copending applications when it actually disclosed the fact of copendency to [one] examiner." Id. at 1384. By virtue of the applicant's notice to one examiner, the PTO as an institution was "on notice of the copendency of the two applications" and there was accordingly no intent to deceive. Id. The Akron rule was applied in Dayco, 329 F.3d at 1366.

In accordance with Akron and Dayco, Dolby's proposal would treat PTO examiners as being "on notice" of information to which the M.P.E.P. specifically directs them. Reliance on notice is justified not just for genealogically associated information, which is discrete in quantity, is

pointed out in the M.P.E.P. and is by its very nature likely to contain information pertinent to patentability, but also for the prior art databases of patents and published articles that the M.P.E.P. requires examiners to thoroughly review. Like in Akron, applicants “hardly could be seeking to deceive the PTO as to the existence” and contents of these obvious sources. Akron, 148 F.3d at 1384.⁵

II. ELIMINATING THE INFERENCE OF INTENT TO DECEIVE FOR FAILURE TO DISCLOSE INFORMATION FOUND IN M.P.E.P.-PRESCRIBED SOURCES WOULD IMPROVE PROSECUTION.

Eliminating the inference of materiality from intent where art is located within routine search locations under the M.P.E.P. would yield practical benefits by reducing to a manageable volume the potential prior art submitted to examiners, without compromising applicant incentives to disclose all which they might regard as material, including that information uniquely in their possession. As long as they face a risk of an inequitable conduct finding arising out of a broad inference of intent from materiality, however, applicants will continue to over-disclose.

⁵ Akron and McKesson are in tension. Akron, in effect, imputes the knowledge of one PTO examiner to another. It is puzzling, then, that McKesson refused to impute the knowledge of one examiner to himself.

A. Dolby’s Proposal Would Ameliorate the Problem of Over-disclosure That Is Endemic to Patent Prosecution Today.

Rampant allegations of inequitable conduct during patent litigation have detrimentally influenced practice before the PTO. The conventional safeguard against these allegations is for an applicant to over-disclose. For example, applicants will “dump” on PTO examiners all office actions and all cited references from all foreign counterpart applications. This protects against the possibility that any reference in the patentee’s possession might later be argued by an adversary or regarded by a court to be “material” and “non-cumulative” even if the applicant himself or herself never thought of it as such.

The volume of submissions that results from this concern is often more burdensome than helpful to examiners. This Court has recognized the harmful potential of over-disclosure. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1184 (Fed. Cir. 1995) (“‘burying’ a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith”). The PTO too has acknowledged the “negative[] impact” of over-disclosure:

Although § 1.56 clearly imposes a duty to disclose material information, that rule neither authorizes nor requires anyone to file unreviewed or irrelevant documents with the Office. Such documents add little to the effectiveness of the

examination process and, most likely, negatively impact the quality of the resulting Office determinations.

Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808, 38,809 (proposed July 10, 2006) (emphasis added).

If applicants did not fear an inference of intent to deceive for omissions of information contained within sources to which the M.P.E.P. independently directs examiners, applicants could make uncluttered disclosures of the most pertinent information which they regard as material and non-cumulative, instead of trying to second guess what others might in prospective litigation argue to be material and non-cumulative. Remedying the over-disclosure problem would lead to higher patent quality.

B. Limiting the Inference of Intent To Deceive As Proposed Would Not Prevent Courts From Finding Inequitable Conduct Where the Evidence Shows Actual Intent to Deceive.

Limiting the inference of an intent to deceive as proposed would still permit courts to apply the doctrine of inequitable conduct where an adversary is able to make an actual showing of intent. Where a defendant proffers evidence directly showing that a patentee hid art whose materiality the patentee recognized, a finding of inequitable conduct might remain

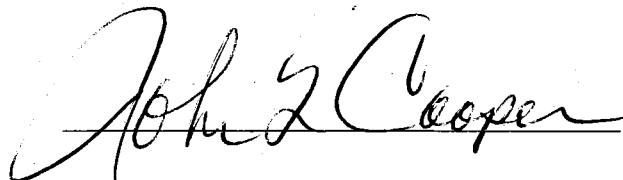
proper. Accordingly, Dolby's proposal would not negatively impact the beneficial aspects of the duty of candor.

C. Patent Applicants Have Motivations Beyond the Duty of Candor to Disclose What They Regard As the Most Pertinent Art.

Dolby's proposal also would not erode incentives for disclosure that exist outside and apart from the doctrine of inequitable conduct. Disclosing strong art benefits applicants by yielding stronger patents. Where the PTO allows a patent over a particular piece of art, the patentee benefits from a strengthened presumption of validity. This creates an incentive for disclosure of the most pertinent information, even when contained within M.P.E.P.-prescribed sources. This incentive would remain intact under Dolby's proposal.

III. CONCLUSION

For the foregoing reasons, the Court should narrow the inference of intent to deceive from materiality so that it does not apply to omissions of information to which the M.P.E.P. expressly directs examiners, regardless of materiality.



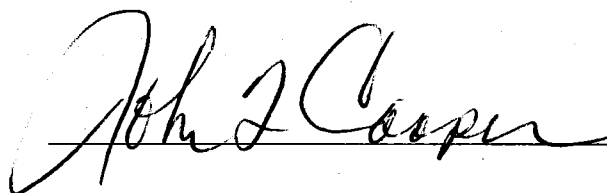
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CERTIFICATE OF COMPLIANCE

I certify that the forgoing BRIEF OF DOLBY LABORATORIES, INC. AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY contains 3569 words as measured by the word processing software used to prepare the brief.

A handwritten signature in black ink, reading "John L. Cooper", written over a horizontal line.

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