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**Summaries of Hynix Semiconductor Inc. v. Rambus Inc. and Micron Technology, Inc. v.*

Rambus Inc. are not included in this edition of the newsletter.

Abbreviations

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Board of Patent Appeals and Interferences
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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In *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-1511, -1512, -1513, -1514, -1595 (Fed. Cir. May 25, 2011) (en banc), the Federal Circuit, sitting en banc, vacated the district court's finding of unenforceability due to inequitable conduct and announced tightened standards for both the intent and materiality prongs of the inequitable conduct analysis. The Court outlined the historical divergence of inequitable conduct from the doctrine of unclean hands and the fluctuations of the standards for intent and materiality. Citing numerous issues of unintended consequences, the majority chose to "now tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." Slip op. at 24. First, as to intent, the Court held that an accused infringer must prove by clear and convincing evidence that the patentee acted with the specific intent to deceive the PTO, noting that the gross negligence and "should have known" standards are insufficient. Moreover, the Court dismissed the "sliding scale" to infer intent from materiality, instead holding that the district court should weigh the evidence of intent to deceive independent of its analysis of materiality. Second, with respect to materiality, the Court held that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality such that the district court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. Finally, the Court carved out an exception to the but-for materiality test for affirmative egregious misconduct, such as filing an unmistakably false affidavit. Accordingly, the Court vacated the district court's opinion and remanded for proceedings consistent with the new standard for inequitable conduct. See the full summary in this issue.

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Looking Ahead

This past April, in *McKesson Technologies Inc. v. Epic Systems Corp.*, No. 10-1291 (Fed. Cir. Apr. 12, 2011), a split panel of the Federal Circuit affirmed a finding of noninfringement, holding that McKesson Technologies Inc. ("McKesson") failed to demonstrate an agency or contractual relationship between licensees and individuals whom in the aggregate practiced McKesson's patented method. Thus, because no single entity directly infringed the claimed method, Epic Systems Corp. could not be liable for induced infringement.

On May 26, 2011, the Federal Circuit vacated its April 2011 panel opinion and granted McKesson's petition for rehearing en banc. The Court requested briefing on the following two issues:

> (1) If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? *See Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983); and
>
> (2) Does the nature of the relationship between the relevant actors—e.g., service provider/user; doctor/patient—affect the question of direct or indirect infringement liability?

The date and time of oral argument has not yet been announced.

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Reissue Claims Rejected for Impermissibly Recapturing Subject Matter Surrendered During Prosecution of Original Patent Application

Timothy P. McAnulty

Judges: Dyk (author), Friedman, Prost

[Appealed from Board]

In *In re Mostafazadeh*, No. 10-1260 (Fed. Cir. May 3, 2011), the Federal Circuit affirmed the Board's rejection of claims 11-23 in Shahram Mostafazadeh and Joseph O. Smith's (collectively "applicants") reissue patent application based on U.S. Patent No. 6,034,423 ("the '423 patent") and held that the reissue claims impermissibly attempted to recapture subject matter surrendered during prosecution of the original patent application.

The applicants appealed a decision from the Board affirming the examiner's rejection of claims 11-23 in the applicants' reissue application for impermissibly recapturing subject matter that was surrendered during original prosecution. The '423 patent is directed to lead-frame-based semiconductor packaging that supports and protects semiconductor "chips" while providing electrical pathways between the chips and external devices. The '423 patent describes two embodiments, a pin-type package and a bottom-surface-mount package. As originally filed, the claims in the '423 patent application encompassed both embodiments. All of the originally filed claims were rejected over prior art that disclosed the pin-type embodiment. To overcome the rejection, the applicants amended the claims to include "circular attachment pads" that are specific to the bottom-surface-mount package embodiment. The '423 patent issued with the amended claims.

The applicants later filed a reissue application to the '423 patent with new claims, stating that the '423 patent claims were partially inoperative because the circular-attachment-pad limitation was "unduly limiting," and presenting reissue claims omitting the circular shape requirement. The examiner rejected the reissue claims under 35 U.S.C. § 251 as improper recapture of surrendered subject matter, noting that the circular-attachment-pad limitation was added and argued to be critical to the invention and distinguishing over the prior art. The applicants appealed to the Board, which affirmed the examiner's rejection. The Board concluded that the reissue claims recaptured surrendered subject matter because the reissue claims were broadened with respect to the patented claims and were not materially narrowed in other respects so as to avoid the recapture rule.

On appeal, the Federal Circuit noted that under the reissue statute, a patent holder may reissue an

existing patent and seek broader claims, but a patentee cannot regain subject matter that was surrendered in an effort to obtain allowance of the original claims. Under this rule against recapture, claims that are broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during original prosecution are impermissible. As explained by the Court, the recapture rule is applied as a three-step process. The first step is to determine whether and in what aspects the reissue claims are broader than the patent claims. The second step is to determine whether the broader aspects relate to surrendered subject matter. The third step is to determine whether the reissue claims include surrendered subject matter.

"[T]he recapture rule is violated when a limitation added during prosecution is eliminated entirely, even if other narrowing limitations are added to the claim. If the added limitation is modified but not eliminated, the claims must be materially narrowed relative to the surrendered subject matter . . . ." Slip op. at 13.

Here, there was no dispute regarding the first and second steps—both parties agreed that the reissue claims were broader than the patented claims in aspects that related to surrendered subject matter. In addressing the third step, the Court specifically pointed out that it is important to differentiate between the original claims (i.e., the claims before surrender), the patented claims (i.e., claims allowed after surrender), and the reissue claims. Violation of the recapture rule may be avoided if the reissue claims materially narrow the claims relative to the original claims such that full or substantial recapture of the subject matter surrendered during original prosecution is avoided. To avoid violating the recapture rule, the narrowing of the reissue claims must relate to the subject matter surrendered during the original prosecution.

Although the Court affirmed the rejection of the reissue claims on appeal, the Court found the Board's analysis of the third step contrary to precedent. In its decision, the Board concluded that a limitation materially narrows a claim only if it is directed to one or more overlooked aspects of the invention. The Board defined "overlooked aspects" as features directed to patentably distinct inventions, embodiments, or species not claimed during original prosecution. The Court rejected this rationale, noting that in such scenarios, i.e., where a reissue claim is directed to a patentably distinct and previously unclaimed invention, embodiment, or species, there is no need to apply the recapture rule. The recapture rule is triggered only where reissue claims are broader than the patented claims and the surrendered subject matter has been reclaimed. Reissue claims that include subject matter that was not originally claimed include subject matter wholly unrelated to the subject matter that was surrendered.

Thus, the Court concluded that the recapture rule is violated when a limitation added during prosecution is eliminated entirely, even if other narrowing limitations are added to the claim. If the added limitation is modified but not eliminated, the claims must be materially narrowed relative to the surrendered subject matter such that the surrendered subject matter is not entirely or substantially recaptured.

Applying this three-step analysis to the applicants' reissue claims, the Court held that the claims violated the recapture rule. During original prosecution, the applicants added the "circular attachment pad" feature to the claims. In the reissue application, the applicants eliminated the "circular shape" requirement while retaining the "attachment pad" feature. The applicants argued that they avoided the recapture rule because they had not broadened the claims to encompass everything that was surrendered. The Court found that retention of the attachment-pad limitation was related to the

surrendered subject matter, but that it was not materially narrowing because the use of an attachment pad itself was well known in the art. The applicants also argued that the reissue claims each have a number of other narrowing limitations relating to a bus bar feature. The Court found that while these features narrowed the reissue claims relative to the original claims, the narrowing relates only to the bus bar, not to the circular attachment pad. That is, these narrowing limitations are unrelated to the surrendered subject matter and thus are not sufficient to avoid the rule against recapture.

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Evidence of Secondary Considerations Can Be Commensurate with the Scope of the Claims Without Testing or Selling Every Conceivable Embodiment of the Claims, but There Must Be a Nexus to the Novel Aspects of the Claimed Invention

Adam M. Breier

Judges: Rader, Linn (author), Moore

[Appealed from Board]

In *In re Kao*, Nos. 10-1307, -1308, -1309 (Fed. Cir. May 13, 2011), the Federal Circuit affirmed the Board's finding of obviousness with respect to U.S. Patent Application Nos. 12/167,859 ("the '859 application") and 11/766,740 ("the '740 application"), but vacated the Board's obviousness finding with respect to U.S. Patent Application No. 11/680,432 ("the '432 application") and remanded for further proceedings.

Endo Pharmaceuticals, Inc. ("Endo") is the assignee of the three patent applications-at-issue. Each application is related to controlled release tablets containing the opioid narcotic oxymorphone.

The '432 application discloses controlled release drug formulations containing oxymorphone that are capable of relieving pain for between twelve and twenty-four hours. Claim 1 recites a range of oxymorphone dissolution rates as measured by the "USP Paddle Method." Although ultimately unpersuasive, Endo submitted declarations in response to an obviousness rejection, in which it explained that (1) the prior art reference ("Maloney") disclosed a dissolution profile for a controlled release formulation containing oxycodone, an opioid with markedly different bioavailability than oxymorphone; (2) the controlled release oxymorphone formulations exhibited an unexpected result in that the formulations caused multiple peaks in oxymorphone blood concentrations over time, which help prevent patients from building up a tolerance to the opioid; and (3) Opana® ER, a commercial embodiment of the invention, had experienced significant commercial success. The Board affirmed the obviousness rejection and focused on Maloney's disclosure of "Formula 6," a controlled release formulation of oxycodone. The Board acknowledged that Formula 6 did not contain oxymorphone and that the reference measured the dissolution data using the "USP Basket Method," a method different than the claimed "Paddle Method." The Board rejected Endo's arguments regarding Maloney and disregarded Endo's evidence of commercial success, finding that it was not commensurate with the scope of the claims because Endo's evidence related to Opana® ER, whereas the claims encompassed a large number of other formulations.

The '859 application discloses a method of relieving pain using oxymorphone in a controlled release delivery system to overcome the difficulties associated with immediate release formulations of opioids. Claim 8 is directed to a method for treating pain by administering a controlled release formulation of oxymorphone that (1) provides at least twelve hours of sustained pain relief and (2) results in a maximum concentration at least about 50% higher when administered to fed versus fasting patients ("food effect"). A second claim required that the controlled release formulation include a hydrophobic material. The Board affirmed a rejection of the claims as obvious over Maloney, again rejecting Endo's evidence of commercial success as not commensurate with the scope of the claims.

The '740 application discloses a method of providing extended pain relief comprising "providing information" about an increase in oxymorphone bioavailability in subjects with renal impairment, and "providing a therapeutically effective amount" of an extended release oral dosage form of oxymorphone. The Board affirmed an obviousness rejection over a combination of references, including Maloney.

On appeal, the Federal Circuit first addressed the '432 application. Procedurally, the Court found that Endo waived its right to argue its claims separately. On the merits, the Court found that the Board lacked substantial evidence for its finding that substituting oxymorphone in Formula 6 of Maloney would satisfy the claimed range of dissolution rates. The Court rejected the Board's attempt to correlate the dissolution results from the Basket and Paddle Method tests. The Court stated: "[I]t matters not whether the hypothetical skilled artisan would have *appreciated* the 'correlation' at issue here, it matters greatly whether anything the skilled artisan would be prompted by the prior art to do is *in fact* within the scope of the pending claim." Slip op. at 14. The declaration, however, upon which the Board relied to find a correlation between the testing methods, expressly stated that there was no general correlation and cited prior art that supported that conclusion. Thus, the Court found that the Board failed to provide any reason, apart from its own conclusion, that there was a correlation. Without a correlation, there was no basis for concluding that Maloney rendered obvious a composition within the claimed dissolution range. The Federal Circuit, however, left the obviousness inquiry open so that the Board could consider the importance, or lack thereof, of the claimed range to the alleged nonobviousness of the invention. If the range was insubstantially different, the Court noted that a prima facie obviousness rejection would still be proper.

Commensurate with the scope of the claims "does not mean that an applicant is required to test every embodiment within the scope of his or her claims. If an applicant demonstrates that an embodiment has an unexpected result and provides an adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner, this will generally establish that the evidence is commensurate with [the] scope of the claims." Slip op. at 17.

The Federal Circuit also reviewed Endo's alleged secondary consideration evidence. First, the Court concluded that the Board erred by rejecting Endo's unexpected results arguments as not commensurate with the scope of the claims. Commensurate with the scope of the claims "does not mean that an applicant is required to test every embodiment within the scope of his or her claims. If an applicant demonstrates that an embodiment has an unexpected result and provides an adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner, this will generally establish that the evidence is commensurate with [the] scope of the claims." *Id.* at 17. The evidence of record indicated that the unexpected results were not unique to the commercial embodiment

of the claims; rather, it appeared that these results were also found in other extended release formulations of oxymorphone. The Court's rejection of the Board's position, however, did not resolve the issue. The Federal Circuit noted that the question of nexus should be considered by the Board on remand, specifically, whether there was a nexus between Endo's "unexpected multiple peaks in oxymorphone blood concentration" and aspects of the claimed invention not already in the prior art, such as the claimed range of dissolution rates as compared to dissolution rates in the prior art.

Second, the Federal Circuit disagreed with the Board's refusal to credit Endo's evidence of commercial success on the basis of not being commensurate with the scope of the claims. "[A]n applicant 'need not sell every conceivable embodiment of the claims in order to rely upon evidence of commercial success, so long as what was sold was within the scope of the claims.'" *Id.* at 19 (quoting *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008)). The Court noted, however, that on remand, the Board should make a factual determination as to nexus, i.e., whether the commercial success resulted from the novel aspects of the claimed invention rather than the prior art or other extrinsic factors.

The Federal Circuit then considered and rejected Endo's three main arguments challenging the Board's obviousness finding with respect to the '859 application. First, the Court agreed with the Board that the "food effect" limitation was an inherent property of oxymorphone itself and that the Board did not err by relying on the disclosure of the '859 application in support of its finding. Second, the Court rejected Endo's assertion that Maloney did not expressly disclose the recited twelve-hour effectiveness limitation because the Board reasonably concluded that Maloney's active agent would still be effective after twelve hours since it was still being released from the dosage form. Further, the Federal Circuit found that the "concerns" expressed by Endo's experts failed to provide record evidence showing that Maloney's disclosure fails to provide a reasonable expectation of obtaining the plasma levels of oxymorphone suggested by Maloney and required by the claims. Finally, the Court rejected Endo's assertion that Maloney failed to teach formulations including a hydrophobic material because Maloney expressly recites adding hydrogenated vegetable oil to its formulation, which the '859 application states is a hydrophobic material.

The Federal Circuit also considered Endo's arguments regarding secondary considerations of nonobviousness. While the Court agreed that the Board erred by failing to consider Endo's evidence, the only claim element not expressly disclosed in the prior art was the "previously-unknown, yet inherent, food-effect property." *Id.* at 24. "[D]iscovering and claiming a new benefit of an old process cannot render the process again patentable." *Id.* Thus, the Court found that Endo's evidence of secondary considerations was insufficient to overcome the strong "primary considerations" that rendered the claims invalid.

The Federal Circuit next considered Endo's arguments challenging the Board's conclusion that the '740 application was obvious. First, the Court agreed with the Board that the applicant did not separately argue the patentability of the claims, and, thus, the Court only needed to address one of the claims presented in the application.

Second, the Court rejected applicant's argument that the claim limitation requiring "providing information" about a previously undiscovered correlation between renal failure and bioavailability was sufficient to overcome the Board's obviousness finding. The Court stated: "Though the correlation between the renal impairment and bioavailability was not known, informing someone of the correlation cannot confer patentability absent a functional relationship between the informing and administering steps." *Id.* at 26. Just as in *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, "the informing step does not 'transform[] the

process of taking the drug,'" *id.* (alteration in original) (quoting *King Pharms.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010)), "because there is no requirement in the claim that the dosage be adjusted in response to the informing step," *id.* Thus, "[b]ecause there is no functional relationship between the two steps in the method, and because the administration of controlled release oxymorphone is squarely present in the prior art, [applicant's] claim must fail." *Id.* In addition, the Court refused Endo's invitation to import a claim limitation—that the dosage be adjusted as a result of the informing step—from the specification.

Third, the Federal Circuit rejected Endo's evidence of secondary considerations. Although the Court found that the Board erred in applying too strict a commensurateness requirement, "[that] error was harmless because there was no nexus between the secondary considerations presented and the claimed invention." *Id.* at 28. Specifically, Endo failed to present evidence that unexpected multiple peaks or Opana® ER's commercial success was attributable to the novel informing step.

Accordingly, the Federal Circuit vacated and remanded the Board's obviousness decision regarding the '432 application, and affirmed the Board's obviousness decisions with respect to the '859 and '740 applications.

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A Supplier Has Standing to Bring a DJ Action When the Patentee's Actions Imply That the Supplier Contributorily Infringes

Daniel A. Lev

Judges: Rader, Newman, Dyk (author)

[Appealed from N.D. Ga., Judge Pannell]

In *Arris Group, Inc. v. British Telecommunications, PLC*, No. 10-1292 (Fed. Cir. May 19, 2011), the Federal Circuit reversed the district court's dismissal of a DJ case for lack of subject matter jurisdiction and found that an Article III case or controversy existed based on the DJ plaintiff's potential liability for contributory infringement.

Arris Group, Inc. ("Arris") sued British Telecommunications, PLC ("BT") in the U.S. District Court for the Northern District of Georgia seeking a DJ that four of BT's patents—U.S. Patent Nos. 5,142,532; 5,526,350; 6,538,989; and 6,665,264 (collectively "the patents-in-suit")—are invalid and not infringed by Arris. The patents-in-suit claim systems and methods related to cable networks for carrying out Voice over Internet Protocol ("VoIP") telephone services. Arris develops and manufactures VoIP telephony equipment that is used by cable system operators, including Cable One. Specifically, Cable One's network employs devices from Arris known as Embedded Multimedia Terminal Adapters ("E-MTAs") and Cable Modem Termination Systems ("CMTSs").

In 2007, BT sent a letter to Cable One accusing it of infringing various claims of the patents-in-suit by operating its VoIP network and later sent a 118-page presentation comparing the claims to Cable One's accused systems. The presentation repeatedly identified Arris's E-MTAs and CMTSs used in Cable One's network as embodying numerous elements and performing numerous method steps of the asserted claims. Cable One then sent a letter to Arris notifying Arris of BT's allegations and demanding that Arris defend and indemnify Cable One. A few months later, BT presented the same presentation to Cable One and Arris again outlining its infringement contentions. On three occasions, Arris contended that its products used in Cable One's networks did not infringe. Later, pursuant to the terms of a nondisclosure agreement, BT sent Arris and Cable One a licensing proposal, which would have granted a license only to Cable One. A few months later, on March 31, 2009, Arris filed this DJ action.

Arris's complaint sought (1) a declaration that Arris does not infringe the patents-in-suit, (2) an injunction preventing BT from suing Arris or its customers for infringement, and (3) a declaration that the patents-in-suit are invalid. The district court found that there was no Article III case or controversy between Arris

and BT, and dismissed the case for lack of subject matter jurisdiction. Because BT had never only discussed Cable One's, and not Arris's, alleged infringement of the patents-in-suit during their discussions, the district court found that BT had only directed its actions toward Cable One and, thus, there was no "real and immediate injury for Article III jurisdiction." Arris appealed.

"[W]here a patent holder accuses customers of direct infringement based on the sale or use of a supplier's equipment, the supplier has standing to commence a declaratory judgment action if (a) the supplier is obligated to indemnify its customers from infringement liability, or (b) there is a controversy between the patentee and the supplier as to the supplier's liability for induced or contributory infringement based on the alleged acts of direct infringement by its customers." Slip op. at 10.

The Federal Circuit, however, agreed with Arris and found that an Article III case or controversy involving Arris and BT was presented by these facts. First, the Court noted that the Supreme Court broadened the Federal Circuit's standard for DJ standing in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). "Under the Court's new standard, an Article III case or controversy exists when 'the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests,' . . . such that the dispute is 'real and substantial' and 'admi[ts] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" Slip op. at 7 (alteration in original) (quoting *MedImmune*, 549 U.S. at 127). The Federal Circuit next disposed with two of Arris's arguments in favor of DJ standing: (1) the Court rejected Arris's argument that it has standing because it suffered economic injury, which is not sufficient alone to meet the "adverse legal interest" requirement of *MedImmune*; and (2) the Court declined to address whether Arris's potential exposure to an indemnification claim from Cable One under Georgia law, in the absence of an express indemnification agreement, was a sufficient basis for Arris to have DJ standing.

Turning to the merits of the Court's legal analysis, the Federal Circuit held that there may be an implicit assertion of indirect infringement against a supplier when a patentee accuses a customer of direct infringement by making, using, or selling an allegedly infringing method or performing an allegedly infringing method. BT argued that it had never accused Arris of infringement, either directly or indirectly. But the Court found that, "[w]hile the presentation did not expressly accuse Arris of contributory infringement, BT explicitly and repeatedly singled out Arris' products used in Cable One's network to support its infringement arguments." *Id*. at 13-14. In fact, BT's 118-page presentation indentified Arris's E-MTAs or CMTSs used in Cable One's network "as satisfying at least one essential element or method step for every asserted claim," which "implies that Arris' products are being used as a 'material part' of the allegedly infringing invention." *Id.* at 16. In addition, the Court found that Arris's direct and substantial involvement in BT's infringement and licensing negotiations "shows that Arris was within BT's primary intended audience." *Id.* at 17.

The Court rejected BT's argument, which was consistent with the district court's decision, that the lack of an explicit accusation of infringement by Arris precludes a finding of an Article III case or controversy. Rather, the Court noted that it has repeatedly held that "a specific threat of infringement litigation by the patentee is not required to establish jurisdiction." *Id.* at 18-19 (quoting *ABB Inc. v. Cooper Indus., LLC*, No. 2010-1227, 2011 WL 553603, at *2 (Fed. Cir. Feb. 17, 2011)). Additionally, the Court rejected BT's argument that its 118-page presentation should not be construed as implicitly accusing Arris of

infringement, because a disclaimer in its presentation stated that "[n]othing in this assertion is meant to accuse any *particular* supplier [of] equipment of patent infringement." *Id*. at 19 (second alteration in original) (citation omitted). The Court found this was "at best a transparent attempt to defeat Arris' standing." *Id*. at 20. Finally, the Court rejected BT's argument that Arris lacked standing because BT had agreed not to sue Arris, where BT had refused to grant Arris an express covenant not to sue when asked by the Court.

Accordingly, the Court found that BT's infringement accusations against Cable One carried the implied assertion that Arris was committing contributory infringement and thus created an Article III case or controversy between Arris and BT. The Court reversed the district court's dismissal of the case for lack of subject matter jurisdiction and remanded the case to the district court for further proceedings.

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A Combination of Ingredients from Two Separate Solutions Previously Used Together as Part of an Overall Treatment Regimen Is Not Necessarily Obvious

Maryann T. Puglielli

Judges: Bryson (author), Dyk (concurring-in-part, dissenting-in-part), Prost
[Appealed from D. Del., Chief Judge Sleet]

In *In re Brimonidine Patent Litigation*, Nos. 10-1102, -1103 (Fed. Cir. May 19, 2011), the Federal Circuit affirmed-in-part and reversed-in-part the district court's validity determination with respect to five of Allergan, Inc.'s ("Allergan") patents and reversed the district court's determination that an ANDA filed by Exela Pharmsci, Inc. and Exela Pharmsci Pvt., Ltd. (collectively "Exela") infringed one of Allergan's patents.

In 1996, Allergan introduced Alphagan®, an aqueous eyedrop solution containing 0.2% brimonidine, an α-2 adrenergic agonist, to reduce elevated intraocular pressure of the eye associated with glaucoma. Due to an allergic reaction many Alphagan® users experienced as a result of brimonidine, Allergan introduced Alphagan® P in 2001. Alphagan® P was sold at two brimonidine concentrations: 0.15% and 0.1%. For the 0.1% concentration, the formulation's pH ranged from 7.6 to 7.8, while the 0.15% concentration's pH ranged from 7.15 to 7.3. Allergan found two therapeutic benefits from the higher pH of Alphagan® P as compared to Alphagan®: (1) the higher pH is closer to that of the human eye and thus did not produce a stinging sensation when administered; and (2) because brimonidine is an ionizable drug, a lower concentration of brimonidine at the higher pH produced therapeutic benefits similar to that of Alphagan®, and thus reduced the risk of an allergic response. In addition to brimonidine, Alphagan® P also contained carboxymethylcellulose ("CMC") to enhance the solubility of brimonidine, and stabilized chlorine dioxide ("SCD") as a preservative. CMC and SCD were also components of Refresh Tears®, an Allergan artificial tears solution with a pH between 7.2 and 7.9.

Allergan submitted five patents to the FDA that were listed in the Orange Book as associated with Alphagan® P. U.S. Patent No. 5,424,078 ("the '078 patent") was directed to a sterilized ophthalmic solution at physiological pH and osmolality. The Court and parties referred to the other four patents as the "related patents."

Apotex submitted two ANDAs for approval to make and sell generic versions of Alphagan® P with 0.1% and 0.15% brimonidine concentrations, while Exela's ANDA was directed only to the 0.15% brimonidine concentration product. Allergan sued Apotex and Exela in different districts and the matters were

consolidated in the District of Delaware. The district court concluded that the asserted claims of the '078 patent and the related patents were not invalid as obvious. Apotex stipulated to infringement, and the district court found that Exela's proposed product would infringe the asserted claims. Thus, the district court enjoined Apotex and Exela from making or selling the products described in their respective ANDAs.

Apotex appealed only the validity portion of the district court's judgment, while Exela appealed only the court's finding of infringement.

On appeal, the Federal Circuit agreed with Apotex that the asserted claims of the '078 patent would have been obvious over a combination of two prior art references, but found that the claims of the related patents would not have been obvious. With respect to the '078 patent, the Court found that it would have been obvious to adjust the SCD solution disclosed in one prior art reference to approximate physiologic pH, include a buffer component to maintain that pH, and include a tonicity component to approximate physiologic osmolality as claimed. The Court noted that a second reference relied upon by Apotex disclosed the modifications that Allergan argued imparted patentability to its claims—using SCD as a preservative in an ophthalmic solution and making the solution isotonic using well-known agents.

"Two ingredients might be therapeutically effective when used separately as part of an overall treatment regimen, yet be incompatible or ineffective when combined in a single solution." Slip op. at 13.

The Federal Circuit also rejected the district court's finding that the second reference taught away from the claimed invention because its use of SCD as the sole preservative would have required a quantity so great, it would have irritated the eye. The Federal Circuit noted that, "[e]ven if a reference discloses an inoperative device, it is prior art for all that it teaches." Slip op. at 8 (citation omitted). Further, the prior art disclosed that SCD can be used effectively as a sole preservative for an ophthalmic solution. Thus, the Federal Circuit found that it would have been obvious to create an ophthalmic solution that was adjusted to ocular pH and tonicity, and that relied on SCD as the sole preservative agent.

With respect to the four related patents, the Federal Circuit noted that neither party argued its validity case on a claim-by-claim basis either before the district court or on appeal. Apotex argued on appeal that every asserted claim of the related patents reads on a combination of Alphagan® and Refresh Tears®, and thus combining the two solutions would have been obvious, or, at a minimum, obvious to try. Although Apotex challenged three factual findings by the district court, the Federal Circuit rejected each of Apotex's arguments.

First, Apotex argued that the district court erred by finding that one of skill in the art would have expected brimonidine to present solubility problems at the elevated pH of Refresh Tears® in light of a table in an NDA filed by Allergan. The Federal Circuit noted that Apotex did not focus on the table at trial, did not provide any supporting testimony calling the district court's attention to the table, and did not explain how one of skill in the art would have assessed the information from the table. Thus, the Court declined to do so for the first time on appeal.

Second, Apotex argued that one of skill in the art would have expected CMC to increase the solubility of brimonidine contrary to the district court's finding because Alphagan® and Refresh Tears® were routinely prescribed together. The Federal Circuit rejected Apotex's argument because that fact alone did not

mean that the combination of the two products in one solution would have been obvious: "Two ingredients might be therapeutically effective when used separately as part of an overall treatment regimen, yet be incompatible or ineffective when combined in a single solution." *Id.* at 13.

Further, the Federal Circuit found that two journal articles relied upon by Apotex did not disclose or suggest the use of CMC in connection with any α-2 adrenergic agonist, let alone brimonidine. Although Apotex acknowledged that deficiency, it argued that the articles would have suggested that CMC enhanced the solubility of many soluble active ingredients. The Court rejected Apotex's argument since it was not supported by expert testimony or other evidence, and thus did not undermine the district court's contrary finding. Finally, the Federal Circuit noted that the articles also required a heating step which was incompatible with brimonidine, thus supporting the district court's conclusion that the articles did not teach the combination of brimonidine and CMC.

Third, Apotex argued that the district court erred in finding that one of skill in the art would not have been motivated to combine Alphagan® and Refresh Tears® because of concerns that SCD would oxidize brimonidine. The Federal Circuit rejected Apotex's challenge because Allergan's expert testified that one of skill in the art would have been extremely hesitant—if not, directed away from—formulating brimonidine with a chlorite solution, such as SCD. In addition, the Court noted that Allergan's documents touting an SCD solution as less reactive than hydrogen peroxide did not establish that one of skill in the art would not have expected SCD to oxidize brimonidine.

In addition, the Federal Circuit rejected Apotex's obvious-to-try argument because the district court found that the solutions that Allergan identified and claimed would not have been an "anticipated success." In light of the district court's well-supported factual findings, the Federal Circuit agreed that the claimed inventions were not invalid as obvious to try.

Finally, with respect to Apotex's appeal, the Federal Circuit found that the district court was well within its discretion in refusing to consider Apotex's post-trial obviousness arguments based on references that were admitted into evidence, but not supported with expert testimony or otherwise relied on at trial. Although the Court noted that there is no invariable requirement of expert testimony, "it is well within a trial judge's discretion to require expert testimony supporting technical references that are relied on to establish obviousness." *Id.* at 17-18.

With respect to Exela's appeal, the Federal Circuit agreed that the district court erred in its finding of infringement of U.S. Patent No. 6,641,834, one of the related patents, and the only patent Allergan asserted against Exela. The Court noted that the only issue was whether the product described in Exela's ANDA infringes the claim element that requires a pH of 7.0 or greater. The Court found that because Exela and Allergan agreed that the highest pH at which Exela requested FDA permission to manufacture and sell its proposed product is 6.7, Exela's proposed product did not infringe under 35 U.S.C. § 271(e)(2)(A). Unlike *Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002), where the Federal Circuit held that the district court could consider other relevant information outside of TorPharm's ANDA because the ANDA did not speak to the precise element claimed, Exela's ANDA does provide its proposed product's pH. Thus, because "neither party disputes that if Exela complies with its ANDA, it will never manufacture or sell a product at a pH above 6.7," the Court would not "assume that Exela will not act in full compliance with its representations to the FDA . . . ." Slip op. at 21.

Accordingly, the Federal Circuit reversed the district court's determination that the asserted claims of the '078 patent were not invalid, affirmed the district court's finding that Apotex failed to show that the claims

of the related patents were invalid as a matter of law, sustained the district court's injunction against Apotex, and reversed the district court's judgment that Exela's ANDA filing was an act of infringement.

Judge Dyk dissented from the majority's conclusion that the four related patents were nonobvious in light of the combination of Alphagan® and Refresh Tears®. According to Judge Dyk, obvious to try does not require absolute predictability of success, but rather a reasonable expectation of success. In this case, a person of skill in the art knew that (1) Alphagan® caused two negative side effects, including eye irritation; (2) the higher pH of Refresh Tears® would likely reduce eye irritation; (3) SCD in Refresh Tears® would likely be less toxic than another preservative in the Alphagan® product; (4) CMC present in Refresh Tears® would likely further reduce eye irritation; and (5) physicians routinely prescribed Refresh Tears® and Alphagan® together. Under these circumstances, Judge Dyk would have found the combination of the two commercially successful products "obvious to try." Dyk Dissent at 2 (citation omitted).

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June 2011

Failure to Pay Royalties Does Not Convert Authorized Sale of Licensed Product into Unauthorized Sale Under Exhaustion Doctrine

Kevin D. Rodkey

Judges: Lourie, Linn (author), Dyk

[Appealed from ITC]

In *Tessera, Inc. v. International Trade Commission*, No. 10-1176 (Fed. Cir. May 23, 2011), the Federal Circuit affirmed the ITC's determination of noninfringement, validity, and exhaustion of U.S. Patent No. 5,633,106 ("the '106 patent"). The Court also vacated and remanded the ITC's determination that there is no section 337 violation with respect to U.S. Patent Nos. 5,679,977 ("the '977 patent") and 6,133,627 ("the '627 patent").

Tessera, Inc. ("Tessera") owns the '106 patent, which is directed to preventing contamination of exposed terminals on semiconductor packages during encapsulation by using an encapsulant barrier and a protective barrier during the encapsulation process. Each semiconductor package accused of infringing the '106 patent includes a chip and a package substrate layer. The accused products are divided into two groups: the "µBGA" products, which have a polyimide-based package substrate; and the "wBGA" products, which use a laminate-based package substrate. Only Elpida Memory, Inc. and Elpida Memory (USA) Inc. (collectively "the Elpida intervenors") import the accused µBGA products, whereas all intervenors import the accused wBGA products.

The accused wBGA products consist of a stack of layers. The bottom layer is a laminate substrate layer. A copper wiring layer is applied on top of the laminate substrate layer. A solder mask layer is applied on top of the copper wiring layer. Holes in the solder mask expose the terminals of copper wiring layer, which are the terminals of the accused wBGA products. During encapsulation, a "protective barrier" contacts the solder mask and prevents the encapsulant from flowing into the holes and contaminating the terminals.

Tessera licenses each of the asserted patents in the so-called "TCC Licenses." Each TCC License contains a grant clause substantially identical to the following: "Subject to the terms and conditions [of this agreement], Tessera hereby grants Licensee a . . . license to the Tessera Patents . . . and to sell . . . and/or offer for sale such TCC Licensed Products." Slip op. at 8 (alterations in original) (citation omitted). Each TCC License also contains an "Exclusion from License" provision stating that "Licensee is licensed only to Licensed Products for which Licensee or a third party has satisfied a royalty obligation to

Tessera." *Id*. (citation omitted). All of the intervenors purchase some portion of their accused packages from parties to the TCC Licenses.

Tessera brought suit in the ITC asserting the '106, '977, and '627 patents. The ALJ's Initial Determination found that there was no section 337 violation because (1) Tessera failed to meet its burden to show that the accused products infringed the '106, '977, and '627 patents; (2) the '106 patent was not invalid for anticipation, obviousness, or indefiniteness; (3) the '977 and '627 patents were not invalid for anticipation or indefiniteness; and (4) Tessera's patent rights are exhausted as to those accused products purchased from Tessera's licensees.

Upon review, the ITC affirmed the finding of no section 337 violation. Specifically, the ITC (1) modified the ALJ's construction of "top layer" and "thereon" in claim 1 of the '106 patent; (2) reversed the ALJ's finding of noninfringement for the µBGA products, but affirmed the finding of patent exhaustion; and (3) affirmed the ALJ's finding that the accused wBGA products do not infringe the asserted claims of the '106 patent. Thus, the ITC found that the µBGA products infringe, but are exhausted, and that the wBGA products do not infringe. Tessera appealed the ITC's construction of claim 1 of the '106 patent, the finding of no infringement by the wBGA products, and the finding of patent exhaustion. Finally, Tessera sought a vacatur of the ITC's decision as it pertains to the expired '977 and '627 patents. A few other intervenors also challenged the validity of the '106 patent as anticipated by numerous prior art references.

On appeal, the Federal Circuit first considered the construction of claim 1 of the '106 patent and Tessera's argument that the ITC adopted a new construction during the infringement analysis. The Court concluded that Tessera could not argue that the ITC applied an incorrect claim construction because the ITC adopted Tessera's proposed construction. Thus, the Court concluded that Tessera was in fact challenging the ITC's infringement determination, noting that the Court reviews the infringement determination for substantial evidence and claim construction de novo.

"That some licensees subsequently renege or fall behind on their royalty payments does not convert a once authorized sale into a non-authorized sale." Slip op. at 22.

The Court next turned to Tessera's argument that the ITC erred in finding that the accused wBGA products do not infringe claim 1 of the '106 patent. Specifically, Tessera argued that the ITC erred when it found that the "top layer" of claim 1 cannot include the solder mask layer of the wBGA products. Under the construction adopted by the ITC, the "top layer" is the layer that "carries the terminals." The Federal Circuit found substantial evidence to support the ITC's determination that the laminate substrate layer of the accused wBGA products is the "top layer" and, as such, the products do not infringe claim 1 of the '106 patent. In so doing, the Court noted that the solder mask comprises the preferred material for the "protective barrier," and the patent specification depicts the "protective barrier" as separate and distinct from the "top layer."

The Federal Circuit next addressed the intervenors' anticipation arguments, holding that the '106 patent was not anticipated by any of the asserted prior art references. The Court determined that two of the references failed to teach at least a "protective barrier in contact with said top layer," and a third reference failed to disclose at least "exposed terminals," as required by claim 1 of the '106 patent.

The Court turned next to the issue of patent exhaustion, considering both a jurisdictional question and the application of the exhaustion doctrine. The ITC and the Elpida intervenors challenged the Court's jurisdiction to hear Tessera's appeal as to patent exhaustion because Tessera did not timely appeal the issue. Tessera filed its Notice of Appeal within sixty days of the ITC's Final Determination, but more than sixty days after the ITC issued its Notice to Review, stating that it would not review the ALJ's exhaustion findings. The ITC argued that when it decided not to review the ALJ's determination on patent exhaustion, the ALJ's decision became the final decision of the ITC and Tessera's appeal was thus untimely. The Federal Circuit found that, because the ITC issued a notice to review certain issues of the Initial Determination related to the '106 patent, whether Tessera could obtain an exclusion order based on the '106 patent was still before the ITC. Accordingly, the Court held that it had jurisdiction because Tessera filed the Notice of Appeal within sixty days of the ITC's Final Determination.

Turning to the applicability of the exhaustion doctrine, the Court considered whether the patentee authorized certain sales of products embodying the '106 patent. Tessera argued that the ITC improperly found patent exhaustion without an authorized sale because, under the terms of the TCC Licenses, sales by its licensees are not licensed, and are therefore unauthorized until royalties are paid. Because royalties were allegedly not paid or paid late, Tessera argued that sales by those licensees did not trigger exhaustion of its patent rights. The ITC and the Elpida intervenors responded that patent exhaustion is triggered "by a sale *authorized* by the patent holder," quoting *Quanta Computer, Inc. v. LG Electronics, Inc*., 553 U.S. 617, 636 (2008). They argued that Tessera authorized these sales when it granted its TCC Licensees the authority to sell and that the payment of royalties is immaterial.

The Federal Circuit held that the licenses expressly authorized the sale of the licensed products and payment of the royalties at the end of the reporting period. Any subsequent nonpayment of the royalties under the TCC Licenses would give rise to an action with Tessera's licensees, but not with the licensees' customers. The Court observed that adopting Tessera's argument would create uncertainty over every sale and every product in possession of a customer of the licensee, and would be wholly inconsistent with the fundamental purpose of patent exhaustion. The Court, therefore, held that Tessera's patent rights were exhausted by the sale of the accused products by Tessera's licensees.

Finally, the Federal Circuit turned to the issue of whether the ITC's determination that there is no section 337 violation with respect to the '977 and '627 patents should be vacated as moot. The Court determined that because the '977 and '627 patents expired during the course of the proceedings and the ITC has a limited statutory mandate and can only issue exclusion orders barring future conduct, nothing remained pending before the ITC with respect to these patents. Noting that the '977 and '627 patents had expired through happenstance and not Tessera's voluntary actions, the Court held that the issues regarding noninfringement of the '977 and '627 patents were moot. The Court therefore vacated this portion of the Final Determination and remanded with instructions to dismiss this portion of the complaint.

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June 2011

Standing Under California's Unfair Competition Laws Only Requires an Allegation of an Injury in Fact That Was Caused by Defendants' Unfair Competition

*Joseph P. Long**

Judges: Newman, Gajarsa (author), Prost

[Appealed from C.D. Cal., Judge Selna]

In *Allergan, Inc. v. Athena Cosmetics, Inc.*, No. 10-1394 (Fed. Cir. May 24, 2011), the Federal Circuit reversed the district court's finding that Allergan, Inc. ("Allergan") lacked standing to bring suit against Athena Cosmetics, Inc. and its numerous codefendants (collectively "Defendants") under California Business & Professions Code ("UCL") §§ 17200 *et seq*.—the statute's unfair competition provisions.

Allergan manufactures and sells Latisse®, an FDA-approved product that comprises a prostaglandin compound, PGF, to treat inadequate eyelash growth. Allergan is the only authorized manufacturer of a prostaglandin product for the stimulation of hair growth.

Allergan sued Defendants under 35 U.S.C. § 271 for infringing or inducing infringement of three of its patents and also alleged that Defendants violated UCL §§ 17200 *et seq*. by unlawfully marketing, selling, and distributing hair and/or eyelash growth products without a prescription, without an approved NDA from the FDA or the California Department of Health Services, and in violation of state and federal misbranding laws. Allergan alleged that Defendants' unfair competition "has resulted in and continues to result in serious and irreparable injury to Allergan, including but not limited to lost sales, revenue, market share, and asset value." Slip op. at 5 (citation omitted). Defendants moved for judgment on the pleadings under Fed. R. Civ. P. 12(c), claiming that Allergan lacked standing to assert a violation of UCL §§ 17200 *et seq*. because Allergan did not allege an injury that was compensable by restitution.

The district court concluded, based on California law existing at the time, that Allergan had failed to plead an injury compensable through restitution because it did not have an ownership interest or a vested interest in the lost profits or market share it sought to recover since Defendants' profits from sales of its products came from third-party consumers, and not Allergan. The district court entered judgment pursuant to Fed. R. Civ. P. 54(b) and dismissed Allergan's claim for relief under the UCL with prejudice. The district court stayed Allergan's patent claims until the outcome of its UCL appeal.

On appeal, the Federal Circuit noted that although Allergan's patent claims are not presently at issue, they give rise to the Court's jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). On the merits, the Court

reviewed the history of UCL § 17204, noting that in 2004 it was amended by Proposition 64—a California voter's amendment—and limited a private person's right to sue under the UCL to someone who has "suffered injury in fact and has lost money or property as a result of such unfair competition." *Id.* at 9 (citation omitted).

"[T]o satisfy the standing requirements of section 17204, a plaintiff must allege exactly what the statutory text requires: '(1) . . . a loss or deprivation of money or property sufficient to qualify as injury in fact, i.e. *economic injury*, and (2) . . . that [the] economic injury was the result of, i.e. *caused by*, the unfair business practice . . . .'" Slip op. at 10 (alterations in original) (quoting *Kwikset*, 246 P.3d at 885).

Initially, the California courts interpreted the amendment to limit claims to individuals who were eligible for restitution, as opposed to those requesting injunctive relief. The Federal Circuit, however, noted that recent California Supreme Court decisions in *Kwikset Corp. v. Superior Court of Orange County*, 246 P.3d 877 (Cal. 2011), and *Clayworth v. Pfizer, Inc.*, 233 P.3d 1066 (Cal. 2010), rejected that reasoning and clarified: "[T]o satisfy the standing requirements of section 17204, a plaintiff must allege exactly what the statutory text requires: '(1) . . . a loss or deprivation of money or property sufficient to qualify as injury in fact, i.e. *economic injury*, and (2) . . . that [the] economic injury was the result of, i.e. *caused by*, the unfair business practice . . . .'" Slip op. at 10 (alterations in original) (quoting *Kwikset*, 246 P.3d at 885). The Federal Circuit reiterated that, in rejecting the earlier California courts' restitution limitation, the California Supreme Court explained that "'nothing in the text or history of Proposition 64 suggests' that the drafters intended 'to make standing under section 17204 expressly dependent on the eligibility for restitution under section 17203.'" *Id.* (quoting *Kwikset*, 246 P.3d at 894-95).

Applying that standard here, the Federal Circuit held that Allergan plainly alleged an economic injury that was the result of an unfair business practice and thus, under *Kwikset*, satisfied the requirements of § 17204. In addition, the Court rejected Defendants' argument that Proposition 64 added a "business dealings requirement" to standing under § 17204. The only amendment made by Proposition 64 was to require that a private person "suffered injury in fact and . . . lost money or property as a result of such unfair competition." *Id.* at 12 (alteration in original) (quoting Cal. Prop. 64 § 3). The Federal Circuit noted that "[r]eading this amendment to encompass a business dealings requirement would contradict the plain language of the statute and improperly elevate one purpose of Proposition 64 over the language of the statute." *Id.* The Court agreed that while a direct business dealing is one way in which a plaintiff could be harmed, California courts have also recognized claims under the UCL where a direct business dealing was lacking.

Accordingly, the Federal Circuit reversed the decision of the district court and remanded for further proceedings consistent with its opinion.

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June 2011

Federal Circuit En Banc Tightens the Standards for Inequitable Conduct for Both Intent and Materiality

Benjamin H. Huh

Judges: Rader (author), Newman, Lourie, Bryson (dissenting), Gajarsa (dissenting), Linn, Dyk (dissenting), Prost (dissenting), Moore, O'Malley (concurring-in-part, dissenting-in-part), Reyna

[Appealed from N.D. Cal., Judge Alsup]

In *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-1511, -1512, -1513, -1514, -1595 (Fed. Cir. May 25, 2011) (en banc), the Federal Circuit vacated the district court's finding of unenforceability due to inequitable conduct and remanded for further proceedings consistent with its tightened standards for inequitable conduct.

In 1984, Therasense, Inc. (now Abbott Diabetes Care, Inc.) and Abbott Laboratories (collectively "Abbott") filed a patent application which led to U.S. Patent No. 5,820,551 ("the '551 patent") regarding disposable blood glucose test strips for testing whole blood without a membrane. During prosecution, the examiner rejected the claims over another Abbott patent, U.S. Patent No. 4,545,382 ("the '382 patent"), which noted that the membrane was optional. To overcome these rejections, Abbott's patent attorney and director of research and development submitted a declaration stating that one skilled in the art would have read the '382 patent specification to require a membrane when used with whole blood. Then, while prosecuting the European counterpart to the '382 patent several years later, Abbott represented that their invention did not require a membrane.

In 2004, Becton, Dickinson and Co. ("Becton") sued Abbott in the District of Massachusetts seeking a DJ of noninfringement of U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent") involving its blood glucose test strip. Abbott countersued in the Northern District of California alleging infringement of the '164, '745, and '551 patents. The District of Massachusetts transferred its case to the Northern District of California. Abbott also sued Nova Biomedical Corp. ("Nova"), Becton's supplier, and Bayer Healthcare LLC ("Bayer"). The Northern District of California consolidated all of these cases.

The district court granted SJ of noninfringement of all asserted claims in the '164 and '745 patents. The district court also found nearly all of the asserted claims of the '745 patent anticipated as well as several of the asserted claims of the '551 patent obvious in light of the '382 patent. Further, the district court held the '551 patent unenforceable for inequitable conduct because Abbott did not disclose to the PTO its

briefs filed with the European Patent Office ("EPO"). Abbott appealed and a panel of the Federal Circuit upheld the judgments of invalidity, unenforceability, and noninfringement, but the Federal Circuit granted Abbott's petition for rehearing en banc.

"This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." Slip op. at 24.

Writing for the majority, Chief Judge Rader stated that inequitable conduct is an equitable defense that evolved from a trio of Supreme Court cases applying the doctrine of unclean hands to patent cases involving egregious misconduct. In addition, the Court explained the divergence of inequitable conduct from the doctrine of unclean hands and the fluctuations of the standards for intent and materiality over time. Due to these fluctuations, the Court noted that the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Therefore, citing numerous issues of unintended consequences, the majority chose to "now tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." Slip op. at 24.

First, as to the intent element, the Court held that an accused infringer must prove by clear and convincing evidence that the patentee acted with the specific intent to deceive the PTO. In reaching this standard, the Court noted that the gross negligence and "should have known" standards are insufficient to satisfy the specific intent requirement. In addition, the majority specifically noted that in cases involving nondisclosure of information, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Moreover, the Court explained that intent and materiality are separate requirements. Therefore, a district court should not use a "sliding scale" to infer intent from materiality, but instead should weigh the evidence of intent to deceive independent of its analysis of materiality. Still, the majority clarified that since direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. Nonetheless, to meet the clear and convincing evidence standard, the Court explained that the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. Further, because the party alleging inequitable conduct bears the burden of proof, the majority explained that the patentee need not offer any good-faith explanation unless the accused infringer first proves a threshold level of intent to deceive by clear and convincing evidence.

Second, addressing the materiality element, the Court held that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality, dismissing the definition of materiality in PTO Rule 56. Therefore, in assessing the materiality of a withheld reference, the district court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the district court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. Recognizing the early unclean hands from which inequitable conduct evolved, the majority carved out an exception to the but-for materiality test for affirmative egregious misconduct. The Court explained that in cases where the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material as a patentee is unlikely to go to great lengths to deceive the PTO unless it believes it will affect the issuance of the patent.

Since the district court applied the PTO's Rule 56 materiality standard, the Court vacated the district court's finding of materiality and remanded for determination under the but-for materiality standard. Further, since the district court found intent to deceive based on the absence of a good-faith explanation for failing to disclose the EPO briefs, the Court vacated the district court's finding of intent and remanded for determination under the Court's specific intent analysis. Ultimately, the Court affirmed-in-part the district court's judgment of obviousness, noninfringement, and anticipation while it vacated-in-part its finding of inequitable conduct and remanded-in-part for further proceedings consistent with its opinion.

In a separate opinion, Judge O'Malley dissented-in-part to the majority's opinion regarding materiality and concurred-in-part to the remainder of the majority's decision and judgment. Judge O'Malley joined the majority's findings regarding the standard for the specific intent to deceive. But, Judge O'Malley's views diverged from the dissent regarding materiality, as she believed that both the majority and the dissent strain too hard to impose hard and fast rules. Instead of the majority's but-for materiality approach, Judge O'Malley would adopt a more flexible test, including discretion as to the remedy, such as rendering fewer than all claims unenforceable, dismissing the action before it, or another remedy as long as it was commensurate with the violation. Specifically, Judge O'Malley would deem conduct material where (1) but for the conduct, the patent would not have issued; (2) the conduct constitutes a false or misleading misrepresentation of fact; or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application-at-issue was wholly undermined. Finally, Judge O'Malley noted that she would have affirmed the district court's finding of materiality under her flexible and discretionary approach.

In a dissenting opinion, Judge Bryson, joined by Judges Gajarsa, Dyk, and Prost, proposed adhering to the materiality standard set forth in PTO Rule 56 instead of the majority's fundamental change to the inequitable conduct doctrine through adoption of a but-for materiality test. The dissent raised two reasons for its preference of the PTO's Rule 56 materiality test. First, the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, i.e., what information is material to the examination process. Second, the higher but-for materiality standard adopted by the majority will not provide appropriate incentive for patent applicants to comply with the disclosure obligations the PTO places upon them. Ultimately, the dissent would affirm the district court's finding that the '551 patent is unenforceable because the court's factual findings were not clearly erroneous and because its legal analysis comports with the proper role of the doctrine of inequitable conduct in patent law.

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