



PATENT HAPPENINGS

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on judicial, legislative, and administrative developments in patent law.

HIGHLIGHTS

1. *Safe harbor provision of § 271(e)(1) did not apply to research tool used in obtaining data for FDA submission where tool itself was not subject to FDA pre-market approval..... 1*
2. *Evidentiary burdens for inequitable conduct must be “strictly enforced” 2*
3. *Patentee must take some affirmative action to show case or controversy for declaratory judgment 3*
4. *Patentee may not base irreparable harm to support an injunction on harm allegedly suffered by non-joined exclusive licensee..... 4*
5. *No grace period for an accused infringer to cease accused activity before being liable for damages when given notice under § 287(a) 5*
6. *“Original application” for purposes of eligibility for inter partes reexamination includes continuing applications 5*
7. *Federal Circuit addresses inherent anticipation of structure claimed with a functional limitation 6*
8. *Oral opinion of counsel, obtained post-verdict, defeats willful infringement charge for post-verdict sales 7*
9. *One district court partially lifts stay during reexamination so patentee can obtain discovery to rebut PTO’s obviousness rejection; second district court refuses to permit accused infringer’s confidential discovery materials to be released for use by patentee in reexamination proceeding 8*
10. *PTO will issue a new effective date for regulations governing applications with patentably indistinct claims 8*

JUDICIAL HAPPENINGS

Research Tools and 271(e)’s Safe Harbor

The Hatch-Waxman Act provides a safe harbor for accused infringing activity that is “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”¹ The Supreme Court has held that “§271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.”² The law has been unsettled on how this exemption should apply to “research tools,” *i.e.*, tools that are used in obtaining data for submission to the FDA, but themselves are not subject to FDA pre-market approval.

The Federal Circuit addressed the applicability of the safe harbor of § 271(e)(1) to research tools in *Proveris Scientific Corp. v. InnovaSystems, Inc.*, No. 2007-1428, 2008 WL 2967100 (Fed. Cir. Aug. 5, 2008). There the accused product concerned a device used to characterize aerosol sprays used in drug delivery devices. The drug and drug delivery device were subject to FDA pre-market approval. But the claimed apparatus to test the delivery device, such as the accused product, was not subject to FDA pre-market approval. The Federal Circuit held that since the testing device was not itself subject to pre-market approval it was not a “patented invention” that fell within the scope of the safe harbor even though the testing device was used solely in connection with testing needed to obtain FDA approval of the drug

¹ 35 U.S.C. § 271(e)(1). *See generally*, Robert A. Matthews, Jr., ANNOTATED PATENT DIGEST § 10:142 FDA Submission Infringement Exemption Under § 271(e)(1); § 10:143 § 271(e)(1) Exemption Applies to Medical Devices; and § 10:144 Research Tools [hereinafter APD]

² *Merck KgaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

delivery device. *Id.* at *6-*8.

In reaching its holding, the Federal Circuit rationalized that because the accused infringer was not subject to regulatory barriers in entering the market with its accused product, it was not undertaking the type of activity Congress sought to protect under the safe harbor provision. *Id.* at *7. The court further noted that its holding has symmetry with the fact that the patentee cannot seek a patent-term extension under § 156³ because the patented invention is not subject to FDA pre-market approval. While the Federal Circuit appeared to agree with the accused infringer, that the accused infringer was offering a device “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products,” the device it was selling was not a “patented invention” under § 271(e)(1), and therefore not entitled to the benefit of the safe harbor provision. *Id.* at *8.

Tightening the Reins on Inequitable Conduct

In May, Judge Rader expressed concerns that the court’s inequitable conduct jurisprudence was coming dangerously close to merging the separate elements of materiality and intent to deceive in view of the increasing use of inferences to prove the element of intent to deceive.⁴ As a result, he concluded there appears to be a “rejuvenation of the inequitable conduct tactic” harking back to the days where the court was faced with a “plague” of questionable inequitable conduct challenges. Perhaps taking to heart these concerns, the court’s recent inequitable conduct opinions appear to be reviewing more rigorously the evidence of materiality and intent to deceive as distinct elements of proof.⁵

Keeping with this trend, the Federal Circuit in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 2007-1448, 2008 WL 3891543 (Fed. Cir. Aug. 25, 2008), instructed that it is “paramount” that courts “strictly enforce the burden of proof and elevated

³ See generally, APD § 9:23 Extensions for FDA Delays under § 156.

⁴ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.* 525 F.3d 1334, 1349-51 (Fed. Cir. 2008) (Rader, J., *dissenting*); see Patent Happenings, May 2008 at p.3.

⁵ E.g., *Research Corp. Tech., Inc. v. Microsoft Corp.*, No. 2006-1275, 2008 WL 2939524, *3-*5 (Fed. Cir. Aug. 1, 2008); *Eisai Co., Ltd. v. Dr. Reddy’s Lab., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008); and *Scanner Tech. Corp. v. ICOS Vision Sys. Corp., N.V.*, 528 F.3d 1365 (Fed. Cir. 2008).

standard of proof in the inequitable conduct context . . . because the penalty for inequitable conduct is so severe[.]” *Id.* at *6. Writing for the panel, Judge Michel further explained that “it is . . . inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith.” *Id.*

Addressing the necessary proof to show intent to deceive as a separate element from materiality, Judge Michel noted the Circuit’s law that “the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct.” *Id.* Judge Michel also instructed that while circumstantial evidence can be used to show intent to deceive, that evidence must still meet the clear and convincing standard—“lesser evidence cannot satisfy the deceptive intent requirement.” *Id.* at *7. While an inference of an intent to deceive may be permissible, the court instructed that “the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be *the single most reasonable inference* able to be drawn from the evidence to meet the clear and convincing standard.” *Id.* (emphasis added)

Applying the foregoing, the court vacated a summary judgment holding two patents unenforceable for inequitable conduct. The district court had accepted the accused infringer’s theory that during prosecution the patentee’s patent counsel had received a letter providing information that arguably cast doubt on the characterization of what the prior art allegedly could not do.⁶ At some point thereafter, the patentee replaced its patent counsel. Its litigation counsel served as an intermediary in the switching of the prosecution counsel. The district court viewed these acts as the patentee attempting to “quarantine” the new prosecution counsel from the letter and knowledge held by the original prosecution counsel. Based on these acts, the district court found a sufficient inference of an intent to deceive.

As to the first patent, the Federal Circuit held that the district court’s judgment of inequitable conduct was clearly erroneous because there was no evidence to support the inference of an intent to deceive. The Federal Circuit noted that the accused infringer had failed to provide evidence to show that the patentee or the named inventor knew about the letter before the decision was made to switch patent counsel. *Id.* at *8-

⁶ 2007 WL 1890709 (D. Md. June 26, 2007).

*9. Hence, the accused infringer had failed to prove by clear and convincing evidence the predicate facts necessary to support the inference of intent to deceive. The Federal Circuit commented that “no inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR’s lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its burden.” *Id.* at *8.

Additionally, the Federal Circuit instructed that in the absence of sufficient evidence from the accused infringer to show indirect evidence of intent to deceive the patentee had no burden to come forward with a good faith explanation of its acts. Accordingly, the accused infringer could not carry its burden to show intent to deceive by pointing to the patentee’s failure to “prove a credible alternative explanation.” *Id.* The court instructed that “[o]nly when the accused infringer has met [its evidentiary]burden [to show intent to deceive by clear and convincing evidence] is it [then] incumbent upon the patentee to rebut the evidence of deceptive intent with a good faith explanation for the alleged misconduct.” *Id.*

As to the second patent, the Federal Circuit vacated the inequitable conduct finding because the information contained in the withheld letter was cumulative to information contained in interrogatory responses that the patentee had submitted to the PTO. *Id.* at *11.⁷

Declaratory Judgment Jurisdiction

The Supreme Court’s opinion in *MedImmune* eliminated the Federal Circuit’s “reasonable apprehension” standard, and arguably lowered the bar for showing a sufficient case or controversy to support subject matter jurisdiction for patent-related declaratory judgment claims.⁸ But, as the Federal Circuit reaffirmed in *Prasco, LLC v. Medicis Pharmaceutical Corp.*, No. 2007-1524, 2008 WL 3546217, *3 (Fed. Cir. Aug. 15, 2008), the mere existence of a patent does not give a declaratory judgment plaintiff a right to haul a quiescent patent

owner into court to defend its patent.⁹ Rather, to show a case or controversy of sufficient immediacy to support subject matter jurisdiction for a declaratory judgment action, a patentee must have taken some affirmative act with its patent that restrains, or threatens to restrain, the declaratory judgment plaintiff’s ability to market its product. *Id.* at *5-*6.

In *Prasco*, a generic drug manufacturer filed a declaratory judgment action seeking a declaration that one of its products did not infringe various patents held by the defendant. The district court dismissed the declaratory judgment action for lack of a case or controversy. On appeal, the plaintiff argued that the patentee’s marking its product with the challenged patents, refusing to give the plaintiff a covenant not to sue, and the prior litigation history between the parties showed there was a sufficient case or controversy. The Federal Circuit disagreed.

First, the court noted that the patentee had not taken any affirmative action to restrain the plaintiff’s ability to market its drug product, and indeed, the plaintiff was marketing its drug product. The court instructed that the mere existence of a patent and a plaintiff’s subjective fear that the patentee will enforce the patent against the plaintiff does not, by itself support jurisdiction for a declaratory judgment claim. *Id.* at *5-*6. The Federal Circuit noted that “[t]he lack of any evidence that the defendants believe or plan to assert that the plaintiff’s product infringes their patents creates a high barrier to proving that Prasco faces an imminent risk of injury.” *Id.* at *7.

Second, the court held that the patentee’s marking of its products to comply with § 287(a) provides little, if any, evidence that [the patentee] will ever enforce its patents.” *Id.* at *7.

Third, the Federal Circuit held that while a history of litigation between parties could, in some instances support a showing of a case or controversy, here the circumstances did not do so. The prior suit involved other patents and an unrelated product. Hence, it concluded that the “prior suit premised on other patents cannot alone create a real and immediate controversy, and [] is entitled to only minimal weight in analyzing whether such a controversy has been created.” *Id.*

Finally, the Federal Circuit held that the patentee’s refusal to give the plaintiff a covenant not to sue, after the plaintiff had filed its declaratory judgment action,

⁷ The Federal Circuit also vacated a summary judgment holding the claims invalid for being indefinite. The Federal Circuit held that the district court erred in concluding that a claim is indefinite if a potential infringer cannot tell if it will infringe *before* it carries out its activity. *Id.* at *13. See generally, APD § 23:6 Need Not Provide Precise Guidance on What Does Not Infringe.

⁸ *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007); see generally, APD § 37:15 Post-MedImmune “All Circumstances” Standard for Showing Actual Controversy.

⁹ See APD § 37:19 Non-threatening Patentees Should Not be Hauled Into Court.

did not show a case or controversy. The court instructed that

A patentee has no obligation to spend the time and money to test a competitor's product nor to make a definitive determination, at the time and place of the competitor's choosing, that it will never bring an infringement suit. And the patentee's silence does not alone make an infringement action or other interference with the plaintiff's business imminent. Thus, though a defendant's failure to sign a covenant not to sue is one circumstance to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy—some affirmative actions by the defendant will also generally be necessary.

Id. at *8.¹⁰

As noted above the allegation regarding the refusal to provide a covenant not to sue arose after the filing of the original declaratory judgment complaint. The plaintiff had raised this fact by way of an amended complaint. Normally, post-filing facts may not be relied upon to prove subject matter jurisdiction existed when the complaint was first filed.¹¹ But, in this case, the court noted that that amended complaint was in effect a supplemental complaint under FRCP Rule 15(d). Relying on Supreme Court precedent permitting the use of a supplemental complaint to correct defective jurisdictional allegations,¹² the court held that it was proper to consider the additional jurisdictional facts alleged in the supplemental complaint even though these facts arose after the original declaratory judgment complaint had been filed. *Id.* at *4.

Notably, *Prasco* did not deal with a competing infringement suit by the patentee filed in a separate forum and the inevitable dispute between the parties as to which suit should have precedence. Future cases will have to work out how a supplemental complaint correcting defective jurisdictional allegations should be

treated in regards to applying the first-to-file rule.¹³

In another interesting declaratory judgment case, the district court in *Fujitsu Ltd. v. Nanya Technology Corp.*, No. C 06-6613 CW, 2008 WL 3539503, *3 (N.D. Cal. Aug. 12, 2008), granted a patentee's motion to dismiss a manufacturer's noninfringement declaratory judgment claim finding there was no case or controversy between the patentee and the manufacturer.¹⁴ The patentee had sued a customer of the manufacturer for infringing the patentee's method patent based on the way the customer used the manufacturer's product. But the patentee had never accused the manufacturer of directly infringing the patented method or inducing its customers to infringe the patented method. Further, the manufacturer's product had substantial noninfringing uses. In view of these facts, the court held that while there was a controversy between the patentee and the customer, there was no controversy between the patentee and the manufacturer.

Personally Suffer Irreparable Harm

Under *eBay* a patentee must prove that *it* will suffer irreparable harm to obtain a permanent injunction.¹⁵ Focusing on the requirement that the plaintiff must demonstrate that it personally will suffer irreparable harm, the Federal Circuit in *Voda v. Cordis Corp.*, No. 2007-1297, 2008 WL 3822801, *15 (Fed. Cir. Aug. 18, 2008), rejected a patentee's argument that the alleged irreparable harm its exclusive licensee would suffer from continued infringement supported granting the patentee a permanent injunction where the exclusive licensee was not a party to the suit.¹⁶

The patentee in *Voda*, a doctor who invented a catheter, had granted an exclusive license to a manufacturer. But the manufacturer had not joined the patentee in its suit to enforce the patent. At trial the patentee failed to identify any irreparable injury to himself due to the infringement and failed to show that monetary damages were inadequate to compensate him

¹⁰ See also APD § 37:45 Patentee's Refusal to Give Clearance Letter.

¹¹ See § 37:18 Post-Filing Facts Cannot Make Up for Lack of Jurisdiction at Time of Filing.

¹² *Mathews v. Diaz*, 426 U.S. 67, 75 (1976); see generally APD § 36:26 Amending Pleadings to Correct Jurisdiction Allegations. For another recent case permitting a supplemental complaint to correct defective subject matter jurisdictional allegations see *The Hertz Corp. v. Enterprise Rent-A-Car Co.*, 557 F. Supp.2d 185, 191-92 (D. Mass. Jun. 2, 2008).

¹³ Cf. *Micron Technology, Inc. v. Mosaid Tech., Inc.*, 518 F.3d 897, 905 (Fed. Cir. 2008) (considering first-to-file rule and convenience factors); see generally, APD. V. First-to-File Rule §§ 37:93 – 37:101.50.

¹⁴ The manufacturer was a third-party defendant facing an indemnity claim asserted by the accused infringer.

¹⁵ *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 126 S. Ct. 1837, 1839 (2006) (“A plaintiff must demonstrate: (1) that *it* has suffered an irreparable injury”); see generally APD § 32:159 Standards for Granting Permanent Injunctions.

¹⁶ Cf. APD § 9:41 —Exclusive Licensee as Co-Owner.

for the infringement. To support his claim for a permanent injunction, the patentee argued that continued infringement would cause irreparable harm to its exclusive licensee.

Rejecting this argument, the Federal Circuit held that denying injunctive relief based on the patentee's inability to show that it personally would suffer irreparable harm without the permanent injunction did not conflict with *eBay*. The court explained:

The Supreme Court held only that patent owners that license their patents rather than practice them 'may be able to satisfy the traditional four-factor test' for a permanent injunction. Nothing in *eBay* eliminates the requirement that the party seeking a permanent injunction must show that 'it has suffered an irreparable injury.' Moreover, we conclude that the district court did not clearly err in finding that Voda failed to show that Cordis's infringement caused *him* irreparable injury.

Id. (emphases in original).

No Grace Period After Receiving § 287(a) Notice

Under § 287(a) of the Patent Act, to recover damages for patent infringement a patentee who does not mark its products must provide the accused infringer with actual notice of a specific charge of infringement.¹⁷ When the patentee provides such notice, the accused infringer is liable for damages associated with any acts of infringement done thereafter. In *DSW, Inc. v. Shoe Pavilion, Inc.*, No. 2008-1085, 2008 WL 3842898, *4 (Fed. Cir. Aug. 19, 2008), the Federal Circuit held that the damages period begins immediately after notice is provided and that an accused infringer does not enjoy a grace period to cease the accused conduct.

In *DSW*, after receiving actual notice from the patentee that its shoe display may infringe the patents, the accused infringer took seven months to switch to a redesigned display and to remove the first accused displays from its store.¹⁸ Finding that the accused infringer acted in good faith and with reasonable effort to remove the first accused display, the district court equated the accused infringer's actions with being an

¹⁷ See generally, APD § 30:163 Providing Actual Notice When Patentee Did Not Mark; § 30:164 Unqualified Charge of Infringement Not Required; and § 30:171 Notice Must Identify Specific Product.

¹⁸ In the meantime, the patentee had sued the accused infringer three months after providing notice and alleged that the original display and the redesigned display infringed its patents.

"immediate" cessation of infringing conduct. It, therefore, granted the accused infringer summary judgment that the patentee could not recover any infringement damages relating to the first accused display for activity done during the seven months after the patentee had provided actual notice.

Reversing the summary judgment, the Federal Circuit rejected the district court's analysis that because the accused infringer acted in a reasonably prompt manner to remove the first design product, its acts should be treated as an immediate cessation of the infringing activity. The Federal Circuit explained that "[w]ithout a doubt, the law offers an infringer no exception to liability for the time it takes to terminate infringing activities, no matter how expeditious and reasonable its efforts. The trial court therefore erred in concluding that Shoe Pavilion's reasonable steps and good faith efforts to bring its infringing activity to a timely end equated to an immediate cessation." *Id.* at *4.

Eligibility for *Inter Partes* Reexamination

The enacting legislation for *inter partes* reexamination proceedings under 35 U.S.C. § 311 *et seq.*, limits the proceedings "to any patent that issues from an *original application* filed in the United States on or after" the enactment date of November 29, 1999.¹⁹ The PTO construed "original application" to "encompass utility, plant and design applications, including first filed applications, continuations, divisionals, continuations-in-part, continued prosecution applications (CPAs) and the national stage phase of international applications." Hence, under the PTO's construction, any patent issuing from a continuing type application filed after November 29, 1999 is eligible for *inter partes* reexamination.²⁰

In *Cooper Technologies Co. v. Dudas*, No. 2008-01130, 2008 WL 3842893 (Fed. Cir. Aug. 19, 2008), a party subject to having one of its patents put in an *inter partes* examination challenged the PTO's interpretation of the enacting legislation. It argued that "original application" should be construed to mean the first application in a chain of applications, and therefore would not permit the filing of an *inter partes*

¹⁹ Public Law 106-113, sec. 4608(a); see generally, § 25:97 Statutory Authority to Reexamine Patent in PTO.

²⁰ Notably, this construction does not include reissue applications. Hence, under the PTO regulations *inter partes* reexaminations of reissue patents are limited to reissues of patents having their "original application" filed after November 29, 1999. *Id.* at *11

reexamination for continuing applications filed after November 29, 1999, if the first application in the chain had been filed before November 29, 1999.

Ruling that, under the circumstances, *Chevron* deference applied to the PTO's construction of the enacting legislation, the Federal Circuit held that "the Patent Office's interpretation of section 4608 is permissible and therefore entitled to deference. Under the Patent Office's construction, 'original application' includes continuation applications." *Id.* at *13.

Of note to those following the appeal of *Tafas v. Dudas*, and the fate of the PTO rules limiting the number of continuation applications an applicant can file and the number of claims that can be presented in an application²¹ the Federal Circuit in *Cooper* discussed in general terms the standards for when a PTO rule is a "procedural" rule governing the conduct of proceedings before it, and when a rule is "substantive." The court noted that since the enacting legislation of the *inter partes* reexamination proceedings was entitled "Optional Inter Partes Reexamination Procedure Act of 1999" (emphasis by Federal Circuit), the PTO's interpretation of the enacting legislation and its construction of "original application" plainly fell within its broad rule making power to govern the conduct of proceedings before the PTO under § 2(b)(2)(A) of the Patent Act. *Id.* at *5. The Federal Circuit also noted that the PTO's rule making power under § 2(b)(2)(A) "does not authorize the Patent Office to issue 'substantive' rules. 'A rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.'" *Id.* at *6. Regarding the PTO's interpretation of "original application" the Federal Circuit found that the interpretation did "not effect any change in existing law or policy; rather, it is a prospective clarification of ambiguous statutory language regarding a matter of procedure." *Id.* Consequently, the Federal Circuit held that the PTO's construction was "'interpretive' rather than 'substantive,'" and therefore the PTO "had the authority under 35 U.S.C. § 2 to interpret section 4608,

²¹ 541 F. Supp. 2d 805 (E.D. Va. Apr. 1, 2008) (granting summary judgment against PTO and ruling that PTO's proposed prosecution rules that would have limited the number of continuation applications an applicant could file and impose additional submission requirements should the total number of claims exceed a certain number was substantive rule making and therefore exceeded the PTO's authority to implement rules affecting the procedural aspects of prosecuting patent applications).

because that interpretation both governs the conduct of proceedings in the Patent Office, not matters of substantive patent law, and is a prospective clarification of ambiguous statutory language."²² *Id.*

The court also noted that because the PTO's interpretation of "original application" came shortly after the statute was enacted, the PTO's interpretation was entitled to "particular weight" since it involved "a contemporaneous construction of a statute by the persons charged with the responsibility of setting machinery in motion..." *Id.* at *11. Arguably, this principle should not apply to the PTO proposed rules limiting the number of continuation applications since § 120 was enacted well over fifty years ago.

The court's discussion of "procedural" and "substantive" rules may also bear on the Federal Circuit's consideration of the erroneous revival issues associated with the appeal of *Aristocrat Technologies Australia Pty Ltd. v. Int'l Game Technology*.²³

Anticipation by Inherency

Under the doctrine of inherency, subject matter inevitably present in a prior art reference may be relied on to prove anticipation even if the reference does not explicitly disclose that subject matter.²⁴ Additionally, one of ordinary skill in the art need not appreciate that the reference implicitly discloses the subject matter for the inherently disclosed subject matter to invalidate the claim.²⁵ In affirming a summary judgment of invalidity, the Federal Circuit reaffirmed these principles of inherency in *Leggett & Platt, Inc. v. VUTEk, Inc.*, No. 2007-1515, 2008 WL 3863471 (Fed. Cir. Aug. 21, 2008).

²² The Federal Circuit issued its opinion in *Cooper* in about nine and one-half months from when the district court handed down its summary judgment opinion on Nov. 30, 2007. If the same timing applies to the *Tafas* appeal, it is possible that the decision on the *Tafas* appeal could come down early in 2009.

²³ 491 F. Supp. 2d 916, 929-30 (N.D. Cal. June 13, 2007) (granting accused infringer summary judgment that PTO improperly revived an abandoned PCT application by applying an "unintentional" standard where the relevant statute § 371(d) only permitted revival for a showing of "unavoidable" delay, and the patentee had not made that showing, also ruling that PTO erred in reviving the patent application where the applicant had delayed more than six months to respond to a notice of missing parts and the PTO had revived the application based on a showing of "unintentional" abandonment where the statute § 133 requires a showing of "unavoidable" delay).

²⁴ See generally, APD § 17:67 General Aspects of Inherency.

²⁵ See generally, APD § 17:69 Unappreciated Recognition Does Not Defeat Inherency.

The patent at issue in *VUTEk* claimed a method of ink jet printing. A claim limitation required the use of a cold UV assembly “being effective to impinge sufficient UV light on the ink to substantially cure the ink without impinging radiation” A prior art reference disclosed the use of an LED to cure ink. One example in the reference disclosed that passing a LED five times over a printed surface at the printer’s slowest speed would cure the ink 75-80%.²⁶ The Federal Circuit noted that a reasonable jury could find that a 75-80% cure met the “substantially cure” limitation. But it also noted that, for purposes of the accused infringer’s summary judgment motion, all inferences had to be taken in the patentee’s favor. Hence, the court concluded that it could not say that as a matter of law, a 75-80% cure met the “substantially cure” limitation. *Id.* at *5. However, the reference also disclosed that if a UV radiation source, such as a LED, was passed over the ink at slower speeds and/or multiple times, the degree of ink curing would be increased. In view of this disclosure, and testimony from the patentee’s and the accused infringer’s experts agreeing that multiple passes would increase the degree of cure, the Federal Circuit concluded, that as a matter of law, the prior art reference inherently disclosed a UV assembly that was effective to substantially cure the ink. *Id.* at *5. The Federal Circuit reached this holding even though the reference left open how many passes would be needed to substantially cure the ink. Since the reference disclosed all the other claim limitations, the Federal Circuit affirmed the summary judgment of invalidity.

In affirming the summary judgment, the Federal Circuit also rejected the patentee’s attempt to create a genuine issue of fact by arguing that LEDs were incapable of fully curing the ink. The court noted that, according to the experts, there was a significant distinction between simply “curing” the ink and only “substantially curing” the ink. Since the claim only required “substantially curing,” the patentee’s arguments regarding a full cure did not create an issue of fact. *Id.* at *6. Further, the patentee argued that LEDs were not practical for commercial use in printers because they were too expensive. Rejecting this argument as raising a fact issue, the Federal Circuit

²⁶ The Federal Circuit also noted that because the claim recited a generic “UV assembly” in functional language, use of a LED could meet the limitation so long as the LED achieved the recited function of “being effective . . . to substantially cure” the ink. *Id.* at *4. See also APD § 23:13 Functional Limitations.

instructed that “[t]he fact that a technology may be impractical does not undermine an otherwise anticipatory disclosure.” *Id.* at *6.²⁷ Finally, the Federal Circuit rejected the patentee’s arguments that because the majority of examples in the reference did not teach multiple passes of the LED, the disclosure suggesting to use multiple passes should be given little weight. The court characterized this argument as resting on the “erroneous assumption that the disclosure of multiple examples renders one example less anticipatory.” *Id.*

Opinion of Counsel Defeats Willful Infringement

In an interesting application of the new “objectively reckless” willfulness standard under *Seagate*,²⁸ the Federal Circuit held in *Lexion Med., LLC v. Northgate Tech., Inc.*, No. 2007-1420 (Fed. Cir. Aug. 28, 2008) (*nonprecedential*), that an opinion of counsel precluded a finding of willful infringement for post-verdict sales.

In *Lexion*, after the jury returned a verdict finding infringement, but before the court issued a permanent injunction or ruled on the accused infringer’s post-trial motions, the accused infringer liquidated its remaining inventory of accused product. Before it sold its remaining inventory, the accused infringer obtained an oral opinion of counsel that it was likely to prevail on its post-trial motions. *Slip opn.* at 14. While the district court disagreed and denied the post-trial motions, it refused to find that the accused infringer committed willful infringement by the post-verdict sales, and therefore only awarded the patentee compensatory damages for those sales.

The Federal Circuit affirmed the finding of no willful infringement. *Id.* at 15. Instructing that willful infringement requires objectively reckless conduct, the court stated that it did “not think it was objectively reckless for Northgate to obtain and rely on the opinion of counsel, which had predicted a favorable outcome in view of the renewed motion for JMOL then pending before the district court.” *Id.* The Federal Circuit also noted that “the reliance on that opinion was nonetheless justified, as we have vacated the judgment of infringement and remanded for further proceedings based upon our new claim construction.” *Id.*

²⁷ See also APD § 17:58 Teaching Away or Disparaging Invention Irrelevant.

²⁸ *In re Seagate Technology*, 497 F.3d 1360, 1370-71 (Fed. Cir. 2007) (*en banc*); see generally, APD § 31:22 “Objective Recklessness” Standard of *Seagate*.

Lifting Reexamination Stay For Discovery

Upon reconsideration of its earlier order granting an accused infringer's motion to stay an infringement case pending an *inter partes* reexamination proceeding,²⁹ the district court in *Equipements de Transformation IMAC v. Anheuser-Busch Cos.*, 2008 WL 3852240, *2-*3 (E.D. Mich. Aug. 18, 2008), granted the patentee's motion to partially lift the stay. The court lifted the stay to allow the patentee to conduct discovery from the accused infringers on the issue of obviousness for purposes of using that discovery in the reexamination proceeding to rebut the PTO's claim rejections.

Explaining its rationale, the district court stated that since the PTO could not order discovery, "the efficiencies gained by awaiting the reexamination process will be superficial if the patentee has insufficient information to challenge the applicant's position or the PTO's initial determination." *Id.* at *2. Noting that it would be powerless to overturn a PTO's rejection of the claims from the *inter partes* reexamination even if discovery ultimately shows the PTO's decision was flawed, the court stated that "[t]he prospect of a subsequent infringement suit may mean little if the PTO invalidates claims erroneously based on incomplete information."³⁰ *Id.* Commenting that its only goal in partially lifting the stay was "to facilitate reexamination," the court stated that it intended "to allow discovery only insofar as it is necessary to allow the plaintiff to engage the issue of obviousness as it has been framed before the PTO." *Id.* at *3.

Coincidentally, on the same day *Equipements* came down, another district court rejected a patentee's argument that a stay should be lifted and a protective order modified so that the patentee could submit to the PTO in the reexamination proceeding material the accused infringer produced to the patentee during discovery. *Avocent Redmond Corp. v. Rose Elecs., Inc.*, 2008 WL 3875869, *3 (W.D. Wash. Aug. 18, 2008). The court noted that even if the discovery

²⁹ 559 F. Supp. 2d 809, 815 (E.D. Mich. June 17, 2008).

³⁰ See 35 U.S.C. § 315(a)(1) (excluding § 145 actions as possible avenue of appeal for an *inter partes* reexamination). A patentee can file a § 145 action in a district court to appeal a decision rendered in an *ex parte* reexamination. In that action, the patentee may introduce new evidence, but not new theories. 35 U.S.C. § 306. See also APD § 16:56 New Evidence in a § 145 Action. Future cases will have to determine whether this lessens the district court's rationale for lifting the stay in the context of *ex parte* reexaminations.

materials were relevant to the PTO's analysis, the patentee failed to provide any "authority showing that documents produced under protective order in a litigation proceeding should be disclosed and made public for use in an administrative proceeding." *Id.* The district court noted that the type of confidential material the patentee wanted to disclose to the PTO was not a type that would be generally available to the PTO during a reexamination proceeding. *Id.* Hence, the court concluded that the patentee "cannot use the litigation forum to acquire evidence for use in an administrative proceeding when the evidence would not otherwise be available in that forum."³¹ *Id.*

ADMINISTRATIVE HAPPENINGS

Regulations for Patentably Indistinct Claims

On August 1, 2008, the USPTO issued a notice clarifying the effective date of 37 C.F.R. 1.78(f), the regulatory provisions relating to applications containing patentably indistinct claims. 73 Fed. Reg. 45,999-46,000. These new rules were part of the 2007 Claims and Continuations Final Rules, which are currently enjoined by *Tafas v. Dudas*, 530 F. Supp. 2d 786 (E.D. Va. 2008). Although the *Tafas* decision is currently under review by the Federal Circuit and the litigation is not expected to be resolved for some time, the USPTO was prompted to issue this notice out of concern that some applicants may be taking preparatory action to comply with the provisions of 37 C.F.R. 1.78(f) in anticipation that the *Tafas* injunction may be removed.

³¹ Provisions of a protective order limiting the use of confidential material to the law suit in which it was produced may also preclude the use of confidential material in a reexamination. In some cases, such a provision may even prevent litigation counsel who received confidential information from advising the patentee regarding the reexamination. Cf. *Silicon Graphics, Inc. v. ATI Tech., Inc.*, 2007 WL 5433478, *2-*3 (W.D. Wis. Aug. 8, 2007) (denying accused infringer's motion to modify protective order to permit its litigation counsel to disclose to the accused infringer confidential material received from the patentee during discovery for the purposes of evaluating whether to seek a reexamination in the PTO, and to use the material to support the request for a reexamination, and noting that under the terms of the protective order the accused infringer's counsel was not allowed to use any confidential material obtained during discovery to advise the accused infringer whether to seek a reexamination in the PTO and stating "it is not enough merely that each litigation team refrain from sharing its opponent's documents with its client. Rather, the legal teams of both parties must wall themselves off from their clients to prevent the dissemination of legal advice on other matters that might be tainted by information gained from reviewing the opposing party's confidential information.").

Should the *Tafas* injunction be removed, the USPTO has announced that the changes in 37 C.F.R. 1.78(f)(1) and (f)(2) will only apply to applications filed on or after any new effective date that would be published by the USPTO after removal of the injunction. Specifically, (a) applicants will only need to comply with the identification requirements of 1.78(f)(1) in applications having an actual filing date on or after this new effective date; (b) commonly-

owned applications that satisfy 1.78(f)(1)(i) need only be identified in applications having a filing date on or after this new effective date; and (c) the rebuttal presumption of 1.78(f)(2) will only apply to applications having an actual filing date on or after this new effective date and will only exist for applications that satisfy 1.78(f)(2)(i) and have a filing date on or after this new effective date.

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