



PATENT HAPPENINGS

during October 2007 (Part II)

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

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ADMINISTRATIVE HAPPENINGS

On October 31, 2007, Judge James C. Cacheris of the Eastern District of Virginia, in response to a motion for a preliminary injunction filed by GlaxoSmithKline, and supported by several amicus curie, including

AIPLA, and after a two-hour hearing, enjoined the PTO from implementing its new rules regarding continuation practice and limiting the number of claims an applicant may present in an application. The new rules were set to take effect on November 1, 2007. The PTO has the right to appeal the denial to the Federal Circuit, 28 U.S.C. § 1292(c)(1), and hence the district court's decision is not necessarily the last word on the matter. If the PTO opts not to appeal, the preliminary injunction will stay in force until a final judgment on the merits in the suit unless otherwise modified by the court.

In the court's 39-page Memorandum Opinion, *SmithKline Beecham Corp. v. Dudas*, No. 1:07cv1008 (JCC), (E.D. Va. Oct., 31, 2007), Judge Cacheris ruled that "GSK raises serious concerns as to whether the [PTO] Final Rules comport with the Patent Act." *Slip opn.* at 21. The PTO had argued that its new rules were merely procedural rules, and therefore it had authority to promulgate them under 35 U.S.C. § 2(b)(2). For purposes of the preliminary injunction, the court found that "GSK has created a colorable question as to whether the Final Rules are truly substantive." *Id.* Judge Cacheris, further found that GSK showed a likelihood of success on the merits that Rule 78, the rule limiting the number of continuation applications an applicant may file, ran "contrary to the mandate of Section 120." *Id.* at 23-24. The court further found that due to the limited briefing, neither party showed a likelihood of success on prevailing on the issue of the whether Rule 114's limitation on filing RCE's was prohibited by 35 U.S.C. § 132. *Id.* at 24. As to Rule 75 and 265, which limit the number of claims an applicant may file before having to submit an ESD, the court found that the PTO likely was not entitled to *Chevron* deference for an agency's acts, but that neither party had demonstrated a strong likelihood of success on the issue. *Id.* at 24-25. On the issue of retroactivity, the court found that GSK had demonstrated a "real likelihood of success" that the

new rules have impermissible retroactive effect. *Id.* at 26-29. GSK also argued that the prior art searching requirements for an ESD are constitutionally vague. Accepting GSK's argument, Judge Cacheris found that "GSK has raised serious concerns as to whether a reasonably prudent person would be able to comply with the ESD requirements," and therefore, GSK "demonstrated a real likelihood of success on this issue." *Id.* at 31.

The court also found that the remaining factors for demonstrating a right to a preliminary injunction – irreparable harm, balance of the hardship, and public interest, all favored granting the preliminary injunction. On the issue of irreparable harm, the court ruled that the "uncertainty caused by the regulations will cause harm to [GSK's] investments and provide a disincentive to their filing of new patent applications for researching new pharmaceutical products." *Id.* at 35. The court rejected the PTO's counter argument that GSK could guard against lost patent protection by following "complicated steps outlined by the PTO." *Id.* Accordingly, it ruled that GSK would suffer irreparable harm if the Final Rules are ultimately determined to be invalid and it did not grant the preliminary injunction. *Id.* While the PTO argued that granting a preliminary injunction would cause it to suffer hardship in terms of "costly computer problems" and costs of retraining their employees should the rules go into effect at a future date, the court found these costs did not outweigh the "uncertainty and loss of investment suffered immediately by GSK." *Id.* at 36. Considering the public interest, the court was persuaded by the three amicus briefs, all urging the court to grant the preliminary injunction so their respective industries would not be harmed, that granting the injunction best served the public's interests. It noted that "[a]llowing the implementation of rules that may or may not remain in effect is likely to cause much greater uncertainty and squelching of innovation than a preliminary injunction giving the Court time to consider the validity of the Final Rules before they go into affect." *Id.* at 38.

JUDICIAL HAPPENINGS

Ongoing Royalty in Lieu of an Injunction

Addressing permissible alternatives to injunctive relief, the Federal Circuit held in *Paice LLC v. Toyota Motor Corp.*, No. 2006-1610, 2007 WL 3024994, *16 (Fed. Cir. Oct. 18, 2007), that "[u]nder some circumstances, awarding an ongoing royalty for patent

infringement in lieu of an injunction may be appropriate." Upon finding that the patentee failed to show it would suffer irreparable harm without a permanent injunction in view of the fact that the patentee did not make a product, had expressed a willingness to license its patent to the infringer, and had failed to show that money damages would not be adequate, the district court had denied the patentee's request for injunctive relief.¹ To account for the infringer's post-judgment sales of its cars containing the infringing component, however, the district court *sua sponte* ordered the infringer to pay an ongoing royalty of \$25 per car; an amount that appeared roughly equal to the royalty rate awarded by the jury for the prior acts of infringement. The patentee opted not to appeal the denial of the permanent injunction, but did appeal the amount of the ongoing royalty.

On appeal, the Federal Circuit held that under § 283, the provision of the Patent Act authorizing injunctive relief, district courts may order an infringer to pay an ongoing royalty instead of granting a permanent injunction where "'necessary' to effectuate a remedy." *Id.* at *16-*17. The court cautioned, however, that such relief should not be ordered "as a matter of course whenever a permanent injunction is not imposed." *Id.* at *17. Rejecting the patentee's argument that concerns of harm to the patentee's ability to offer an exclusive license should prohibit a district court from ordering ongoing royalty payments, the Federal Circuit noted "the fact that § 283 is permissive indicates that concerns regarding exclusivity do not outweigh other equitable factors." *Id.* at *16 n.14.

Despite authorizing the use of an ongoing royalty, the Federal Circuit vacated the district court's *sua sponte* order of an ongoing royalty of \$25 per car because the record failed to show what reasons the district court applied to set that rate. *Id.* at *17. The Federal Circuit remanded the action for the district court to redetermine the amount of the ongoing royalty rate. It further instructed that on remand the district court could take additional evidence to account for any economic factors that became relevant upon the finding of infringement and to address the patentee's concerns about the terms of the infringer's continuing use. *Id.* The court also suggested that the better course of action in such situations would be to allow the parties

¹ *Paice LLC v. Toyota Motor Corp.*, 2006 WL 2385139, *5-*6 (E.D. Tex. Aug. 16, 2006).

the first opportunity to negotiate an ongoing royalty rate between themselves with the district court stepping in only if the parties failed to reach an agreement. *Id.*

Judge Rader concurred in the judgment. He wrote separately stating his view that royalty rates for pre-judgment infringement may not be proper for accounting for post-judgment infringement given the change in legal relationship between the parties. *Id.* at *19. Judge Rader also suggested that courts should always have the parties first attempt to negotiate the amount of an ongoing royalty, before the court sets a rate, as a mechanism to protect the patentee and avoid having the ongoing royalty be, in effect, a compulsory license. *Id.*

Failure to Show Apparent Reason Saves Patent

Upon a bench trial, Judge Robinson of the U.S. District Court for the District of Delaware, rejected an obviousness challenge of claims directed to an antibacterial drug, sold under the trade name AVELOX®, in *Bayer AG v. Dr. Reddy's Labs., Ltd.*, 2007 WL 3120794, *5-*9 (D. Del. Oct. 25, 2007). There, the generic argued that the claims were obvious because one of ordinary skill in the art could have modified a structurally similar chemical composition by only applying routine skill and arrive at the claimed invention. The court found, however, that the generic failed to prove that one of skill in the art would have had an apparent reason to start with the lead compound that the generic alleged could be modified by routine skill to arrive at the claimed composition. Further the patentee had presented evidence that those of skill in the art at the time the invention was made had actively been pursuing two other starting compounds because these other compounds had the “best known activity.” The court also rejected the generic’s argument that the inventor’s admission that if a person of ordinary skill in the art “had been *told* to make” a substituent from the particular lead compound he would have made the claimed invention proved the obviousness of the claims. Dismissing this hindsight argument, Judge Robinson noted that the admission was “a far cry from establishing an independent motivation” to make the claimed invention.

Judge Robinson also rejected the generic’s argument that the asserted claims were invalid for statutory and obviousness-type double patenting where the challenged patent claims claimed a species of a genus that was claimed in another patent. The court held that “[a]lthough claim 1 and/or 2 of the ’517 patent may dominate claim 1 of the ’942 patent,

domination is not *per se* double patenting.” *Id.* at *18. Accordingly, she found that the parties’ stipulation that some claims of the ’942 patent cannot be practiced without infringing at least one claim of the ’517 patent “indicates that there is overlapping subject matter; [but] this is not an admission that the sets of claims are not patentably distinct from one another.” *Id.*

Construing Method of Measuring

Addressing aspects of claim construction in *Osram GmbH v. Int’l Trade Comm’n*, No. 2006-1282, 2007 WL 3171408 (Fed. Cir. Oct. 31, 2007), the Federal Circuit reversed the ITC’s finding of no infringement because the ITC erred in its construction of the asserted claims. Directed to a certain powder, the claims at issue included a limitation that the particles of the powder have a certain “mean grain diameter.” The problem arose from the fact that two methods, each producing different results, could be used to measure the average grain diameter – a volume-based approach and a number-based approach. The ITC construed the claims as requiring application of the volume-based approach to measure mean grain diameter. Under this approach the data showed that the accused product did not meet the claim limitation, and neither did the patentee’s commercial embodiment.

Relying of the principle of *Phillips* that the claims must be construed in view of the specification, the Federal Circuit reversed. It found that the specification was more consistent with using the number-based measuring approach since that approach allegedly better fulfilled the purposes of the invention than the volume-based approach. The court instructed that “[w]hen there is more than one method of measurement and the patent does not explicitly discuss the methods, persons experienced in the field are reasonably deemed to select the method that better measures the parameters relevant to the invention.” *Id.* at *5. The court also rejected the accused infringer’s argument that the volume-based approach was the proper measuring technique to apply since it provided better sensitivity to “boulder” sized particles, something that was undesirable in the invention. Noting that “the purpose of the claim limitation is to state the parameters of the products that work in the desired way, not those that may not,” the court rejected this argument since it focused on ways that the invention would not properly work. *Id.* at *6. Relying on the claim construction cannon that claims generally should not be construed in a manner that omits the preferred embodiment, the court noted that its

“conclusion is reinforced by the undisputed fact that the volume-based measure would exclude the OSRAM products that the patents were designed to cover.” *Id.* Finally, the court also rejected the argument that the presence in the prosecution history of two commercial product specification sheets that used a volume-based measuring approach showed that the volume-based approach should apply since neither the applicant or the examiner ever referenced the two specification sheets during prosecution. The court stated “[i]t is rare that references that were submitted with a disclosure document, but not even cited by the examiner, are probative of an intent to depart from the plain technical meaning of terms used in the specification and claims.” *Id.* at *5.

Judge Dyk dissented. In his view the patent was directed to a commercial product and the evidence showed that from a commercial perspective the volume-based measuring approach was the preferred measuring approach. The number-based approach was allegedly limited for use in the research and development field. Accordingly, Judge Dyk would have affirmed the ITC’s claim construction and resulting findings of no infringement and no domestic industry.

No Jurisdiction based on Bayh-Dole Act

Transferring to the regional circuit an appeal of an action involving a dispute over ownership rights in a patent, the Federal Circuit in *Wisconsin Alumni Research Foundation v. Xenon Pharmaceuticals, Inc.*, No. 2007-1026, 2007 WL 3094979, *1 (Fed. Cir. Oct. 24, 2007) (*nonprecedential*), held that a plaintiff’s invocation of the Bayh-Dole Act, 35 U.S.C. § 200, *et seq.*² did *not* make its claim “arise under” the patent laws for purposes of securing jurisdiction in the Federal Circuit under 28 U.S.C. § 1295(a). The court explained that the “mere inclusion in Title 35 of the United States Code does not make a statute a patent law under which a claim may arise. At its heart, the Bayh-Dole Act concerns government funding agreements – contracts in the language of 35 U.S.C. § 201 – an area that is outside our section 1295(a) jurisdiction.” *Id.*³ Noting that the plaintiff had also based its right to relief on aspects of state contract law, the Federal Circuit held that the presence of the state-law theory showed that even if a claim under the Bayh-

Dole Act arose under the patent laws, the plaintiff’s right to relief did *not* necessarily depend on resolution of a substantial question of federal patent law. Accordingly, under *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 810 (1988), the state-law based alternative theory of recovery precluded asserting “arising under” jurisdiction. *Id.*⁴

Enablement and Claim Breadth

In *Pharmaceutical Resources, Inc. v. Roxane Labs., Inc.*, No. 2007-1093, 2007 WL 3151692, * 4-5 (Fed. Cir. Oct. 26, 2007) (*nonprecedential*), the Federal Circuit affirmed a summary judgment that claims directed to an oral pharmaceutical composition reciting the presence of “a surfactant,” were invalid for lacking an enabling disclosure. Noting that the claims literally covered *any* and *all* surfactants, the court found ample evidence that the specification failed to enable the claims where the art was highly unpredictable, not all surfactants would work, and the specification only provided working examples that all used the same surfactant. Cautioning that a broad claim requires a correspondingly broad scope of enablement, the Federal Circuit noted that since the patentee had “sought extremely broad claims in a field of art that it acknowledged was highly unpredictable,” the patentee “has set a high burden that its patent disclosure must meet to satisfy the requisite *quid pro quo* of patent enablement.” *Id.* at *2. Turning to the evidence, the court held that a disclosure of only three working examples that all used the same surfactant failed to “provide an enabling disclosure commensurate with the entire scope of the claims.” *Id.* at *4. Expert declarations submitted by the patentee failed to raise a genuine issue of fact that the claims were fully enabled because the declarations were “conclusory and lack[ed] evidentiary support or specifics as to the experimentation that would be needed to practice the entire scope of the claims.” *Id.* The Federal Circuit also held that evidence from the patentee that it successfully made the claimed composition with seven different surfactants did not raise a genuine issue of fact given the broad scope of the claim and the high unpredictability of the art. *Id.* at *5.

Inadequate Incorporation by Reference

In *Adang v. Umbeck*, No. 2007-1120, 2007 WL

² See generally Robert A. Matthews, Jr., ANNOTATED PATENT § 35:44 Federal Licenses. [hereinafter “APD”]

³ See also APD § 36:54 Ownership or Licensing Disputes.

⁴ See also APD § 36:5 All Theories of the Cause of Action Must Implicate Patent Law.

3120323, *2 (Fed. Cir. Oct. 25, 2007) (*nonprecedential*), the court affirmed a finding by the Board that a junior party's specification did not have adequate written description support for the claims at issue in an interference where the claims required transforming cotton plants with any foreign DNA material and the specification only disclosed transforming cotton plants with insecticidal resistance genes. In doing so, the Federal Circuit agreed with the Board that the inventors mere mention in the specification of a prior patent application of one of the coinventors and a prior art article written by the coinventor did not incorporate by reference the disclosures of those materials for purposes of assessing whether the claims had sufficient § 112 support. The court noted that the PTO regulations then in force did not require the applicant to explicitly identify material as being incorporated by reference; as is now required under 37 C.F.R. § 1.57(b) (2004).⁵ But this did not save the inventors where in the specification the inventors had used the phrase "incorporated by reference" eight times in referring to other disclosures. Hence, the notable absence of the phrase "incorporated by reference" when referencing the coinventor's work made clear that the inventors had not intended to incorporate by reference those disclosures.

Insolvency Warranted Injunction

After originally denying a patentee's motion for a permanent injunction because it found that money damages would be adequate to compensate the patentee,⁶ the district court held in *Sundance, Inc. v. DeMonte Fabricating Ltd.*, No. 02-73543, 2007 WL 3053662, *1 (E.D. Mich. Oct. 19, 2007), that post-judgment evidence showing that the infringer was likely insolvent provided sufficient evidence of changed circumstances to warrant granting a permanent injunction.⁷

Patentee's Opinion of Counsel

The district court in *The Boler Co. v. Tuthill Corp.*, No. 2:04-cv-286, 2007 WL 3046450, *3 (S.D. Ohio Oct. 17, 2007), denied a prevailing accused infringer's request for attorney's fees under § 285 after finding that the patentee had not litigated its infringement

claim in bad faith where the patentee had obtained two opinions of counsel opining that the accused product did infringe and during the litigation performed additional testing to confirm its infringement contentions. The court found that while the opinions and later testing were flawed, given the court's finding of noninfringement, the patentee's case was not "without an arguable basis of infringement." Further, the court stated that the patentee's post-filing testing and re-solicitation of an opinion of infringement showed "prudent conduct" on the patentee's part, and not bad faith as the accused infringer had argued. Accordingly, the court concluded that "reliance on the opinion of multiple counsel that infringement existed, although certainly not dispositive of the issue, helps the company avoid a finding of bad faith. The mere asserted reliance on the opinion of counsel is not an absolute shield to an award of fees. But this Court must give appropriately qualified credit to the opinions of the various Boler counsel who indicated a viable case of infringement."⁸

Limiting Waiver of Sovereign Immunity

Addressing the issue of whether a state's waiver of sovereign immunity for claims of patent infringement in one action extends to a second action based on the same patent, the Federal Circuit held in *Biomedical Patent Mgmt. Corp. v. State of California*, No. 2006-1515, 2007 WL 3071687, *8 (Fed. Cir. Oct. 23, 2007), that the waiver from the first action generally does not extend to a second action that is not a continuation of the first action. In *Biomedical*, an agency of the state of California had intervened in a declaratory judgment action against a patentee. The patentee successfully moved to dismiss the action for improper venue. Several years later the patentee filed a suit against the state agency on the same patent and in the same forum as the original suit. The agency asserted sovereign immunity as a defense, and the district court granted the agency summary judgment dismissing the infringement claims on the basis of sovereign immunity. 2006 WL 1530177, *2 & *6 (N.D. Cal. June 5, 2006). At the district court level and on appeal, the patentee argued that the agency's waiver of sovereign immunity in the first action applied to the second action. Noting that the agency was not obtaining an unfair tactical advantage by asserting sovereign immunity in the case, 2007 WL 3071687, at

⁵ See also APD § 16:44 Affirmatively State Material is Incorporated.

⁶ *Sundance, Inc. v. DeMonte Fabricating Ltd.*, No. 02-73543, 2007 WL 37742, *2 (E.D. Mich. Jan. 4, 2007).

⁷ See also APD § 32:40 Inability of Accused Infringer to Satisfy a Money Judgment.

⁸ See also APD § 33:12— Necessity for Patentee to Have an Opinion of Counsel.

*9, the Federal Circuit held that “a waiver that does not ‘clearly’ extend to a separate lawsuit generally would not preclude a State from asserting immunity in that separate action.” *Id.* at *8. The court instructed, however, that it was not drawing a bright-line rule that a State’s waiver of sovereign immunity could never extend to a re-filed or separate lawsuit. *Id.*

The court also rejected, as meriting “little consideration,” the patentee’s argument that since the State of California, through its universities, was actively involved in patent litigation to enforce patents, the State should be deemed to have constructively waived its sovereign immunity for all patent claims. *Id.* at *12.

The patentee also asserted that in view of the arguments the agency raised to support its intervention in the first action, judicial estoppel should apply to preclude the agency from asserting sovereign immunity in the second action. Rejecting this argument, the Federal Circuit ruled that since the first action was commenced before the Supreme Court’s decision in *Florida Prepaid Postsecondary Education*

Expense Board v. College Savings Bank, 527 U.S. 627 (1999), which restored to the states sovereign immunity for patent infringement actions, the intervening change in controlling law justified not applying judicial estoppel. *Id.* at *10-*11.

Appointing Pro Bono Infringement Counsel

A district court in New Jersey granted an indigent *pro se* plaintiff’s application for *pro bono* counsel to represent her in pursuing claims for patent infringement in *Wallace v. Spin Spa*, No. 06-CV-05673 (DMC), 2007 WL 3026681 (D.N.J. Oct. 16, 2007). Applying Third Circuit law and its factors in determining whether to grant an application for *pro bono* representation, the court held that it would order the appointment of *pro bono* counsel since the plaintiff was indigent, her complaint appeared capable of withstanding a motion to dismiss, and the plaintiff appeared unable to litigate her case without the assistance of a lawyer. *Id.* at *2. The opinion did not provide details on how the *pro bono* counsel would be selected, compensated, or reimbursed for expenses necessary to prosecute the infringement claim.

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