



PATENT HAPPENINGS

during June 2007 (Part I)

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

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JUDICIAL HAPPENINGS

Willful Infringement

Although a non-patent case, the Supreme Court’s opinion in *SafeCo Ins. Co. of Am. v. Burr*, 127 S. Ct. 2201 (June 4, 2007), will likely impact how the Federal Circuit construes willful infringement under § 284; especially in view of the attention given to the case during the oral argument in *In re Seagate* discussed below. In *SafeCo*, the Supreme Court held that statutes specifying penalties for “willful” conduct apply when the conduct is done knowingly or with “reckless disregard.” *Id.* at 2208-09. Describing “recklessness” as being “conduct violating an objective standard: action entailing ‘an unjustifiably high risk of harm that is either known or so obvious that it should be known[.]’” the court distinguished reckless conduct from negligent conduct. *Id.* at 2215. The Court also noted that subjective bad faith does not make conduct willful if there is an objectively reasonable basis to view the conduct as being proper. *Id.* at 2216 n.20. The Supreme Court’s view of “willful” conduct arguably supports Judge Dyk’s views that treble

damages for willful infringement should not be found from the negligent failure to obtain an opinion of counsel. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1351 (Fed. Cir. 2004) (Dyk, J., *concurring-in-part, dissenting-in-part*).

On June 7, 2007, an *en banc* panel of the Federal Circuit in the matter of *In re Seagate* heard a one hour oral argument and considered whether the court should continue to adhere to its precedent imposing an “affirmative duty of due care” on an accused infringer not to infringe. The judges questioned the parties on whether the affirmative duty of due care sets the willfulness standard to a negligence standard, and whether this is proper under Supreme Court precedent, including *SafeCo*. Additional questions showed a concern for whether a supportable basis for the duty of due care exists in the words of the statute, its legislative history or Supreme Court precedent. None of the participants offered any sources for the affirmative duty of care other than Federal Circuit precedent. We note that there does appear to be one ancient Supreme Court case that, in *dictum*, arguably imposed a duty of care on an accused infringer, with the instruction:

[I]t would seem to be no injustice, or hardship, to expect [a potential infringer], before he begins to infringe, to ascertain that the patentees’ title is not valid, and if its invalidity depends on what is in a public work, that he should inform himself what that work contains[.] We do not think it necessary . . . to enable the defendant to do, what we fear is too often done, to infringe first, and look for defen[s]es afterwards.

Silsby v. Foote, 55 U.S. 218, 233 (1852).

Obviousness

A district court rejected an obviousness challenge to a drug product after finding that the formulation of the drug product presented numerous challenges whose

solutions were not obvious or within the background knowledge of one of skill in the art. The court also rejected the argument that market forces would have motivated one of skill in the art to make the patented combination given that there were thousands of possible permutations rather than a finite number of possibilities as in *KSR*. The court concluding that the patents “are genuine innovations, not predictable upgrades,” and therefore were not invalid for being obvious. *In re Omeprazole Patent Litig.*, 2007 WL 1576153, *141 & *143 (S.D.N.Y. May 31, 2007).

Claims covering the antacid product Pepcid Complete and requiring the combination of an antacid with a coated form of famotidine were held invalid for obviousness by a district court. The court found that the prior art taught generally combining an antacid with famotidine. The prior art also taught that famotidine had a bitter taste, and that the taste could be masked by coating the famotidine granules. Given that the drug product was a chewable tablet, the court held it was obvious to use a coated form of famotidine with an antacid as claimed. Rejecting the patentee’s argument that a person of ordinary skill would not have been motivated to use an impermeable coating for taste-masking purposes, the court explained that “[u]nder *KSR*, [t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.’ The ’340 patent does no more than combine the predictable results of Davis and Wolfe with the predictable results of the ’072 and ’114 patents.” The court also found that an apparent contemporaneous invention by another based on the taste-masking rationale further supported finding that one of skill would have had the motivation to make the claimed combination. The court also rejected the patentee’s evidence of commercial success since the patentee failed to show a nexus between the merits of the claimed invention and the commercial success in view of the substantial advertising efforts undertaken by the patentee, its preexisting brand recognition, and its marketing plan to have its new product cannibalize its prior product. *McNeil-PPC, Inc. v. Perrigo Co.*, 2007 WL 1624764, *7-*9 (S.D.N.Y. June 5, 2007).

A district court stuck to its decision setting aside a jury verdict finding asserted claims invalid for being obvious where the court had ruled that there was no evidence in the record to show that one of skill in the art would have been motivated to combine the two prior art references as suggested by the accused

infringer. Rejecting the accused infringer’s argument that its analysis was inconsistent with *KSR*, the court held that it “did not apply a rigid application of the ‘teaching, suggestion and motivation test.’” Rather, it found that there simply was “nothing in the record to conclude that a person skilled in the art would combine . . . the prior art references relied on by defendants [] to come up with” the claimed invention. The court also supported its ruling by noting there was a long-felt need for the invention and that the accused infringer relied on the patent when it developed its accused product. *Sundance, Inc. v. De Monte Fabricating, Ltd.*, 2007 WL 1655423, *2 (E.D. Mich. June 7, 2007).

Appealability of Contempt Order

In a published opinion, the Federal Circuit held in *Integrus, Inc. v. Pall Corp.*, 2007 WL 1695092 (Fed. Cir. Jun. 13, 2007), that an accused infringer could not immediately appeal an order finding it in contempt for violating a preliminary injunction by selling a product that was a mere “colorable imitation” of an enjoined product and imposing a specific monetary sanction for the violation. Instead, the accused infringer had to wait until the district court entered a final judgment in the case before it could appeal the contempt order and sanction. Because the district court’s contempt order only interpreted, but did not modify or extend, the original preliminary injunction, the Federal Circuit held that it was not one of the permissible interlocutory orders immediately appealable under 28 U.S.C. § 1292(a). *Id.* at *3-*5. Citing several Supreme Court cases holding that civil contempt orders given during the course of a lawsuit remain interlocutory, and therefore not immediately appealable, the Federal Circuit also rejected the argument that the contempt order was a “final” judgment because it imposed a specific monetary fine for the contempt. *Id.* at *6-*7.

While dismissing the accused infringer’s appeal for lack of subject-matter jurisdiction, the Federal Circuit held that it did have jurisdiction to hear the patentee’s cross-appeal of the district court’s dissolution of the preliminary injunction based on a new question of validity. Even though the district court included the order dissolving the injunction in the same physical document in which it set forth the order finding contempt, this fact did not provide a basis to hear the appeal of the contempt order. Writing for the court, Judge Moore explained that “[p]resenting a ruling that is not otherwise appealable in the same physical document as an order dissolving an injunction does not make the unappealable ruling reviewable by this court

under 28 U.S.C. § 1292.” *Id.* at *8.

The Federal Circuit also rejected the accused infringer’s argument that the court should exercise pendent jurisdiction over the contempt order in view of the appeal of the dissolution of the preliminary injunction. Since the contempt order was based on the district court’s finding that the accused infringer sold a product that was a colorable imitation of the enjoined product, and the appeal of the dissolution of the injunction was based on invalidity considerations, the Federal Circuit ruled that the contempt order was not “inextricably intertwined” with the dissolution order, and therefore pendent jurisdiction could not be exercised. *Id.* at *8

As to the dissolution of the preliminary injunction, the Federal Circuit affirmed that ruling. The court found that the district court did not abuse its discretion in dissolving the preliminary injunction after the accused infringer presented new prior-art references and new invalidity arguments based thereon. Since the accused infringer had supported its new invalidity arguments with credible expert testimony and the patentee failed to show that the district court’s analysis of the invalidity issues had clearly erroneous factual determinations or clear legal error, the patentee’s contention that the new invalidity arguments lacked substantial merit failed. *Id.* at *10-*11.

In an unpublished order handed down a week before *EnterGIS*, the Federal Circuit dismissed an appeal of contempt order based on an accused infringer violating a preliminary injunction where the district court, while making a specific award of attorneys’ fees and ordering disgorgement of profits as a sanction, had not yet determined the amount of the disgorgement sanction or how the sanction was to be paid. The Federal Circuit noted that parties may not appeal an award of attorney fees ordered before entry of a final judgment. Hence, the award of attorney fees did not make the contempt order appealable. Since the district court had yet to even determine the amount of the sanction, the Federal Circuit held that accused infringer had no right to appeal the mere finding of contempt. The Federal Circuit further instructed that after the district court determined the amount of the sanction, an appeal might be proper depending on how the district court ordered the accused infringer to pay the sanction. Citing *In re Christensen Eng’g Co.*, 194 U.S. 458, 460-61 (1904), the Federal Circuit explained that if the accused infringer had to pay a portion of the sanction to the court, then the sanction would be appealable as

criminal contempt. But if the entire sanction was to be paid to the patentee, then the sanction “‘is to be regarded as merely an interlocutory order, and to be reviewed only on appeal from the final decree.’” *Fuji Photo Film Co. Ltd. v. Benun*, 2007 WL 1662642, *1 (Fed. Cir. June 5, 2007) (*nonprecedential*).

False Marking

A district court granted a patentee summary judgment dismissing a § 292 false patent marking claim based on press releases that advertised the patentee’s product as being patented at a time when the patentee only had a patent application pending. The court found that the plaintiff failed to offer anything other than conjecture that the patentee made the mismarking in the press release with the required deceptive intent. In view of the patentee’s declaration explaining how it told its advertising agency that it had only applied for a patent, its explanation that through an honest oversight no one caught the error in the press release describing the product as being patented when reviewing the agency’s draft, and the plaintiff’s lack of any contrary evidence to suggest the patentee mismarked with deceptive intent, the court granted summary judgment. It instructed that “[a] bald assertion of intent to deceive falls far short of sufficient evidence to survive summary judgment in a case brought under § 292.” *Bibow v. Am. Saw & Mfg. Co.*, 2007 WL 1667043, *1 (D. Mass. June 11, 2007). The court also found highly doubtful the plaintiff’s 200 million dollar penalty calculation since it appeared the plaintiff improperly based its calculation on the number of times Defendants’ erroneous press release might have been seen in some medium, such as an internet website. The court noting that “[i]t is doubtful that the statute ever intended to create such a lucrative game of ‘gotcha!’” Indeed, this is consistent with the view that “the amount of a penalty is not generally measured based on the number of individual products or pieces of advertising material that have been falsely marked, but on the number of occasions that the defendant has engaged in false marking regardless of the number of products or pieces falsely marked during an individual occasion.” *Annotated Patent Digest* § 34:98 Penalties for Violation.

Witness Intimidation

An accused infringer and its trial counsel were sanctioned for witness intimidation arising from i) the counsel’s harassing questioning of an expert witness as to his authority to conduct tests on behalf of the

patentee; and ii) the in-house counsel's actions, aided by trial counsel, to bring pressure on the expert witness to cease working for the patentee. The expert witness was a named inventor on the asserted patent and a former employee of the patentee/university. The university had retained the expert in his capacity as a principle of a subsidiary corporate laboratory of a parent corporation. The patentee tasked the expert to run tests on the accused product to develop evidence to show infringement. During the expert's deposition, the accused infringer's trial counsel repeatedly questioned the expert as to his authority to assist the patentee in the matter and whether the parent corporation had knowledge of the expert's role in using the laboratory to run tests for the patentee's use in the litigation. Additionally, after the deposition concluded the trial counsel gave the confidential deposition transcript to the accused infringer's in-house counsel who then wrote e-mails to the executives of the parent corporation demanding an explanation for why the expert had been permitted to aid the patentee. Thereafter, the expert informed the patentee that he could no longer serve as an expert. The court found that the totality of the conduct violated the rules of professional conduct. As to the deposition questioning, the court ruled that "the questioning was . . . undertaken as part of a deliberate stratagem to deprive MIT of Dr. Gillies' services as an expert witness." The court also found that the trial counsel had aided the in-house counsel in violating the terms of the protective order by using the contents of the confidential deposition transcript to bring pressure on the expert witness through the communications with the parent corporation. Among the several sanctions allowed, the court ordered that the patentee could "offer evidence of the improper conduct of ImClone's attorneys to lay a foundation for an instruction permitting the jury to draw an inference that ImClone believed that Dr. Gillies' 2005 test results supported MIT's claims in the litigation." Further, the court barred the accused infringer's in-house counsel from receiving any confidential information. The court considered whether to disqualify the accused infringer's counsel and his firm, but deemed that sanction too harsh since the trial was only a few months away. *Massachusetts Institute of Technology v. Imclone Sys., Inc.*, 2007 WL 1654001 (D. Mass. June 8, 2007).

Stays Pending Reexamination

A district court ruled that by delaying to seek a stay of an infringement litigation pending a PTO

reexamination while continuing to litigate its invalidity and noninfringement case in the court, an accused infringer tried to "game the system" when it sought the stay only after suffering an adverse judgment in the litigation. The court noted that irreparable harm generally flows from an accused infringer's obligation to pay court-ordered infringement damages on a patent that the PTO later holds invalid, and this typically favors staying an infringement suit until the completion of the reexamination proceeding. But where the accused infringer deliberately chooses to proceed with the litigation and not timely move for a stay, any irreparable harm resulting from a contrary ruling of the PTO is of the accused infringer's own making, and does not justify a stay to the prejudice of the patentee. *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431 SBA, 2007 WL 1655625, *6 (N.D. Cal. June 7, 2007).

In a case decided last year, but only recently posted to Westlaw, the Eastern District of Texas granted a motion to sever and stay claims from some of the asserted patents during the pendency of a related PTO *ex parte* reexamination. But, the stay came at a high cost. The district court required each accused infringer to stipulate that it would not raise in the litigation any invalidity defenses based on the prior-art references considered by the PTO during the reexamination. According to the court, "Quite simply, Defendants should not have two bites at the apple." The district court rejected that accused infringers' contention that requiring such a stipulation deprived them of due process rights since the accused infringers could not participate in the PTO reexamination. The court rationalized that each accused infringer could file its own *ex parte* reexamination request and participate through that means. *Datatrans Corp. v. Wells Fargo & Co.*, 2006 WL 4568052, *5 (E.D. Tex. Oct. 25, 2006).

In consolidated ANDA cases, a district court granted a patentee's motion to stay the cases pending completion of PTO reexamination proceedings. Finding that the cases were in the early stages of discovery, that the stay would likely simplify the issues in the cases "because it may result in the cancellation, clarification, or limitation of the claims, and that the PTO's "findings would provide a valuable analysis to the court," the court granted the stay. The generic drug manufacturer argued that a stay of the litigation would unduly prejudiced it since the stay would effectively ensure that the 30-month stay of FDA approval of its

ANDA could not be shortened based on an early completion of the litigation. The court, however, rejected that argument as being speculative. It, additionally, refused to impose “certain conditions on the stay” since the generic manufacturer failed to cite any case law to support its request for conditions. *Cima Labs, Inc. v. Actavis Group HF*, 2007 WL 1672229, *9-*11 (D.N.J. Jun. 7, 2007).

Privilege

The June 7, 2007, *en banc* hearing in *In re Seagate* addressed as a secondary issue to the question on the affirmative duty of due care not to infringe, the scope of waiver when an accused infringer relies on an opinion of counsel. One of the judges characterized the Federal Circuit’s privilege jurisprudence as being “Swiss cheese” and stated that the court should take the *en banc* opportunity to “fill-in” all the holes. Nonetheless, the issue of whether waiver should extend to trial counsel was the only privilege issue addressed during the argument. Citing to the “substantial need” standard of Rule 26(b)(3), the accused infringer’s counsel argued that waiver should not extend to trial counsel since a patentee has mechanisms other than discovery from trial counsel to test the objective competency of an opinion and the reasonableness of an accused infringer’s reliance thereon. The patentee’s counsel argued that waiver should extend to trial counsel to prevent the privilege from being used as both a sword and shield, and that any alleged inequity was tempered because relying on an opinion was a voluntary choice. Both arguments appeared to receive some support from different members of the court. Some judges thought it important that a patentee know if trial counsel gave contradictory assessments, even if not in the guise of an opinion. But, other judges also thought it would be unfair to permit the patentee to probe the accused infringer’s trial counsel’s thoughts, analysis and assessments of likelihood of success of the issues of infringement, validity, or enforceability. Some judges expressed the view that if the burden of proof effectively placed on the accused infringer via the affirmative duty of due care was removed, the Hobson choice on whether to rely on an opinion of counsel would be reduced to a purely voluntary choice, thereby making any waiver resulting from relying on an opinion of counsel an acceptable calculated risk.

A district court held that the attorney-client privilege did not apply to communications between patent prosecution counsel and a translator hired by the counsel to translate a foreign inventor’s article so that

the article could be submitted to the PTO. The court ruled that since the patent attorney had hired the translator to provide an independent translation and not to assist the attorney in advising the foreign inventor, the communications with the translator were not made in furtherance of the attorney-client relationship, therefore no privilege applied. *Regents of the Univ. of Cal. v. Micro Therapeutics, Inc.*, 2007 WL 1670120, *4 (N.D. Cal. June 6, 2007).

LEGISLATIVE HAPPENINGS

On June 6, 2007, the Senate Judiciary committee held further hearings concerning patent reform. The Honorable Jon Dudas testified as to the views of the PTO on some of the proposed reforms. To improve patent quality and avoid discouraging an applicant and its attorney from providing complete information to the PTO, the PTO recommended that the bill be amended to expressly address inequitable conduct and to impose a materiality standard “of whether a reasonable examiner would have allowed the patent, without more, but for the misrepresentation or omission.” The PTO also appeared to express the view that the best mode requirement should remain intact. Regarding the litigation-based proposed patent reforms, the PTO opposed interlocutory appeals of claim construction orders, and limited its support of the proposed revisions to the doctrine of willful infringement to the requirement that the patentee provide a specific notice of infringement and that no adverse inference should result from an accused infringer asserting attorney-client privilege to withhold producing its opinions of counsel.

Opposition to other aspects of the current proposed legislative reforms continue to arise, particularly the provision for determining infringement damages by requiring the district courts to engage in a mandatory apportionment analysis. Several senators penned a June 11, 2007 letter asking the subcommittee to hold more hearings to address concerns over “the issue of mandatory apportionment of damages, post-grant opposition, and broad rulemaking authority for [the] USPTO” before the committee proceeded to generate a mark-up of the proposed bill on patent reform. On June 7, 2007, Judge Michel wrote a follow-up letter to his May 3 letter and again expressed his concern that the proposed provision making an apportionment analysis mandatory for all infringement cases was not needed and would overburden the courts. Indeed, Judge Michel cautioned the committee to pay more heed to the concerns and comments of seasoned patent

litigators rather than the views of law professors he characterized as having little or no experience in how patent damage theories are actually litigated in court. The PTO also seems to share the view that a mandatory apportionment analysis is not warranted. In his June 6 testimony, Mr. Dudas stated that the "USPTO does not believe that a sufficient case has been made for a legislative provision to codify or emphasize any one or more factors that a court must apply when determining reasonable royalty rates."

ADMINISTRATIVE HAPPENINGS

On June 15, 2007, the USPTO will begin a limited year-long pilot program that will accept public submissions of peer-reviewed prior art for certain computer-related applications. Specifically, volunteers having applications assigned to Technology Center

2100 may consent to a collaborative review and submission of prior art conducted on the peer-to-patent website developed by the Community Patent Review Project of the Institute for Information Law and Policy at the NY Law School (<http://dotank.nyls.edu/communitypatent/>). The PTO seeks to have up to 250 applications participate in the program. Applicants must consent to the inclusion of comments by the peer-to-patent group with the submission of prior art, and up to ten items of prior art may be submitted for each application. Applications having prior art submitted by the peer-to-patent group will be advanced out of turn for examination so results of the project can be seen relatively shortly. More information of the specifics of the program are in the Official Gazette Notice "Pilot Concerning Public Submission of Peer Reviewed Prior Art."

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