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Biotechnology and Pharmaceutical Litigation

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Joint Infringement Update

On April 20, 2011, the Federal Circuit announced it will rehear the case *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 2009-1372, *en banc*. This case, while not a bio/pharma case, will impact bio/pharma cases where joint infringement could be an issue, *e.g.*, where two or more parties practice a patented method.

As part of the order, the parties were asked to file new briefs addressing the following issue: “If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?”

The original panel (Judges Rader, Linn, and Prost) rendered a decision on December 20, 2010, which held that “joint infringement” of a patent required an “agency relationship” or “contractual obligation” between the parties.

In the December decision, the court affirmed the decision made by Judge Zobel in the Massachusetts District Court, Case No. 06-11109, that Limelight didn’t infringe the relevant patent claims by itself. While most of the steps of Akamai’s patented system were allegedly carried out by Limelight, some of the patented steps were performed by Limelight customers. However, because there was no “agency relationship” or “contractual

obligation” between the parties, there was no direct infringement.

On April 12th in *McKesson Technologies, Inc. v. Epic Systems Corporation*, [Case No. 2010-1291] the Federal Circuit issued a decision in a healthcare case, which likewise found that there can only be “joint infringement” when there is an agency relationship between the parties who perform patented method steps or when one party is contractually obligated to the other to perform the method steps.

In *McKesson* the patented invention [US 6,757,898] was directed to an interactive electronic method of communication between healthcare providers and patients involving personalized “MyChart” Web pages for doctors and their patients. The method allows patients to access specific content online following every doctor visit.

The first step of the method claims requires “initiating a communication by one of the plurality of users to the provider for information wherein the provider has established a preexisting medical record for each user.” There was no dispute that Epic’s customers, *i.e.*, the healthcare providers, did not perform the first step of the asserted method claims; this step was performed by the patients of the healthcare providers.

The Federal Circuit, affirming the district court’s grant of summary judgment of non-infringement, held

that because *no one party performed each step of the claimed method*, there was no direct infringement and consequently, no induced or indirect infringement, which required a direct infringer.

In her 17-page dissent, Judge Newman argued that the majority had departed from the “prior panel rule” that requires appellate panels to conform to the “earlier” of conflicting panel precedent. Judge Newman’s position was that this panel’s obligation was either to obtain an *en banc* resolution of divergent statements from various panel opinions or else to follow the earlier panel holding, but in this case the judges did neither. According to Judge Newman:

It is a cynical, and expensive, delusion to encourage innovators to develop new interactive procedures, only to find that the courts will not recognize the patent because the participants are independent entities. From the error, confusion and unfairness of this ruling, I respectfully dissent.

Contempt Update

On April 20, 2011, the *en banc* Federal Circuit in *TiVo Inc. v. EchoStar Communications Corp.*, No. 2009-1374, changed the standard for deciding when a contempt proceeding should be used to evaluate whether a “modified product” continues to infringe.

Again, although the particular case is not a bio/pharma case, the decision will certainly impact contempt proceedings for future bio/pharma cases.

Here the Federal Circuit revised the standard for deciding when contempt proceedings may be used to evaluate purported re-designs, which had been formulated in the case of *KSM Fastening Systems v. H.A. Jones Co.* [776 F.2d 1522 (Fed. Cir. 1985)].

The *KSM* test was a two-step test. At step one, the district court was to determine whether contempt proceedings were appropriate by examining whether the adjudged and modified products were “more than colorably different,” such that they raised “substantial open questions of infringement.” Then, if the modified product was not more than “colorably different,” the district court could proceed to step two and determine whether the modified product still infringed, in which case a contempt finding was warranted.

The *en banc* Federal Circuit declared the *KSM* two-step test as “unworkable.” In its place, the court established the following new test:

First, a district court may entertain a contempt proceeding based on “a detailed accusation from the injured party setting forth the alleged facts constituting the contempt.” A decision to hold such a proceeding will be reviewed only for abuse of discretion. Second, the adjudged infringer’s good faith in attempting to design around the patent is irrelevant to whether its modifications are in fact significant enough to avoid violation of the injunction. Third, the party seeking to enforce the injunction must prove, by clear and convincing evidence, *both* (1) that the newly accused product is not more than colorably different from the product found to infringe and (2) that the newly accused product actually infringes.

In this new test, the primary question should be whether the newly accused product is “**so different**” from the product previously found to infringe that it raises a fair ground of doubt as to the wrongfulness of the defendant’s conduct. For example, where one or more of those elements of the product previously

found to infringe has been modified, or removed, the court must make an inquiry into whether that modification is significant. If it is, *contempt is inappropriate* and the claim of continued infringement must be pursued in a new proceeding.

Reissue Update

An April 15th ruling by the Federal Circuit gives patent owners a new basis for filing patent reissue applications. In *the case* *In re Tanaka*, *Appeal No.* 2010-1262, the court held that “adding dependent claims as a hedge against possible invalidity of original claims” is a proper use of the reissue process.

This decision reversed a decision from Board of Patent Appeals and Interferences, which had ruled in December 2009 that filing a reissue patent application that retained all of the original patent claims, and only differed by adding narrower claims, was impermissible. See MPEP Section 1402:

A reissue application in which the only error specified to support reissue is the failure to include one or more claims that is/are narrower than at least one of the existing patent claim(s) without an allegation that one or more of the broader patent claim(s) is/are too broad together with an amendment to such claim(s), does not meet the requirements of 35 U.S.C. 251.

The Federal Circuit’s majority opinion, authored by Judge Linn and joined by Judge Bryson, held that the court has interpreted the reissue statute as imposing only two requirements; (1) the original patent must be “wholly or partly inoperative or invalid” and (2) the patent issued that way “through error without deceptive intent,” citing the court’s 1989 ruling in *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556 (Fed. Cir. 1989).

False Marking Update

On April 5, 2011, in the case *Hollander v. Ortho-McNeil-Janssen Pharmaceuticals Inc.*, C.A. No. 10-00836 (ED PA), the defendant failed in its efforts to dismiss a false marking suit that accused the company of marking five medical supplies with expired patents, despite the Rule 9(b) heightened pleading standard for false marking plaintiffs set by the Federal Circuit in the recent *BP Lubricants* case (discussed in a previous column).

Judge Buckwalter denied Ortho’s motion to dismiss the suit, ruling that the plaintiff, Dr. Bentley Hollander, had fulfilled the particularity requirement of Rule 9(b). After his initial complaint had been dismissed for failing to sufficiently demonstrate defendant’s intent to deceive the public, Hollander filed an amended complaint detailing Ortho’s involvement in recent litigation regarding the patents as “proof” that the defendant knew its patents had expired.

In his opinion, Judge Buckwalter stated that “both the Federal Circuit and courts within the Third Circuit have noted that intent to deceive may be inferred from a defendant’s active involvement in litigation over a disputed patent.” Accordingly, the court found these allegations “sufficient to support an inference of deceptive intent.”

Microsoft v. i4i Update

On April 18, 2011, the Supreme Court heard one (1) hour of oral argument in the *Microsoft v. i4i* case. This case has the potential to change a long standing precedent in patent law, namely, how much proof must be provided when an accused infringer alleges that a patent is invalid.

Currently a defendant must prove that the patent is invalid by “clear and convincing evidence.” Microsoft is asking the Court to lower the burden of proof for an invalidity defense to a preponderance of the evidence standard—at least

when the proof was not before the USPTO during the prosecution of the patent.

Observers of the argument report a lively exchange between counsel and members of the Court regarding Congressional intent regarding the presumption of validity in Section 282 of the Patent Act. The 50-page transcript was not so lively.

My prediction is that the Court will not change the standard, as they will submit that any such change is solely within the purview of Congress.

Myriad Case Update

On April 4, 2011, oral argument was held in the Federal Circuit in *The Association for Molecular Pathology v. Myriad*. The panel judges were Lourie (Ph.D. Penn.), Bryson (AB Harvard) and Moore (MS MIT).

The questioning from the Court focused on three main topics. The first topic was a procedural matter—whether the plaintiffs have standing to sue. The second topic was a discussion of the merits of the case—analyzing whether isolated DNA is or is not a “product of nature.” The final topic was the patentability of Myriad’s method claims for comparing genetic sequences. The oral proceedings are available at the court’s Web site <http://www.cafc.uscourts.gov/oral-argument-recordings/search/laudio.html>.

My prediction is that the court will rule in favor of Myriad. A simple ruling would be based on a lack of standing by the plaintiffs. A better ruling would be a clear holding that isolated DNA is not a product of nature; it is this ruling that I believe the court will make. The patentability of the method claims is unclear due to the *KSR* standard of obviousness.

Fast Track Patent Prosecution Update

In early April, the USPTO announced that it would begin

accepting requests for prioritized (Track One) examination of patent applications on May 4, 2011.

On April 21st, Director Kappos sent a message to USPTO employees notifying them that the Track One program has been postponed. The cancellation is due to budget cuts—the FY 2011 PTO budget was cut by \$100 Million.

Patent Reform Update

On March 30, 2011, the House of Representatives announced their version of the Patent Reform Act—H.R. 1249. The House bill as set forth on Representative Lamar Smith’s Web site has the following sections (sections that are unique to the House bill are indicated in italics; where the numbering of sections differs, the Senate section number is indicated in brackets):

- Sec. 1. Short title; table of contents
- Sec. 2. First inventor to file
- Sec. 3. Inventor’s oath or declaration
- Sec. 4. Defense to Infringement Based on Earlier Inventor
- Sec. 5. Post-grant review proceedings
- Sec. 6. Patent Trial and Appeal Board
- Sec. 7. Preissuance submissions by third parties
- Sec. 8. Venue
- Sec. 9. Fee setting authority
- Sec. 10. Fees for patent services
- Sec. 11. Supplemental examination [Sec. 10, S. 23]
- Sec. 12. Funding agreements [Sec. 13, S. 23]
- Sec. 13. Tax strategies deemed within the prior art [Sec. 14, S. 23]
- Sec. 14. Best mode requirement [Sec. 15, S. 23]
- Sec. 15. Marking [Sec. 4, S. 23]

- Sec. 16. Advice of counsel [Sec. 4, S. 23]
- Sec. 17. Ownership; assignment
- Sec. 18. Transitional program for covered business method patents
- Sec. 19. Clarification of jurisdiction [Sec. 17, S. 23]
- Sec. 20. Technical amendments [Sec. 16, S. 23]
- Sec. 21. Travel expenses and payment of administrative judges [Sec. 19, S. 23]
- Sec. 22. Patent and Trademark Office funding [Sec. 20, S. 23]
- Sec. 23. Satellite offices [Sec. 21, S. 23]
- Sec. 24. Patent Ombudsman Program for small business concerns [Sec. 22, S. 23]
- Sec. 25. Priority examination for technologies important to American competitiveness [Sec. 23, S. 23]
- Sec. 26. Designation of Detroit satellite Office [Sec. 24, S. 23]
- Sec. 27. Effective date [Sec. 25, S. 23]
- Sec. 28. Budgetary effects [Sec. 26, S. 23]
- Sec. 11 (Residency of Federal Circuit Judges) and Sec. 12 (Microentity defined) from S. 23 are not included in the House version of the bill.

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