WHAT'S HOT IN PATENT LAW?

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This year has proven to be a memorable year in patent law with far-reaching implications. From the long-anticipated enactment of patent reform legislation, signed into law by President Obama only last week, to a number of significant Supreme Court and important Federal Circuit *en banc* decisions, this year had it all. Also, the Supreme Court has granted *certiorari* and the Federal Circuit has granted petitions for rehearing *en banc*, previewing important decisions still to come.

Enactment of Patent Reform Legislation ("America Invents Act")

After many years, patent reform has finally arrived with President Obama's signing of the Leahy-Smith America Invents Act on September 16, 2011. While several controversial measures did not make it into the final bill (including hotly debated legislation addressing patent law damages), the Act does contain several important provisions that may have far-reaching implications both in the PTO and the courts. We will be addressing these in greater detail in upcoming IP Education programs scheduled for October 26 & 27, 2011.

Some of the Act's key provisions include:

- **Effective Immediately:**
    - **False Patent Marking** – the Act potentially eliminates false patent marking actions from district court dockets by removing the *qui tam* provision. Now, only the United States and persons who have suffered a competitive injury may recover damages for false patent marking;
    - **Joinder** – the Act precludes patent holders from joining multiple defendants in a single action solely because they are alleged to have infringed the same patent; and
    - **Best Mode Defense** – eliminated.
- **Also of note:**
    - **First to File** – the Act adopts a "first to file" approach whereby the "effective filing date" of a patent application is the actual filing date / this eliminates the ability to "swear behind" references;
    - The Act includes important sections addressing **Post-Grant Review Proceedings** and ***Inter Partes* Review Proceedings**; and
    - **Failure To Obtain Advice of Counsel –** can no longer be used to prove that the accused infringer willfully infringed the patent or intended to induce infringement of the patent.

- **What's <u>not</u> in the America Invents Act?** Earlier versions of the Patent Reform Act included a number of provisions that are not a part of the "America Invents Act." The following previously proposed provisions, among others, did not make it in the version of the bill that was enacted.

    - **Damages** – Early versions included a "valuation calculation" provision that required the court to "conduct an analysis to ensure that a reasonable royalty is applied only to the portion of economic value of the infringing product or process properly attributable to the claimed invention's specific contribution over the prior art."

    - **Willfulness** –Early versions included restrictions on willfulness findings, requiring clear and convincing evidence that the infringer acted with "objective recklessness" (meaning the infringer (1) performed infringing acts after receiving adequate notice from the patentee, (2) intentionally copied the invention with knowledge it was patented, or (3) after having been found by a court to have infringed that patent, the infringer engaged in conduct that was not colorably different from the conduct previously found to have infringed the patent, and which resulted in a separate finding of infringement of the same patent). These restrictions also stated that a court may not find that an infringer willfully infringed for any period of time during which the infringer had an informed good faith belief that the patent was invalid or unenforceable, or would not be infringed by the conduct later shown to constitute infringement of the patent. Early versions also placed limitations on pleading willfulness: "Before the date on which a court determines that the patent in suit is not invalid, is enforceable, and has been infringed by the infringer, a patentee may not plead and a court may not determine that an infringer has willfully infringed a patent. The court's determination of an infringer's willfulness shall be made without a jury.''

        - The only portion of the willfulness provision later enacted, albeit in somewhat different form, is regarding opinion of counsel. The 2009 version of the bill stated: "The decision of the infringer not to present evidence of advice of counsel is not relevant to a determination of willful infringement…."

    - **Forum shopping** - Early versions of the bill also contained a provision regarding patent litigation venue, specifying that venue is proper only where defendant is incorporated, has its principal place of business, or is permanently located and has committed substantial acts of infringement, or where the plaintiff resides if the plaintiff is a nonprofit or individual inventor, and requiring transfer where it would not cause undue hardship to plaintiff.

The Year's Notable Supreme Court And Federal Circuit Patent Decisions

I. SUPREME COURT CASES

a. UPHOLDING THE CLEAR AND CONVINCING STANDARD FOR INVALIDITY CHALLENGES: *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (decided June 09, 2011)

In an 8-0 decision, the Supreme Court affirmed that invalidity must be established by clear and convincing evidence, based on the presumption of validity written into the Patent Act. The decision put an end to speculation that that the Supreme Court might lower the evidentiary standard for invalidity to a preponderance of the evidence standard to combat the issuance of "bad" patents by the Patent and Trademark Office (PTO). The opinion left open questions about how juries should be instructed if prior art before the jury was not before the PTO.

b. AFFIRMING THE FEDERAL CIRCUIT'S FINDING OF INDUCED INFRINGEMENT, BUT UNDER A NEW STANDARD: *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (decided May 31, 2011)

In an 8-1 ruling, the Supreme Court examined the intent standard for inducement and affirmed the result in the Federal Circuit, finding that Global-Tech infringed by inducement. The Supreme Court ruled that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement. The Supreme Court applied a more stringent intent standard than the Federal Circuit, requiring "willful blindness" (imported from the criminal law context) to satisfy this element in the absence of actual knowledge, and finding that "deliberate indifference," the standard applied by the Federal Circuit, was insufficient to support a finding of inducement. The Supreme Court agreed with the Federal Circuit, however, on a larger point: that a state of mind short of actual knowledge would suffice.

II. FEDERAL CIRCUIT CASES

a. CLARIFYING THE STANDARD FOR CONTEMPT PROCEEDINGS: *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869 (Fed. Cir. April 20, 2011) (*en banc*)

In an *en banc* decision, the Federal Circuit clarified the standard for contempt proceedings, which may be brought where there is an existing injunction, and post-verdict the accused infringer develops an alleged design-around that the patentee argues is in contempt of the existing injunction.

The Federal Circuit made clear that the decision whether to initiate a contempt proceedings is in the trial court's discretion and also clarified the standard for the merits of contempt, overturning its previous decision in *KSM Fastening Systems, Inc. v. HA Jones Co., Inc.*, 776 F.2d 1522 (Fed. Cir. 1985). The court collapsed the previous two-step process for seeking contempt, which required a threshold finding of whether the modified product is colorably different to determine whether a contempt proceeding should be initiated, prior to getting to the merits, noting that the previous two-step inquiry "confuse[d] the merits of the contempt with the propriety of initiating contempt proceedings." The court stated that district courts have broad discretion in judging whether to hold a contempt proceeding so long as the injured party offers a detailed accusation alleging contempt.

Once the court is evaluating the merits of a contempt claim, the "colorable differences" test must be applied first, before any infringement analysis. If there are more than colorable differences or if the "modification is significant," the inquiry ends, an infringement analysis is never reached in contempt proceedings, and the patentee seeking redress must initiate a separate proceeding for infringement. If there are no more than colorable differences, then the court must determine infringement based on the existing claim construction.

Notably, the Federal Circuit appears to have imported analysis from the obviousness context into the "colorable differences" test: "The significance of the differences between the two products is much dependent on the nature of the products at issue. The court must also look to the relevant prior art, if any is available, to determine if the modification merely employs or combines elements already known in the prior art in a manner that would have been obvious to a person of ordinary skill in the art at the time the modification was made."

b. **SIGNIFICANT CHANGES TO THE STANDARD FOR INEQUITABLE CONDUCT: *Therasense, Inc. v. Becton, Dickinson and Company,* --- F.3d --- , 2011 U.S. App. LEXIS 10590, 2011 WL 2028255 (Fed. Cir. May 25, 2011) (*en banc*)**

A six-judge majority tightened the standards for inequitable conduct defenses, cracking down on the growing frequency of inequitable conduct allegations in recent years. The Federal Circuit made evident its dislike of the overabundance of inequitable conduct allegations in litigation, calling it an "absolute plague" and noting that one result of the frequency of inequitable conduct allegations in litigation is that prosecutors, in fear of inequitable conduct charges, "bury PTO examiners with a deluge of prior art references, most of which have marginal value." This then hinders the effectiveness of the PTO.

The court's opinion raised the bar for inequitable conduct, holding that evidence of a "deliberate decision" to deceive is required to satisfy the intent element for inequitable conduct, and that when such evidence is circumstantial, intent to deceive must be "the most reasonable inference." The court also required evidence of "but-for" materiality. Further, doing away with the "sliding scale," the court held that intent and materiality are separate requirements, so that a showing of high materiality cannot make up for a lower degree of intent. Both requirements must be met, separately.

It remains to be seen whether this new standard will have the result, and the magnitude of result, that the Federal Circuit is hoping for: a significant reduction in the frequency of inequitable conduct allegations in litigation, and a reduction in the frequency in which applicants cite large numbers of prior art references during prosecution.

c. **SECTION 145 ACTIONS: *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. Nov. 8, 2010) (*en banc*) *(certiorari* granted June, 2011)**

Faced with a final rejection from the patent office, an applicant must first appeal to the Board of Patent Appeals and Interferences (Board) at the U.S. Patent and Trademark Office (PTO). If the applicant is dissatisfied with the Board's decision, there are two options for appeal: (1) to appeal the

decision by proceeding in a 35 U.S.C. § 141 action before the Court of Appeals for the Federal Circuit, or (2) to initiate a Section 145 action (formerly heard in the District of Columbia but now after passage of the America Invents Act will be heard in the District Court for the Eastern District of Virginia). In a § 141 action, the applicant is not permitted to introduce new evidence that was not presented to the PTO. The case before the Federal Circuit here involved the second path, appeal through Section 145.

The 6-2-1 *en banc* decision set new rules for Section 145 actions, holding that (1) a patent applicant ***is*** allowed to introduce new evidence in a Section 145 civil action filed to challenge a PTO refusal to grant patent rights, and (2) the issues implicated by the new facts must be considered *de novo*. Judge Moore wrote the *en banc* decision that was joined by Chief Judge Rader and Judges Lourie, Bryson, Linn, and Prost. The majority decision focused on the fact that a Section 145 civil action is not an appeal, but rather a new, separate lawsuit.

> "[W]e hold that the only limitations on the admissibility of evidence applicable to a § 145 proceeding are the limitations imposed by the Federal Rules of Evidence and Federal Rules of Civil Procedure. Therefore, we hold that the district court applied the wrong legal standard for the admissibility of evidence in a § 145 proceeding and abused its discretion when it excluded Mr. Hyatt's declaration. . . .
>
> The particular significance of a § 145 civil action is that it affords an applicant the opportunity to introduce new evidence after the close of the administrative proceedings—and once an applicant introduces new evidence on an issue, the district court reviews that issue de novo."

On June 30, 2011, the Supreme Court granted *certiorari*, to examine the Federal Circuit's ruling. The questions presented are:

1. Whether the plaintiff in a Section 145 action may introduce new evidence that could have been presented to the agency in the first instance.

2. Whether, when new evidence is introduced under Section 145, the district court may decide de novo the factual questions to which the evidence pertains, without giving deference to the prior decision of the PTO.

d. REIGNING IN REASONABLE ROYALTY DAMAGES: *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. Jan. 04, 2011)

Although the America Invents Act as enacted did not address reasonable royalty issues, the Federal Circuit recently rejected as "fundamentally flawed" the 25% "rule of thumb" for assessing reasonable royalty damages in infringement cases. Instead, the Federal Circuit held that reasonable royalty calculations must be determined under the unique facts of each case according to the *Georgia-Pacific* factors, without using 25% as a starting point. The court noted that the 25% percent rule of thumb is not tied to the context of a particular industry or technology, much less the facts of any particular case. This decision decisively ended the period of "passive[] tolerat[ion]" of the rule of thumb

by the Federal Circuit. The ruling affirmed the district court's grant of a new trial on damages, overturning a $388 million damage award against Microsoft which was based on the 25% rule of thumb.

e. INFRINGEMENT OF METHOD CLAIMS INVOLVING MULTIPLE ENTITIES: Federal Circuit *En Banc* Rehearing Granted in *Akamai v. Limelight (en banc rehearing petition granted April 2011)* and *McKesson Technologies (en banc rehearing petition granted May 2011)*

In *Akamai* (rehearing of *Akamai Techs, Inc. v. Limelight Nets., Inc.*, 629 F.3d 1311 (Fed. Cir. 2010)), the court presented the following question for briefing:

> 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?

In *McKesson* (rehearing of *McKesson Technologies Inc. v. Epic Systems Corp.*, --- F.3d ---, 2011 WL 1365548 (Fed. Cir. Apr. 12, 2011)), the court presented the following questions for briefing:

1. If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? *See Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983).

2. Does the nature of the relationship between the relevant actors—e.g., service provider/user; doctor/patient—affect the question of direct or indirect infringement liability?

Akamai and *McKesson*, which will likely be heard together, deal with alleged infringement of method claims by multiple actors. Particularly interesting is the question of whether a patentee can prevail on a direct infringement claim where not all elements are performed by one actor. Direct infringement is a strict liability offense, and generally, to be liable for direct infringement of a method claim, the accused infringer must perform each element or step of the claimed method. It remains to be seen how the Supreme Court will balance the interests of punishing infringing conduct with protecting innocent actors.

III. PATENTABLE SUBJECT MATTER

The Federal Circuit addressed a large number of cases this year relating to the scope of patentable subject matter under 35 U.S.C. Section 101 in the wake of the Supreme Court's opinion in *In Re Bilski*, 130 S. Ct. 3218 (2010). The holdings of these cases are difficult to reconcile, and the Supreme Court is once again poised to address the issue of what constitutes patentable subject matter.

a. ***Mayo Collaborative Services v. Prometheus Laboratories*** *(certiorari granted June 20, 2011)*

The Supreme Court has granted *certiorari* for the second time in *Prometheus*, having already vacated and remanded to the Federal Circuit last year for further consideration in light of *Bilski*. The Federal Circuit's second opinion in this case issued December 17, 2010. *Prometheus Labs., Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010). The patent claims at issue in *Prometheus* are method claims directed at administering a drug to treat autoimmune disorders, and determining whether the metabolite level of the drug falls within a range correlated with efficacy but not toxicity (as established through research). Two patents were at issue:

(1) the '623 patent, which claims a method comprising the steps of administering the drug, and then determining the level of metabolite, wherein the level of metabolite indicates either a need to increase or decrease the level of drug (depending on where the metabolite level falls given correlations between metabolite levels and efficacy or toxicity);

(2) the '302 patent, which claims a method comprising the steps of determining the level of metabolite, which will give an indication to either increase or decrease the amount of drug in light of the correlation, allowing for calibration of proper dosage of drugs to treat autoimmune diseases in light of those correlations. The claims of the '302 patent largely match those of the '623 patent, but lack the initial "administering" step.

The Federal Circuit held that the methods were patentable under Section 101, as (1) the claims do not preempt all uses of the natural correlations, but utilize them in a series of specific steps, and (2) the treatment methods claimed in Prometheus's patents in suit satisfy the transformation prong of the machine-or-transformation test, as they "transform an article into a different state or thing," (the transformation of the drug into metabolite by the human body).

The question presented in this case on *certiorari* to the Supreme Court offers an opportunity for the Supreme Court to clarify the patentable-subject-matter analysis, and the interplay between the multiple tests for determining patentable subject matter (preemption and machine-or-transformation). The Supreme Court defined the question presented as follows:

> Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve "transformations" of body chemistry.

b. *The Ass'n For Molecular Pathology v. U.S. Patent and Trademark Office*, --- F.3d ----, 2011 WL 3211513 (Fed. Cir. July 29, 2011) (*request for rehearing en banc denied*)

In a majority opinion written by Judge Lourie, the Federal Circuit addressed the holdings from the S.D.N.Y. regarding whether isolated gene sequences of the BRCA1 and BRCA2 genes, which are linked to breast cancer, and diagnostic method patents involving the BRCA genes fall within patentable subject matter under § 101. The majority held that:

- the district court erred in holding that composition of matter patents on isolated DNA sequences were invalid under § 101, because the isolated DNA exists in a distinctive chemical form from the native DNA found in the body, as the isolated sequences are manipulated (either cleaved or synthesized) and are thus markedly different molecules than those found in the body;

- the district court correctly held that the method claims for comparing or analyzing gene sequences were invalid under *Bilski*, as the comparison of genes is simply an abstract mental process, and the limitation of the method to the BRCA field of use cannot rescue the claimed methods from invalidation under § 101; and

- the district court erred in holding that Myriad's claims directed to screening potential cancer therapeutics via changes in cell growth rates were invalid, since the method claims involve the transformative steps, critical to the purpose of the claimed process, of growing host cells transformed (a term of art) with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic, and thus the process involves physical manipulation of the cells, not just the process of comparing two cells' growth rates (and therefore is not simply an abstract mental process).

The Federal Circuit denied both sides' requests for rehearing *en banc*, on September 13 and 16, 2011, respectively. Thus, the opinion of the panel stands.

c. *Classen Immunotherapies, Inc. v. Biogen IDEC*, --- F.3d ----, 2011 WL 3835409 (Fed. Cir. Aug. 31, 2011)

A fractured Federal Circuit panel addressed § 101 challenges to three patents that claimed immunization methods and schedules aimed at lowering the risk for development of a chronic immune-mediated disorder.

The majority opinion, written by Judge Newman, found that two of the patents (the '139 and '739 patents) met the requirements of § 101, while the third (the '283) did not. The difference discerned between the patents falling within § 101 and the '283 patent was a tangible application step. In the patent holder's own words, the '139 and '739 patents covered uses where "a health care provider reads the relevant literature and selects and uses an immunization schedule that is of lower risk for development of a chronic immune-mediated disorder," while the '283 patent did not involve the step of selecting an immunization schedule, and thus someone could infringe by merely reviewing the relevant

literature. Although the '139 and '739 patents also included a mental step, this was not fatal to § 101 eligibility, because the claims of these patents also included a "specific, tangible application."

Interestingly, Chief Judge Rader, joined by Judge Newman, offered "additional views" noting (and criticizing) the "rising number of challenges under 35 U.S.C. §101."

d. *CyberSource Corp. v. Retail Decisions, Inc.*, -- F.3d ----, 2011 WL 3584472 (Fed. Cir. Aug. 16, 2011)

In *CyberSource*, two types of claims were at issue: a standard method claim and a method claim directed at a computer readable medium drafted in *Beauregard* form (named after *In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995)). The patent claims a method for validating online credit card purchases, using IP address information to prevent fraud by triggering an alert if the buyer was attempting to make a large internet purchase through an IP address that had been previously used for a fraudulent transaction.

The Federal Circuit based its holding on the machine-or-transformation test, finding that the claim as written does not require use of a machine or a physical transformation to a different state or thing, and that tying the abstract mental processes to the internet did not rescue the otherwise ineligible subject matter. The court further found the method to be a mental process because it can be performed "by a human using a pen and paper." The court also found the *Beauregard* claims ineligible for protection, finding the different form was "nothing more than a computer readable medium containing program instructions for executing the [method claim the Court invalidated]." Tying the method claim to software, and the storage device for the software (a "computer readable medium") did not render it patentable just by placing the invention in a different category, as the underlying invention does not meet the requirements of § 101.

e. *Ultramercial, LLC v. Hulu, LLC*, --- F.3d ----, 2011 WL 4090761 (Fed. Cir. Sept. 15, 2011)

In its most recent opinion on patentable subject matter, authored by Chief Judge Rader, the Federal Circuit found a method for monetizing and distributing copyrighted products over the internet to be eligible for patent protection, as it was an application of an abstract idea to a new and useful end, and was deserving of protection. The court found that "as a practical application of the general concept of advertising as currency and an improvement to prior art technology, the claimed invention is not 'so manifestly abstract as to override the statutory language of section 101.'" (citing *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010). The court based its ruling in part on the fact that the patented method was an improvement patent, reasoning:

> [I]nventions with ***specific applications or improvements*** to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act." The '545 patent seeks to remedy problems with prior art banner advertising, such as declining clickthrough rates, by introducing a method of product distribution that forces consumers to view and possibly even interact with advertisements before permitting access to the desired media product. ***By its terms, the claimed invention purports to improve existing***

> ***technology in the marketplace. By its terms, the claimed invention invokes computers and applications of computer technology***…. [T]he '545 patent does not simply claim the age-old idea that advertising can serve as currency. Instead the '545 patent discloses a practical application of this idea. The '545 patent claims a particular method for monetizing copyrighted products, consisting of [multiple] steps…. Many of these steps are likely to require intricate and complex computer programming. In addition, certain of these steps clearly require specific application to the Internet and a cyber-market environment…. The digital computer may be considered by some the greatest invention of the twentieth century, and ***both this court and the Patent Office have long acknowledged that "improvements thereof" through interchangeable software or hardware enhancements deserve patent protection. Far from abstract, advances in computer technology—both hardware and software—drive innovation in every area of scientific and technical endeavor.*** (emphasis added, internal citations omitted).

Use of Court-Appointed Experts To Testify To The Jury In Patent Cases: *Oracle v Google*

Federal Rule of Evidence 706(a) governs court-appointed experts, and provides that:

> The court may on its own motion … enter an order to show cause why expert witnesses should not be appointed …. The court … may appoint expert witnesses of its own selection.

In a recent order that has drawn national attention (*see* the attached article), District Court Judge William A. Alsup of the Northern District of California used this Evidence Code provision to appoint an expert to assist the court in connection with the determination of damages in the hotly litigated *Oracle v. Google* patent infringement action (Case No. 3:10-cv-03561, set for trial to begin on October 31, 2011). This is believed to be one of the first times Rule 706 has been used in this fashion in a patent case. What makes this case unusual is that – in this instance – the court-appointed expert will be testifying ***to the jury***, rather than simply advising the court in connection with *Markman* proceedings, as has been done in many other patent cases.

Is Judge Alsup's order the beginning of a trend, or an aberration? Is this a positive or negative development for patent holders or those who face off against them in court?

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