



OCPLA NEWSLETTER

Orange County Patent Law Association

www.ocpla.org

October 2009

THURSDAY, OCTOBER 22, 2009 LUNCHEON

Our October luncheon will feature *Case Within a Case: Patent Law and Business Torts Meet in Malpractice Claims*, presented by Scott Garner and Ryan Lindsey from Howrey, LLP. This presentation will satisfy **one MCLE ethics credit**.

The luncheon will be held at the Sports Club/LA Orange County from 12:00-1:30 PM. We look forward to seeing you there!

Registration and payment for OCPLA luncheons must be made online ONLY at www.ocpla.org. Payment must be made at the time of registration using a credit card or a PayPal account.

OCTOBER BOARD MEETING

The October OCPLA board meeting will be conducted October 22, 2009 at 11:00 AM at the Sports Club/LA, prior to the October luncheon. Members who wish to present items for the Board's consideration should contact our president, TJ Singh, at tjsingh@koslaw.com to have their items placed on the agenda, and to verify the time and location of the meeting.

ELECTION FOR 2010 OCPLA OFFICERS

The annual election for the 2010 OCPLA officers will be held Thursday, October 22, 2009 in conjunction with our monthly luncheon. If you are unable to attend, please complete and e-mail the attached proxy form to Tom Dao at TDao@koslaw.com by October 22, 2009.

STATE BAR OF CALIFORNIA 2009 INTELLECTUAL PROPERTY INSTITUTE IN ORANGE COUNTY

The 34th Annual Intellectual Property Institute hosted by the State Bar of California Intellectual Property Law Section will be held at the St. Regis, Dana Point, November 12-14. See http://www.calbar.ca.gov/state/calbar/calbar_generic.jsp?cid=12488 to register and for more information.

MARK YOUR CALENDAR: OCPLA ANNUAL HOLIDAY PARTY

OCPLA will be hosting our annual Holiday Party for 2009 at The Ritz-Carlton in Dana Point on December 10. We are really looking forward to this event – more details coming soon!

2009 OCPLA MEMBERSHIP RENEWAL

Membership for 2009 is now available online only. Payment must be made at the time of registration using a credit card or a PayPal account. Go to www.ocpla.org and use the "Membership App" link on the left column. If you have any questions regarding 2009 membership applications or renewals, please contact Tom Dao at tdao@koslaw.com.

NEW MEMBERS

Please encourage your colleagues to renew their OCPLA membership or to join as new members. We look forward to growing the organization with all of you.

INTERNET SIGHTINGS

BY JIM HAWES

This column highlights some of the more notable recent internet notices, newsletters and blogs dealing with IP prosecution issues. The full IS column, with compilations of some of the sources such as Hal Wegner's newsletter, is now up and available at www.internetsightings.com. Check it out.

Hal Wegner's newsletter – a lot of great stuff – Contact: hwegner@foley.com

- The 9/3/09 email states that Bob Stoll will be the new Commissioner of Patents beginning 10/1/09, and Peggy Focarino will be the new Deputy Comm.
- Hal's top ten list of cases on appeal are discussed in his newsletters of 9/3/09, 9/11, 9/14, 9/15 (2), 9/16 and 9/17.
- The 9/9/09 message reports that Chief Judge David Sams of the TTAB will retire on 11/1/09.
- Hal's 9/12/09 commentary surveys the questionable views of Gene Quinn in his no. 2 blog, IPWatchdog (per Pat-O survey of 7/11/09).
- The 9/22/09 posting focuses on the recent WIPO IP report showing the 2007 top patent application filings of China (673K), Japan (443K) and the US (347K).

Patently-O – a blog written by Dennis Crouch – www.patentlyo.com.

- The 9/1/09 blog reports the *Bose* CAFC decision holding that fraud in trademark prosecution requires more than “should have known;” it will excuse false statements based on inadvertence, misunderstandings, etc.
- The 9/2/09 email discusses new PTO Director Kappos' desire to give examiners sufficient incentives to ensure complete and competent first actions and compact prosecution, with applicant interviews early and often.
- The 9/3/09 blog is a data master's delight. It reports a study of Jan – Aug 09 original patent applications – the favorite day to file is Friday, the average

number of words (8000) and the average number of claims (20).

- The 9/4/09 email discusses the design patent issued to Google for its home page.
- The 9/8/09 blog offers more for data masters. It reports that about 30% of patents issued in 1975 had at least one method claim, with a gradual rise to more than 60% in 2009 having at least one such claim.
- The 9/15/09 email summarizes Director Kappos' speech to the IPO about the PTO's near-term future. See also Hal's 9/16 posting.
- The 9/17/09 posting presents a paper by Prof. Collins discussing method claims in light of the *Bilski* and *Prometheus* decisions. Hal Wegner's email of 9/17 lists many other comments about *Prometheus*.
- The 9/26/09 email discusses the recent 40% increase in BPAI filings, the upswing in decisions, and the likely reasons behind these increases.
- The 9/28/09 message reports that Prof. Espinel is the new IP Czar for the Administration. Trademarks and copyrights are her likely focus.
- The 9/29/09 blog reports that the government has filed its brief with the Supreme Court in *Bilski*, asking the Court to limit “process” to the machine or transformation test of *Alappat*.

Carl Oppedahl – emails of PCT practice matters: carl@oppedahl.com.

- The 9/3/09 emails discuss the last day to file a PCT application under a valid claim of priority to a provisional US application. Interesting.
- The 9/5/09 emails discuss filing a demand for preliminary examination with an IPEA. Also interesting.
- The 9/12/09 and subsequent emails discuss the need for claims in a provisional application.

Incontestable – a monthly review of trademark developments – www.finnegan.com

- The July-Aug review reports that the CAFC has held *Hotels.com* to be generic for obvious reasons.

Patent Docs – a frequent newsletter about patents – zuhn@mbhb.com

- The 9/29/09 message discusses the *AstraZeneca* en banc CAFC decision on inequitable conduct, requiring both an omission (or misstatement) and evidence of deceptive intent.

WIPO – madrid@wipo.int

- On 9/21/09 WIPO published a report on worldwide IP rights showing recent IP trends, including an apparent drop in 2008 filings.

Other Stuff –

- *Signals* magazine reports a 41% funding increase in specialty drug companies for the first half of '09.
- In an article in the August *Life Sciences Leader* magazine a VC – CEO opines that biotechnology is entering a “golden era” of discoveries. I guess that means a golden era for biopatents too.
- The American Conference Inst. announced a Foreign Patent Law & Regulation for Life Sciences conference in NYC on 12/7-8/09.
- ACI is also holding a patent opinion writing boot camp in Philadelphia on Oct. 28-29.

For more information about any of the patent topics mentioned consult *Patent Application Practice*, and for trademark topics consult *Trademark Registration Practice*, both published by West and updated twice a year.

RECENT IP CASES

BY IRFAN LATEEF
KNOBBE, MARTENS, OLSON & BEAR

♦ In *Martek Biosciences Corp. v. Nutrinova, Inc.*, Nos. 2008-1459 and -1476, the Federal Circuit affirmed the district court's decision upholding the validity of two U.S. Patents owned by the plaintiff, Martek, and finding infringement of those patents by the defendant, Lonza. The Federal Circuit reversed the district court's finding of invalidity with respect to two other U.S. Patents owned by Martek.

Lonza and Martek make and sell docosahexanoic acid (DHA) products, an omega-3 fatty acid obtained by extraction of lipids from fermented microorganisms such as algae. Martek had obtained several patents directed to these compounds and methods of obtaining such compounds, and sued Lonza for infringement of the same.

The district court denied Lonza's motion for JMOL for invalidity based on a parent application being prior art against one of the asserted patents. The Federal Circuit affirmed the denial of JMOL, finding there was sufficient written description to support the two main limitations of the patent's claims (extracting lipids from a mixed culture and combining the extracted lipids with a food material to make a food product) when considered together with an expert's testimony that a person of ordinary skill in the art would find adequate written support in the parent application. The Federal Circuit also affirmed a finding of infringement of another asserted patent, finding that a claim limitation calling for a “non-chloride sodium salt” encompassed the sodium hydroxide used by Lonza, and Lonza did not produce sufficient evidence to support invalidity due to prior inventorship under 35 U.S.C. § 102(g).

Martek also appealed the district court's claim construction that the term “animal” in a third asserted patent did not encompass humans. On appeal, the Federal Circuit found there was no clear disclaimer of claim scope to humans, and that the patent's claims were applicable to humans.

♦ In *In re Skvorecz*, No. 2008-1221, the Federal Circuit reversed the rejection of Claims 1-5 and 7 in a reissue application and remanded for further proceedings.

The reissue application was based on a patent directed to a wire chafing stand for supporting a dish to keep food warm. Wire legs supporting the stand are attached to an upper rim of the stand and are indented (or “offset”) at the upper ends of the legs such that two nested stands will not significantly wedge together.

Claim 1 of the reissue application recites a "chafing stand comprising: a first rim . . . and having at least two wire legs with each wire leg having two upright sections . . . and further comprising a plurality of offsets located [] in said upright sections . . . for laterally displacing each leg." The PTO cited a reference having three wire legs, in which only two of the wire legs included offsets. The BPAI held the reference anticipated Claim 1 because the claim could be construed to include wire legs without offsets due to use of the term "comprising" in the claim. The Federal Circuit reversed, explaining that not every limitation of Claim 1 is present in the reference because each wire leg of the reference did not include an offset.

The Federal Circuit further reversed the Board's holdings that Claim 1 fails to comply with the written description requirement and that dependent Claim 5 is indefinite. The Federal Circuit held that Claim 1 complies with the written description requirement because the offset being claimed was shown in a partial figure, and a person skilled in the mechanical arts would understand the specification as including the offset in each wire leg. The Federal Circuit further held that although Claim 5 recited "the separation," which is not recited in Claim 1, Claim 5 is not indefinite because a person skilled in the art would understand the claim when viewed in the context of the specification.

◆ In *Nystrom v. Trex Co., Inc.*, No. 2009-1026, the Federal Circuit affirmed, on *res judicata* grounds, the district court's judgment that the case should be dismissed.

The patent at issue relates to outdoor wood-flooring boards. In a prior proceeding, Nystrom stipulated that a wood-composite board made by Trex did not infringe after an unfavorable claim construction. In this proceeding, Nystrom accused a second version of the board of infringement under the doctrine of equivalents. Trex moved for summary judgment on *res judicata* and other grounds. The district court granted the motion but denied it on the issue of *res judicata*.

For purposes of appeal, Trex conceded that there were material differences between the first and second versions of the boards. Holding that the focus of the *res judicata* analysis is on the claim limitations at issue in a particular case, the Federal Circuit found that the differences between the boards did not materially alter the infringement analysis of the limitations that were the basis of Nystrom's stipulation in the prior proceeding. Since the boards were materially identical with respect to the pertinent claim limitations, the second suit was precluded.

◆ In *Fresenius USA, Inc. v. Baxter International, Inc.*, Nos. 2008-1306 and -1331, the Federal Circuit affirmed in part and reversed in part the district court's grant of JMOL that the asserted claims are not invalid as obvious, and vacated the district court's grant of permanent injunction.

Baxter owns patents directed to a hemodialysis machine with a touch-screen interface. The jury found all asserted claims invalid as obvious. The district court then granted JMOL that the asserted claims are not invalid as obvious and issued a permanent injunction.

The Federal Circuit reversed the district court's grant of JMOL of no invalidity for most of the claims, finding that the jury's verdict was supported by substantial evidence. With respect to the means-plus-function claims, however, the Federal Circuit found that no evidence—let alone substantial evidence—was presented that structure for performing the recited function existed in the prior art. Consequently, the Federal Circuit affirmed the grant of JMOL of no invalidity with respect to the means-plus-function claims. In view of its reversal-in-part of the district court's grant of JMOL, the Federal Circuit vacated the permanent injunction for reconsideration.

In his concurrent opinion, Judge Dyk wrote that the district court has discretion to issue a stay in view of the reexamination of the remaining claims that are of "dubious validity" in light of the Court's holding.

In a separate concurring opinion, Judge Newman responded that a stay, when adjustment to damages and modification of

the permanent injunction are the only issues that remain on remand, would be a “distortion of the role of reexamination.”

◆ In *Lucent Technologies, Inc. v. Gateway, Inc.*, Nos. 2008-1485, -1487, and -1495, the Federal Circuit affirmed on validity, infringement, and non-infringement, vacated on damages, and remanded on damages.

The asserted patent generally relates to methods of entering information into fields on a computer screen without using a keyboard. The district court found the patent valid and infringed and awarded damages of \$358 million. This result was upheld on motion for JMOL, and the defendant appealed.

The Federal Circuit first determined that there was sufficient evidence for a jury to find that the patent was nonobvious in view of the evidence presented at trial. Although the issue was close, the jury could reasonably find at least one limitation (of four discussed on appeal) missing from the prior art presented.

The court next affirmed findings of both contributory and induced infringement, while also affirming the underlying finding of direct infringement. Regarding the question of substantial non-infringing uses of the infringing software, the court noted that such non-infringing uses must be related to the relevant portion of the software and not the entire software program.

Regarding damages, the court found that the lump-sum award of \$358 million was unsupported by the evidence. While reviewing most of the *Georgia-Pacific* factors, the court focused on rates paid by the licensee for the use of other comparable patents. The court noted that the similarities and differences between the licenses presented as evidence and the relevant patents were not adequately discussed. Accordingly, the court held that the damages were too speculative.

Finally, the court affirmed the district court's finding of non-infringement on other claims. The court noted that the plaintiff presented very little evidence of infringement at trial.

◆ In *Amgen, Inc. v. F. Hoffman-La Roche, Ltd.*, Nos. 2009-1020 and -1096, the Federal Circuit vacated and remanded the grant of summary judgment and JMOL that certain claims were not invalid for obviousness-type double patenting, vacated and remanded the grant of JMOL that a claim was not infringed, and affirmed the court's judgment in all other aspects.

Because the parent of the asserted patents was subject to a restriction requirement, the district court determined the patents were protected by the safe harbor provision of 35 U.S.C. § 121, which states that “[a] patent issuing on an application with respect to which a [restriction] requirement . . . has been made, or on an application filed as a result of such requirement, shall not be used as a reference . . . against a divisional application or against the original application or any patent issued on either of them” Accordingly, the district court granted summary judgment and JMOL that certain claims were not invalid for obviousness-type double patenting. At trial, the jury found the asserted claims were valid and infringed.

The Federal Circuit vacated and remanded the judgment that certain claims were not invalid for obviousness-type double patenting. The Federal Circuit determined the safe harbor only applies to divisional applications, or continuations descended from a divisional application. Because the asserted patents were all designated as continuations, the judgment was vacated and remanded.

The scope of the factual inquiry for obviousness-type double patenting was also addressed for consideration upon remand. In *Takeda Pharmaceutical Co. v. Doll*, the Federal Circuit held that a patentee could overcome a double-patenting rejection of a process patent over a product patent by presenting post-invention evidence of an alternative process for making the product. The Federal Circuit held that *Takeda* only allows the patentee to show alternative processes that would render a process patentably distinct and that the defendant may only use the same evidence to rebut the patentee.

The Federal Circuit also affirmed validity and infringement of various product-by-process claims, noting that product-by-process claims can be anticipated by prior art that is structurally the same as the product of a product-by-process claim, even if the prior art uses a different process to make the product. However, because there was considerable evidence that the prior art was structurally different, the grant of JMOL finding no anticipated was affirmed.

Also, with regard to the product-by-process claims, the Federal Circuit noted it was correct for the court to require that anticipatory prior art be structurally the same as the product; whereas infringement by a product only requires evidence that the recited process was used to make the product.

♦ In *AsymmetRx, Inc. v. Biocare Medical, LLC*, Case No. 2009-1094, the Federal Circuit vacated and remanded the district court's grant of summary judgment of non-infringement.

Harvard College granted a nonexclusive license to Biocare under two of Harvard's patents. The Biocare license defined, but did not actually limit the license grant to, a limited field of use in the life science research market. A few years later, Harvard entered into an "exclusive" licensing agreement with AsymmetRx for the same patents but limited the agreement to a field defined as the "sale of clinical and diagnostic products and services." AsymmetRx sued Biocare for patent infringement, alleging that Biocare's sale of certain antibodies violated AsymmetRx's exclusive rights in the field. The parties made cross-motions for summary judgment. The district court granted Biocare's motion for summary judgment of non-infringement based on, among other grounds, its interpretation of the Biocare license as not being limited to the life sciences research market. AsymmetRx appealed.

On appeal, despite the parties' focus on whether the district court properly interpreted the language of the Biocare license, the Federal Circuit instead turned its attention to whether AsymmetRx had standing to bring an action for

infringement without joining the patent owner, Harvard. This issue was not raised by either party or by the district court.

The Federal Circuit held that the critical determination regarding a party's ability to sue in its own name is whether an agreement transferring patent rights to that party is, in effect, an assignment or a mere license.

The court found that despite a broad conveyance of rights to AsymmetRx, Harvard retained substantial interests under the patents, including the right to sue for infringement. Harvard also retained the right to make and use the patented antibodies for its own academic research and the right to provide the antibodies to non-profit or governmental institutions for academic research. Furthermore, Harvard retained control over aspects of the licensed products, such as requiring certain commercial use, availability, and FDA filing benchmarks, specifying that manufacture had to take place in the United States, maintaining input on sublicensing, and receiving a share of sublicensing royalties. Finally, AsymmetRx was required to grant sublicenses suggested by Harvard and to cooperate with Harvard in maintaining the patent rights.

The retention of all of those rights, the Federal Circuit held, is inconsistent with an assignment of patents. Accordingly, AsymmetRx was held to be a licensee, not an assignee, and thus did not have standing to sue for infringement in its own name. The Federal Circuit vacated the grant of summary judgment and remanded the case to the district court.

♦ In *In re Lister*, No. 2009-1060, the Federal Circuit vacated a BPAI decision rejecting an application's claims for anticipation.

Dr. Lister conceived of an improved method of playing golf and recorded his invention in a manuscript. Dr. Lister obtained a copyright registration on the manuscript and, more than two years later, filed for a patent. The examiner rejected the claims under 35 U.S.C. § 102(b) as anticipated by the manuscript. Concluding that the manuscript was publicly accessible through searching

databases of copyrighted works by title, the Board affirmed the rejection.

The Federal Circuit reversed. Because the PTO failed to introduce evidence pertaining to the general cataloging and indexing practices of the databases that permitted keyword searching of titles of copyrighted works, it was unclear when the manuscript was added to these databases. Accordingly, the PTO failed to establish that the manuscript was publicly accessible more than one year before the filing date of Dr. Lister's patent application.

◆ In *Edwards Lifesciences LLC v. Cook, Inc.*, Case No. 2009-1006, the Federal Circuit affirmed the district court's claim construction and grant of summary judgment of noninfringement.

Plaintiff-patentee Edwards holds four patents to intraluminal grafts for treating aneurisms and occlusive diseases of blood vessels. The claims all recited a "graft," "graft body," "graft structure," "bifurcated base structure," or a "bifurcated base graft structure." The district court construed all of the terms identically, to require that (1) the graft be intraluminal, (2) the graft have wires, (3) the wires be malleable, and (4) malleability and resilience be mutually exclusive. By this construction, the devices of defendant Cook were held to not infringe. Edwards appealed.

After affirming that it was proper to construe the five terms identically, the court considered the requirement that the graft be intraluminal. It noted statements where "the graft" had as its antecedent "an intraluminal graft." Additionally, it noted that the specification never spoke of non-intraluminal grafts, and it referred to intraluminal grafts as "the present invention." Finally, some of the claims required "graft bodies" to be attachable "while inside of a vessel." The court dismissed Edwards' claim differentiation argument as unsupported by the specification and prosecution history. For these reasons, the Court affirmed the construction of "graft" to include the term intraluminal.

The court affirmed the construction that the graft has wires, and then turned to the

requirement that the wires be malleable. It noted that the specification disparaged the use of resilient wires in the background section. Additionally, during prosecution, although the claims themselves did not use the term "malleable," the prosecuting attorneys distinguished the claims over the prior art by pointing the examiner to teachings of malleability in the specification. Thus, the court affirmed this construction.

Finally, the court affirmed the construction that malleable wires and resilient wires were mutually exclusive. The specification stated that the wires "are maleable [sic]...ie [sic] they are not resilient to any substantial extent." The court reasoned that the "i.e." signal "signals an intent to define the word to which it refers," in this case "malleable." Thus, the specification disclaimed the possibility of resilient wires.

◆ In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 2008-1403, the Federal Circuit reversed a district court's grant of summary judgment for invalidity due to unpatentable subject matter under 35 U.S.C. § 101.

Prometheus sued Mayo in district court for infringing patents it exclusively licensed claiming methods for calibrating the proper dosage of thiopurine drugs used in the treatment of both gastrointestinal and non-gastrointestinal diseases. Specifically, the claimed methods included three steps: 1) administering the drug to a subject; 2) determining metabolite levels; and 3) warning that an adjustment in dosage might be required. Relying heavily on the three justices dissenting from the dismissal of the grant of certiorari in *Laboratory Corp. v. Metabolite*, the district court granted a summary judgment motion for Mayo, holding the patents invalid for claiming unpatentable subject matter under § 101. Prometheus appealed.

On appeal, the court concluded that the asserted claims were statutory subject matter. The Federal Circuit restated the prior Supreme Court decisions in *Diehr* and *Benson*, as applied by *Bilski*, regarding patentable subject matter. Specifically, the Federal Circuit stated that "while a claim drawn to a fundamental principle - i.e., a law

of nature, natural phenomenon, or abstract idea - is unpatentable, an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." The court restated the *Bilski* requirement that for a process to be patentable, it must either 1) be tied to a particular machine or apparatus, or 2) transform a particular article into a different state or thing. The court further reiterated that the transformation must not be merely a data gathering step or an "insignificant extra-solution activity," but rather must be "central to the purpose of the claimed process." The court further reiterated that the patent eligibility of a claim § 101 should be determined by analyzing the claim as a whole, not by dissecting the elements.

Applying these principles, the court determined that the claims were patentable subject matter under § 101, stating:

1) the claimed administering and determining steps were transformative, reasoning that "[t]he transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined," with a central purpose to "treat the human body";

2) although the claimed administering and determining steps gathered useful data, they were not merely data-gathering steps or an algorithm tied to data gathering steps; specifically, the steps were transformative, and were "part of treatment regimes for various diseases using thiopurine drugs . . . not drawn merely to correlations between metabolite levels and toxicity or efficacy";

3) the final claimed step of providing a warning based on the results of the prior steps was a mental step, but the claim must be analyzed as a whole for patent eligibility, and "a subsequent mental step does not, by itself, negate the transformative nature of prior steps."

◆ In *Vita-Mix Corp. v. Basic Holding, Inc.*, Nos. 2008-1479 and -1517, the Federal Circuit vacated and remanded summary judgments of no direct infringement and no invalidity for anticipation or obviousness or lack of enablement, and affirmed summary

judgments of no inducement, no contributory infringement, and no inequitable conduct.

The patent at issue was directed to methods of preventing the formation of an air pocket around the moving blades of a food blender by inserting a plunger into the body of the blender, thereby blocking the air channels that create the pocket.

The Federal Circuit affirmed the construction of the preamble as excluding "methods of stirring to disperse, dislodge, or break-up an air pocket after it has begun to form" but disagreed with the district court's reasoning that, under this construction, all forms of stirring were excluded. As a result, the Federal Circuit reversed the finding that the patentee had not raised a genuine issue of material fact as to whether employees of the accused infringer had engaged in acts of direct infringement.

The Federal Circuit affirmed the judgment of no contributory infringement, because the accused blenders could be put to substantial non-infringing use by stirring with the included stir-stick to break up air pockets around the moving blades. Likewise, the Federal Circuit affirmed the judgment of no inducement because there was no evidence that the accused infringer had intended to encourage infringement by its customers.

The Federal Circuit reversed the judgment of no invalidity, holding that the distinct court's grant was improperly based on the defendant's failure to cite expert testimony in its motion for summary judgment of invalidity, when the defendant had cited expert testimony in its opposition motion to the patentee's motion for summary judgment of no invalidity.

Finally, the Federal Circuit affirmed the judgment of no inequitable conduct since there was no evidence of deceptive intent.

Dissenting in part, Judge Bryson argued that the patentee had introduced sufficient evidence to raise a genuine issue of material fact regarding both induced and contributory infringement.

♦ In *Kara Technology Inc. v Stamps.com Inc.*, Nos. 2009-1027 and -1028, the Federal Circuit vacated the district court's claim interpretation and judgment of noninfringement.

Kara brought suit against Stamps.com alleging infringement of two patents relating to stamp technology.

The district court's claim construction turned on whether the claim term "security indicia" must be created and validated under control of a cryptographic key contained in pre-established data. The district court noted that the specification repeatedly discussed a key embedded in the pre-established data in each of the detailed embodiments and that "the history of secure systems design supports that this invention requires a key." Thus, the district court construed "security indicia" to require "created under control of a key."

The Federal Circuit disagreed. The Federal Circuit explained that the asserted claims do not recite a "key" in contrast to other claims which did explicitly recite an "encryption key" or "key data," thereby suggesting that the asserted claims were intended to have a different scope. Relying on the plain language of the claim, the Federal Circuit held that the claims do not require the use of a "key" (cryptographic or otherwise).

♦ In *In re '318 Patent Infringement Litigation*, Nos. 2008-1594 and 2009-1070, the Federal Circuit affirmed the district court's judgment of invalidity for lack of enablement.

Janssen brought suit against several generic drug manufacturers after they filed abbreviated new drug applications and Paragraph IV certifications for using galanthamine to treat Alzheimer's disease. Janssen's patent claims methods for treating Alzheimer's disease using galanthamine.

The district court found that the specification provided almost no basis for its stated conclusion that it was possible to administer a therapeutically effective amount of galanthamine to treat Alzheimer's disease. The specification did not provide dosage information and the patent issued two

months before the results of animal tests. The claims were therefore invalid for lack of enablement.

The Federal Circuit agreed, explaining that the specification did no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. This is not enough to satisfy the enablement and the closely related utility requirements.

In dissent, Judge Gajarsa argued that the district court failed to make the necessary factual findings necessary to support the legal conclusion regarding enablement. In his opinion, the district court committed error by neglecting to consider what the patent text discloses to an ordinarily skilled artisan.

♦ In *Astrazeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc.*, Nos. 2008-1480 and -1481, the Federal Circuit affirmed summary judgment of no inequitable conduct by Astrazeneca.

Astrazeneca is the assignee of a patent that claims quetiapine, an atypical antipsychotic drug. Teva and Sandoz each filed abbreviated new drug applications with paragraph IV certifications for approval to sell quetiapine under 21 U.S.C. § 355(j). The district court granted summary judgment of no inequitable conduct in the prosecution of the patent application.

The Federal Circuit affirmed, holding that there was insufficient evidence to establish the threshold facts of material withholding with the intent to deceive. With respect to materiality, the Federal Circuit held that Astrazeneca's failure to submit internal test data for certain potentially atypical antipsychotic drugs that were disclosed to the examiner was not a material withholding because Astrazeneca disclosed internal test data for other compounds that were structurally closer to quetiapine and specifically relied upon by the examiner in a *prima facie* obviousness rejection.

The court also held that there was no evidence or suggestion of deceptive intent, other than the fact that the nonmaterial internal test data was not provided to the PTO. On this point, the court noted that intent to deceive cannot be

inferred simply from a decision to withhold information where the reasons given for the withholding are plausible.

◆ In *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, Nos. 2008-1509 and -1510, the Federal Circuit vacated the district court's judgment of invalidity and remanded with instructions to dismiss Stanford's action, because the district court incorrectly declined to consider Roche's affirmative defense based on ownership rights of the patents-in-suit and Stanford was unable to establish ownership rights of the patents-in-suit.

The asserted patents relate to methods for using PCR to measure RNA from HIV in the blood plasma of infected humans. Mark Holodniy was one of three named inventors—Stanford researchers that helped develop the technology in conjunction with a third-party company named CETUS. Holodniy signed both a "Copyright and Patent Agreement" that assigned inventions to Stanford and a "Visitor's Confidentiality Agreement" that assigned the rights to the ideas, inventions and improvements he devised "as a consequence" of his work at CETUS.

After unsuccessfully attempting to establish chain of title to the patents, Stanford argued that the Bayh-Dole Act voided Holodniy's assignment of rights to CETUS. However, the Federal Circuit found that the Bayh-Dole Act's primary purpose was to regulate relationships of small businesses and non-profit grantees with the government and did not automatically void otherwise valid assignments.

Stanford additionally challenged the propriety of Roche's counterclaim of ownership of the patents-in-suit. The Federal Circuit agreed with the district court that the California statute of limitations precluded Roche's counterclaim for a judgment of ownership of the patents-in-suit. However, Roche mistakenly designated an affirmative defense as a counterclaim and the district court abused its discretion by refusing to adjudicate Roche's affirmative defense on its merits.

The Federal Circuit defers to regional procedural law when those laws do not implicate issues of patent law. Under California Law, a defense may be raised at any time, even if the statute of limitations would preclude the matter from being asserted as a basis for affirmative relief. Therefore, Roche should not have been precluded from challenging Stanford's lack of standing to maintain its action against Roche.

◆ In *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, No. 2008-1152, the Federal Circuit affirmed summary judgment dismissing claims against Reserve Banks based on alleged acts being "for the United States."

Advanced Software asserted patents relating to detecting fraudulent checks using information encoded on the check, based on Federal Reserve Banks' use of such technology in conjunction with Treasury checks. The Banks, which do not themselves qualify for infringement protection under 28 U.S.C. § 1498, contended that they still deserved such protection in this case because, in the inventors' pilot program contracts with Banks, they acted "in conjunction with" a bureau of the U.S. Treasury, which itself qualifies for such protection.

According to § 1498, alleged infringement by a non-government entity is "for the United States" when it is conducted "for the Government" and "with the authorization or consent of the Government." Here, the contracting Banks met both of these requirements despite Plaintiff's arguments that the Treasury was not a party to the contract and that no express words of authorization or consent were used.

The Federal Circuit and district court viewed the Treasury's agreement to participate with the Reserve Banks in testing and using the system as constituting authorization or consent to use the technology and accept liability for potential patent infringement. Thus, the Reserve Banks' actions were "for the United States" and, according to § 1498, suit against them could only be brought in the Court of Federal Claims, though action

against other private banks could proceed in district court.

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OCPLA NEWSLETTER

Orange County Patent Law Association

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The OCPLA reserves the right to determine which, if any, submitted articles will appear in this Newsletter.

We hope that the Newsletter is helpful, informative, entertaining and interesting. Comments, ideas, announcements,

proposed articles, suggestions and any other communications concerning the content, form or other aspect of this newsletter may be directed to:

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OCPLA Upcoming Events

Event	Date	Details
October OCPLA Luncheon	Oct. 22, 12:00-1:30 PM, Sports Club/LA Orange County, California 92614 (949) 975-8400	Topic: <i>Case Within a Case: Patent Law and Business Torts Meet in Malpractice Claims</i> Speakers: Scott Garner and Ryan Lindsey, Howrey, LLP
34th Annual Intellectual Property Institute, hosted by the State Bar of California Intellectual Property Law Section	November 12-14 St. Regis, Dana Point	Website: http://www.calbar.ca.gov/state/calbar/calbar_generic.jsp?cid=12488
OCPLA 2009 Holiday Party	December 10 The Ritz-Carlton, Dana Point	More details to come

OCPLA Election of Officers Annual Meeting




SPORTS CLUB / LA
Thursday, October 22, 2009
12:00 p.m.



All OCPLA Members must submit their vote.
The Officers and Board of Directors up for Election and Re-election for 2010
are:

V.P./President Elect Tom Dao
Secretary Stacey Halpern
C.F.O./Treasurer Valerie Sarigumba
Director Alyson Barker
Director Sean O'Neill
Director Lynne Boisineau

The President for the year 2010 will be Marlene Klein

	Proxy Statement Form*
I, _____, a member of the Orange County Patent Law Association, vote by proxy for the proposed slate of officers listed above for the 2010 term unless one of the following boxes is checked:	
<input type="checkbox"/> designate Marlene Klein or _____ as my proxy at the October 22, 2009 meeting; or	
<input type="checkbox"/> abstain from voting but submit this proxy for purposes of establishing a quorum only.	
This Proxy Statement form should be mailed or faxed to:	
Tom H. Dao Klein, O'Neill & Singh, LLP 43 Corporate Park, Suite 204, Irvine, CA 92606 (949) 955-1920 (Tel) (949) 955-1921 (Fax) Email: TDao@koslaw.com	

*If you are unable to attend the Annual Election Meeting on October 22, 2009, please fill out this proxy statement form if you wish to designate your proxy or abstain.