United States Patent Law Developments in 2010: Supreme Court and Federal Circuit Decisions

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In calender year 2010, the United States patent system was blessed with a major decision by the Supreme Court on patent-eligible subject matter, *Bilski v. Kappos*, 130 S. Ct. 3218 (2009), and more than 120 precedential decisions by the Federal Circuit, including three decisions en banc. *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010) (en banc) (right of application to introduce new evidence in Section145 action reviewing PTO rejection of claims); *Princo Corp. v. U.S. Int'l Trade Comm'n*, 616 F.3d 1318 (Fed. Cir. 2010) (en banc) (limiting patent misuse doctrine); *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (written description requirement separate from enablement and applicable to some original claims).

Calender year 2011 should equal or surpass 2010 in terms of case law developments on patent law. In 2010, the Supreme Court granted certiorari to review three patent-related cases. *i4i Limited Partnership v. Microsoft Corp.*, 598 F.3d 831 5010 (Fed. Cir. 2010), *cert. granted,*

131 S. Ct. 647 (2010); *Board of Trustees of Stanford University v. Roche Molecular Systems, Inc.*, 583 F.3d 832 (Fed. Cir. 2009), *cert. granted*, 131 S. Ct. 502 (2010); *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360 (Fed. Cir. 2010), *cert. granted sub nom. Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 458 (2010). The Federal Circuit granted en banc review of two cases, one on the determination of infringement in contempt proceedings, *TiVo Inc. v. Echostar Corp.*, 376 Fed. Appx. 21, 2010 U.S. App. LEXIS 9971 (May 14, 2010), *vacating, TiVo Inc. v. Echostar Corp.*, 597 F.3d 1247 (Fed. Cir. 2010), and another important one promising to broadly review the "inequitable conduct" doctrine. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010), *vacated and rehearing en banc granted*, 374 Fed. Appx. 35, 2010 U.S. App. LEXIS 9549 (Fed. Cir. 2010).

In this paper, which has been mandated to be no more 20 pages in length and presented in about 40 minutes, there can be no pretense of doing justice to even a significant percentage of these important developments. Below is a sampler of decisions that are either particularly noteworthy or exemplary interest.

Contents

1.0 Patent Eligible Subject Matter: *Bilski* and Beyond.

1.1 The Supreme Court's *Bilski* Decision. In *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), a majority of a sharply divided Supreme Court rejected categorical approaches to what constitutes a patent eligible process under 35 U.S.C. Section 101. The majority disdained the Federal Circuit's enshrinement of a machine-or-transformation ("MORT") test as the *sole* measure for a patentable "process." It refused to ban categorically business method patents. Justice Stevens wrote a lengthy opinion for four of the nine justices advocating, based on history and policy, a bar on business method patents. The justices unanimously agreed that the patent claims in question, which concerned commodities trading hedging transactions, were unpatentable because they "preempted" the concept of hedging. All the justices agreed that MORT was an important "tool" or "clue" for determining patent eligibility, but none explained what that meant.

In *Bilksi*, the Court relied on its own precedent, primarily a hoary trilogy of cases, *Gottschalk* v. *Benson*, 409 U.S. 63 (1972); *Parker* v. *Flook*, 437 U.S. 584 (1978), and *Diamond v. Diehr*, 450 U.S. 175 (1981). The Court did not critically reevaluate any of those cases. Of the three, the first, *Benson*, is most significant. *Benson* held that claims to a presumptively novel and useful algorithm, a step-by-step procedure for converting one form of numbers (binary-coded) into another form

(binary), were unpatentable because the claims preempted an "idea." The Court equated (questionably) an algorithm with an "idea." The Court's opinion suggested, in dictum, that computer programs would not be patentable unless Congress made an affirmative decision that they should be.

Bilski closely tracks *Benson* by reasoning that the claims at issue, which were to a commodities hedging method, were to the "concept of hedging" and were bad because they "preempted" that concept and were, therefore, for unpatentable "abstract ideas."

For an article critical of *Bilski* for perpetuating the flawed *Benson* doctrine, see Chisum, *Patenting Intangible Methods: Revisiting* Benson *(1972) After* Bilksi *(2010)*, — Santa Clara Computer & High Tech. L. J. —- (2011) (SSRN 1698724). For an article praising *Bilski* for pointing to a sounder approach to patent claim scope, see Chisum, *Weeds and Seeds in the Supreme Court's Business Method Patents Decision: New Directions for Regulating Patent Scope*, — Lewis & Clark L. Rev. —- (2011) (SSRN 1698633).

1.2. Post-*Bilski* Federal Circuit Decisions. Federal Circuits decisions in the latter half of 2010 declined to give broad scope to the *Bilski* bar on patent claims preempting abstract ideas.

1.2.1. *Research Corp. Technologies* (2010). In *Research Corp. Technologies, Inc. v. Microsoft Corp.*,

627 F.3d 859 (Fed. Cir. 2010), the court, per Chief Judge Rader, rebuffed a Section 101 challenge to claims in two patents to methods of "digital image halftoning." The claims implemented certain "blue masks" used in computer generation of digital color and black-and-white images. Reversing a district court decision to the contrary, the court held that the subject matter of the claimed processes did not fail for abstractness. The invention had "functional and palpable applications" in computer technology. Some claims required hardware, such as film, memory and a display. The claimed methods used "algorithms and formulas that control the masks and halftoning," but these "do not bring this invention even close to abstractness that would override the statutory categories and context."

In *Research Corp. Technologies*, Chief Judge Rader threw down a generally restrictive approach to *Bilski* abstractness.

> "[T]his court ... will not presume to define "abstract" beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act."

Judge Rader cautioned that Section 112 contained

"powerful tools to weed out claims that may present a vague or indefinite disclosure of the invention."

1.2.2. *Prometheus* Rebound; Medical Diagnosis.

In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010), *on remand from* 130 S. Ct. 3543 (2010), the Federal Circuit, per Judge Lourie, reaffirmed, after remand by the Supreme Court, its pre-*Bilski* decision that medical diagnostic claims were to patent eligible subject matter.

The facts (briefly): a category of drug, thiopurines, including 6-MP and AZA, had been used to treat gastrointestinal disorders. When administered to a patient, the patient's body transformed the thiopurine drug into metabolites (6-MMP and 6-TG). The patents at issue ('623 and '302) disclosed a correlation between the level of the metabolites in a patient and the efficacy and toxicity of the drug. The correlation could be used to adjust a patient's dosage of the drug. Claims in the patents recited two steps: first, administering a 6-TP drug to a patient and second, determining the levels of metabolite (6-TG and 6-MMP) in the patient. The claims concluded with a "wherein" clause. The clause provided that the measured level of metabolite "indicated a need" to increase drug dosage to optimize drug efficacy, if the metabolite was above a designated level, or to decrease drug dosage to reduce toxicity, if the metabolite was below a designated level. Some claims omitted the

administering step, reciting only the "determining" step.

In the original *Prometheus*, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009), *vacated and remanded*, 130 S. Ct. 3543 (2010), the court held that the claims were directed to patent-eligible subject matter. Applying the Federal Circuit's exclusive machine-or-transformation (MORT) test, which the Federal Circuit had adopted in its en banc *Bilski* (2009) decision, the panel held that the claims' "administering" and "determining" steps were transformative and not merely data-gathering steps. After its *Bilski* decision, the Supreme Court remanded *Prometheus*.

In the rebound *Prometheus*, the Federal Circuit noted that the Supreme Court's *Bilski* decision did not dictate "a wholly different analysis or a different result." True, the original decision did rely on the MORT test, finding that the claimed methods were transformative as part of body-transforming treatment methods. However, the Supreme Court did not reject the MORT test, only its exclusivity. Thus, transformation was still an important "clue" or "tool." Also, the original decision addressed the "preemption" concept of *Bilski*. As the original decision reasoned, the claims here are *not* "drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in" *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978). The claims

recited specific steps of treating a specific disease by administering specific drugs and measuring specific metabolites. The claimed invention was an improvement in a treatment process.

In *Prometheus*, the Federal Circuit dismissed an accused infringer's argument that the claims here are similar to those found to be unpatentable in an opinion by three Supreme Court justices. *Lab. Corp.*, 548 U.S. 124 (Breyer, J., dissenting from dismissal of certiorari as improvidently granted). However, the Federal Circuit noted, a dissenting opinion is not controlling law and need not be discussed. The accused infringer argued that two concurrences in *Bilski*, representing a majority of five Supreme Court justices, cited the *Lab. Corp.* dissent. However, that citation did not turn a dissent into controlling law. One opinion (by Justice Stevens) cited *Lab. Corp.* for the proposition that excessive patent protection can retard technological progress, but it did so in arguing for a rule categorically banning business method patents. "[T]his case does not involve business method patents."

1.3. Printed Matter. Two Federal Circuit decisions invalidated claims that recited "printed matter" or "instructions" as the sole basis for distinguishing prior art methods or products. In each, the patents were based on the alleged discovery of new uses or advantages of existing processes and devices.

1.3.1 *King Pharmaceuticals*: Step of Informing Someone About Inherent Property of a Method. In *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010), the court gave a negative answer to the question: does "an otherwise anticipated method claim become[] patentable because it includes a step of 'informing' someone about the existence of an inherent property of that method"? The negative answer was dictated by the "analogous context" of precedent on "printed matter," which holds that printed matter will not distinguish an invention from the prior art unless the printed matter is functionally related to the printed matter's substrate. See *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983).

A compound, metaxalone, was a known muscle relaxant, having been discovered, patented, and marketed as the drug "Skelaxin" in the 1960s. In two related patents, issued in 2002 and 2004, based on a 2001 application, the claimed invention was an unexpected finding that the administration of metaxalone to a patient *with food* enhanced metaxalone's bioavailability. The patents included claims to methods of increasing oral bioavailability by administering an effective amount of metaxalone to a patient with food. Other claims narrowed the method, limiting administering metaxalone with food by including as steps (1) "*informing*" the patient that taking metaxalone with food will increase bioavailability,

or (2) using a container with a *printed label* advising that taking metaxalone with food will increase bioavailability. HELD: all the patent claims were invalid for lack of novelty or obviousness. The prior art disclosed administering metaxalone with food and in dosages and time frames falling within the claims. The prior art did not expressly disclose increased bioavailability, but the "food effect" occurred naturally and was, therefore, inherent.

1.3.2. *AstraZeneca*; "Kit Claims"; Label Directions for Using Drug. In *AstraZeneca LP v. Apotex, Inc.*, 2010 U.S. App. LEXIS 22660, 97 USPQ2d 1029 (Fed. Cir. 2010), the court applied the printed matter doctrine to invalidate "kit" claims that recited a combination of a prior art drug and a label instructing a novel once-daily administration regime. This case is discussed below in connection with active inducement of infringement.

In *AstraZeneca*, the drug, budesonide, was known in the prior art for treating lung conditions but only for twice or more daily administration. The patents at issue disclosed once-daily administration of the drug for the same condition. The patents contained both method claims to once-daily administration and "kit" claims to a combination of the drug and a label instructing once-daily usage.

The court noted that the "printed matter" doctrine precludes printed matter from being given weight in

distinguishing a prior art product except when there is a functional relationship between the "printed matter" and its substrate. Here, the claims differed from the prior art only in reciting the label with the once-daily dosage instruction.

The parties disputed what was "the substrate" for purposes of the printed matter doctrine. The accused infringer argued that the substrate of the instructions (printed matter) was the paper label. The patent owner argued that the substrate was the drug. However, the dispute was immaterial. Under *In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004), adding new instructions to a known product does not create the functional relationship between printed matter and a substrate necessary to distinguish the product from the prior art.

The patent owner argued that "FDA regulations require a label containing information needed for the safe and effective use of any drug," but "this is a requirement for FDA approval, not patentability."

2.0 Disclosure; Section 112; Written Description

2.1. The En Banc *Ariad* Decision.

In *Ariad Pharmacueticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 2010 U.S. App. LEXIS 5966 (Fed. Cir. 2010) (en banc), the Federal Circuit reaffirmed two propositions about the meaning of the "written description of the invention" language in 35 U.S.C. Section 112, first

paragraph. First, written description of the invention is a requirement independent of the enablement requirement. Second, original claims do not necessarily comply with the written description of the invention requirement. The majority confirmed its prior, controversial decision, *Regents of the University of California v. Eli Lilly & Co*., 119 F.3d 1559 (Fed. Cir. 1997).

For a critical analysis of *Ariad*, see Chisum, *Written Description of the Invention:* Ariad *(2010) and the Overlooked Invention Priority Principle*, 2010 Patently-O Patent L.J. 72.

2.2. Post-*Ariad* Decisions; Priority Support. In several post-*Ariad* panel decisions, the Federal Circuit applied written description in its "classic" mode, that is, in determining whether later-added claims were supported by disclosures in a prior application. *E.g., Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333 (Fed. Cir. 2010); *Yorkey v. Diab*, 601 F.3d 1279 (Fed. Cir. 2010).

The decisions show that support issues can be close. For example, in *Honeywell International, Inc. v. United States*, 609 F.3d 1292 (Fed. Cir. 2010), a patent concerned night vision goggles (NVGs) that were compatible with aircraft cockpit color displays. The patent's claim 2 recited, inter alia, a "local color display." The originally-filed specification for the patent gave as illustrated examples of a local display "three monochromatic CRTs" (cathode ray tubes). In the patent

owner's suit against the government, the Court of Federal Claims held claim 2 invalid for lack of written description, finding that the description was only of CRTs whereas the claim phrase (color display) encompassed "a variety of displays." HELD: the lower court erred in finding that the original disclosure was limited to CRTs. The original specification stated that CRTs "or other display transducers" could be used to filter colors. The specification also stated that "the present invention can be applied to a wide variety of display and vision aid devices." The court concluded:

> "While original figure ... may have disclosed a CRT, there is no reason, in light of the other statements in the specification, to limit the disclosure to only CRTs."

Judge Mayer dissented, noting that the invention of claim 2 "filters a single source of light carrying multiple color bands."

> "[T]he original disclosure of three separate, monochromatic light generators would not demonstrate to one skilled in the art that the inventor possessed the subject matter of claim 2 at the time the application was filed."

3.0 Infringement; Active Inducement

3.1 *Global Tech.*; Pending Supreme Court Review.

The Supreme Court granted certiorari in the *Global-Tech*

Appliances case. *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 2010 U.S. App. LEXIS 2454 (Fed. Cir. 2010), *cert. granted sub nom. Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 458 (2010). The issue presented is:

> "Whether the legal standard for the 'state of mind' element of a claim for actively inducing infringement under 35 U.S.C. § 271(b) is 'deliberate indifference of a known risk' that an infringement may occur or instead 'purposeful, culpable expression and conduct' to encourage an infringement."

3.2 The Federal Circuit Decision; Messy Facts; Multiple Holdings. The facts and holdings of the Federal Circuit's decision did not focus precisely or exclusively on the issue framed to the Court on certiorari. Nor does the case involve a typical "inducement" allegation. The accused infringer was not accused of selling an unpatented component that was used by customers in either practicing a patented method or making a patented combination. Rather, the accused infringer was charged with making a patented product outside the United States and thereby inducing an importer and distributor to infringe by selling the product in the United States.

The patent at issue concerned a deep fryer with a skirt and a pan. U.S. Pat. No. 4,995,312. An accused manufacturer (Pentalpha) had sold accused fryers to three

United States-based customers (Sunbeam, Fingerhut and Montgomery Ward) "f.o.b. Hong Kong." A jury rendered a verdict that the accused manufacturer committed direct infringement and inducement of infringement. The law and facts supported a verdict based on either theory (direct infringement by sale in the United States and inducement of sales by customers in the United States).

Turning to the alternative inducement theory, the court, per Judge (now Chief Judge) Rader addressed the "knowledge of the patent" requirement, which the Federal Circuit had prescribed in its 2006 en banc opinion, *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc) (stating that "The requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement *that he or she knew of the patent*." Judge Rader reasoned that a patent owner can establish the *DSU Medical* "knowledge-of-the-patent" requirement without *direct* evidence of actual knowledge: subjective deliberate indifference would suffice.

On the facts of this case, the evidence before the jury supported a conclusion that the accused infringer "deliberately disregarded a known risk" that the patent owner had a "protective patent" on a product that the accused infringer copied. The accused manufacturer bought the patent owner's product in Hong Kong and "copied all but the cosmetics." The accused manufacturer

obtained a "right-to-use" study from an attorney in Binghamtom, New York. The attorney analyzed 26 patents and concluded that the patents did not read on the accused manufacturer's fryer. The accused manufacturer did *not* tell the attorney that it had copied the patent owner's product. The patent owner was "well versed" in the U.S. patent system, being a named on 29 patents. The patent owner and infringer had had "an earlier business relationship" that involved the infringer's patented products.

In the face of this "considerable evidence of deliberate indifference," the infringer produced no "exculpatory evidence." The infringer did not contend that it actually believed that a patent did not exist.

The infringer noted that the product it copied did not bear a U.S. patent mark. However, it did not argue that it relied on the lack of a marking to form a belief that the product was not patented. Such an argument would "likely lack credibility" unless the infringer explained "why one would expect an SEB deep fryer purchased in Hong Kong to have U.S. patent markings."

3.3 *AstraZeneca*; Active Inducement in the Complex World of FDA-Regulated Drugs. With Supreme Court review of active inducement standards pending, one would expect that the Federal Circuit would hesitate to address them. However, the pressing question of a preliminary injunction involving a generic version of

an FDA-approved drug forced inducement issues on a Federal Circuit panel. *AstraZeneca LP v. Apotex, Inc.*, 2010 U.S. App. LEXIS 22660, 97 USPQ2d 1029 (Fed. Cir. 2010).

As described above, at issue were two patents on once-daily administration of a drug, budesonide, in solution, to treat lung conditions, such as asthma, by inhalation. Budesonide was an anti-inflammatory corticosteriod. The patents contained both method claims to once-daily administration and "kit" claims to a combination of the drug and a label instructing once-daily usage. The prior art showed the same drug for twice-daily administration. It also showed the drug in liposomes rather than in solution for once-daily administration.

The FDA approved the patent owner's drug for either once- or twice-daily usage, but the FDA required a label that warned users to "titrate down" from recommended starting dosages to the lowest effective dose.

An accused infringer obtained FDA approval of its abbreviated new drug application (ANDA) to market a generic version of the patent owner's drug. To obtain the approval, the accused infringer filed with the FDA a "section viii" statement indicating that it would market the drug only for more than once-daily administration (and thus would not infringe the patents). As required by the FDA, the accused infringer's label was identical to that of the patent owner, including the downward titration

statement, except that it deleted ("carved out") any reference to once-daily dosage. On "carve outs" with FDA-mandated labels, see *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd*., 601 F.3d 1359, 1361 (Fed. Cir. 2010).

The same day the accused infringer's ANDA was approved, the patent owner sued and sought a preliminary injunction against the accused infringer's marketing of the generic drug. After a five-day hearing, a district court granted the injunction.

On appeal, the Federal Circuit held that the district court did *not* err by granting a preliminary injunction because, inter alia, the patent owner demonstrated that it was likely to demonstrate infringement by active inducement of the asserted method claims. The patent owner also demonstrated that it was likely to refute the accused infringer's invalidity defenses as to those claims. Note: this question is discussed below.

3.3.1 Titrate-down Statement on Label; Instructing Users on Infringing Once-Daily Dose Use. The district court found that the downward-titration statement would lead some patients to use the accused infringer's drug in a once-daily and, hence infringing, manner because titrating down from the recommended starting dosages necessarily required switching to once-daily dosing, given that some of the starting doses were the minimum for twice-daily dosing and given that the marketed drug units were for immediate delivery and

could not be divided.

The accused infringer argued that (1) the downward-titration statement was merely a general recommendation, which was "applicable to any dosing regimen," (2) drug label warnings "do not influence how a drug is used," and (3) some users would ignore the warning and, therefore, would not titrate down to an infringing dose. The arguments were not responsive to the "pertinent question," which was "whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [the accused infringer]'s affirmative intent to induce infringement. *See Vita-Mix Corp. v. Basic Holding, Inc*., 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009)." Here, the district court found that the downward titration language "would inevitably lead some consumers to practice the claimed method."

3.3.2. Specific Intent. The district court did not clearly err in finding that the "specific intent" requirement for inducement was satisfied by the accused infringer's affirmative acts of launching its drug product with knowledge that the titrate-down statement in its label created infringement problems.

The accused infringer argued that its product had noninfringing uses and, therefore, that the district court improperly inferred intent to induce infringement from the accused infringer's planned distribution of the product. The accused infringer was correct that intent to induce

infringement cannot be inferred from sale of a product that has substantial noninfringing uses, even when the accused inducer has actual knowledge that some users of its product may be infringing. See *Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348, 1365 (Fed. Cir. 2003). However, actual inducement may be found when there is evidence beyond a product's characteristics and knowledge of its uses that shows "statements or actions directed to promoting infringement." *Ricoh Co. v. Quanta Computer Inc*., 550 F.3d 1325, 1341 (Fed. Cir. 2008); *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd*., 545 U.S. 913, 935 (2005).

As the Supreme Court noted its copyright decision, *Grokster*, evidence of "active steps," such as advertising or instructing an infringing use, may show an affirmative intent that a product be used to infringe. 545 U.S. at 936. Here, the district court found inducement, not from the distribution of the drug alone, but rather on the accused infringer's active steps of (1) including a label "that will cause at least some users to infringe the asserted method claims," and (2) proceeding with the distribution of its generic drug "despite being aware of the infringement problem presented by the proposed label."

3.3.3 Label Dictates by FDA? Hobson's Choice? The accused infringer argued that it had no intent to induce because its label was required by the FDA. It protested that it faced a "Hobson's choice" of (1)

complying with the FDA requirement and risking an infringement suit or (2) removing the downward-titration language and ensuring that the FDA would not approve its application (ANDA) to market the generic drug. HELD: the accused infringer faced "no such dilemma."

The accused infringer's research director testified that efforts to change the label were rejected by the FDA or would have been futile because of FDA requirements. As the district court found, the accused infringer had "options at its disposal that it chose not to pursue." It could have (1) waited until the patent expired, (2) appealed the FDA's decision requiring the titration-down statement on the generic label, or (3) filed a "suitability petition" or "paper NDA" seeking FDA approval to produce a half-strength drug (0.125 mg).

3.3.4. Validity: Journal Advertisement; No Disclosure of Daily Dosage; Prior Art Advertisement Distinguished from Infringing Label. The Federal Circuit held that the district court did not err in finding that the patent owner demonstrated that the method claims would likely withstand the accused infringer's validity challenge based on the patent owner's advertisement in a British medical journal. The advertisement (1) touted the patent owner's drug product, (2) disclosed a twice-daily recommended dose (1 to 2 mg), (3) warned that the maintenance dose should be the lowest effective one and (4) gave recommended doses as

0.5-1 mg twice daily for adults and 0.25-0.5 mg twice daily for children. HELD: the district court did *not* err in finding that the advertisement did not anticipate because the "warning" statement would not be read as disclosing once daily dosing, given that at the time (1994), such dosing was not known to be effective.

The accused infringer argued that the 1994 advertisement was "essentially the same" as its label, which was found to suggest once-daily dosing and, therefore, to induce infringement. It noted that such inconsistent findings violated the patent law axiom: "that which would literally infringe if later in time anticipates if earlier."

The question is "close," but the district court did not err in determining that the patent owner had demonstrated that the asserted methods claims would likely withstand a validity challenge based on the advertisement. There was a "key difference" between the accused infringer's inducing label and the advertisement. The label recommended a 0.25 mg starting dose and also that the dose be lowered, which necessarily meant once a day because there was no way to administer less than the 0.25 mg drug unit. On the other hand, the "most natural reading" of the advertisement was that the lowered maintenance doses were the recommended ones that were explicitly twice daily (0.5 mg twice daily for adults and 0.25-0.5 mg twice daily for children).

4.0 Invalidity Defenses; Burden of Proof

4.1 *Microsoft Corp. v. i4i Limited Partnership*; Pending Supreme Court Review. The Supreme Court granted certiorari in the *Microsoft-i4i* case. *i4i Limited Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010), *cert. granted,* 131 S. Ct. 647 (2010). The issue presented is: "Whether the invalidity defense provided for in the Patent Act, 35 U.S.C. § 282, must be proved by clear and convincing evidence."

4.2 Federal Circuit's Decision; Context: Jury Trial; Patent Owner's Own Potentially Patent-Defeating Acts. The Federal Circuit's decision discussed at length many interesting issues, but *not* among them was the *general* question of whether the burden of proof on invalidity of a patent claim should be clear and convincing or the lower, usual civil burden of a preponderance of the evidence. The Federal Circuit has held, consistently and throughout its 28-year history, that the burden is clear and convincing and is not lowered, as such, regardless of whether the allegedly invalidating evidence had been considered by the Patent and Trademark Office (PTO) in deciding to issue the patent. E.g., *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983). See CHISUM ON PATENTS § 5.06[2][c], § 5.06[2][d][iii]. The Federal Circuit has said that a validity challenger may more easily carry its burden based on prior art or other information not before the PTO. E.g., *SIBIA*

Neurosciences, Inc. v. Cadus Pharmaceutical Corp., 225 F.3d 1349, 1355–56 (Fed. Cir. 2000).

4.2.1 Effect of *KSR* (2007). In *i4i Limited Partnership*, the adjudicated infringer, Microsoft, argued that the burden should be less "for prior art that was not before the PTO," citing the Supreme Court's 2007 *KSR* decision on obviousness.

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007), the Court held that a patent's claim 4 was invalid as obvious in view of an Asano prior art reference and other references. The Court noted that it "need not reach the question whether the failure to disclose [a pertinent prior art reference] Asano during the prosecution of [the patent in suit] avoids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption." Yet, the Court thought "it appropriate to note that the rationale underlying the presumption–that the PTO, in its expertise, has approved the claim–seems much diminished here."

In *i4i*, the Federal Circuit noted that it had already rejected the argument based on *KSR*.

> "This court's decisions in *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1311-16 (Fed. Cir. 2009), and *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008), make clear that the Supreme Court's decision in *KSR International Co. v.*

Teleflex Inc., 550 U.S. 398, 426 (2007) did not change the burden of proving invalidity by clear and convincing evidence.

4.2.2. Inventors' Prior Sales of Software; Did the Software Contain the Patented Invention? Uncorroborated Testimony by Inventors. Whatever the merits of the general rule requiring clear and convincing evidence, the particular validity issue in *Micro-i4i* was a particularly attractive one for easing the burden on a validity challenger.

The patent in question concerned software. The inventors named in the patent in suit had sold a software program more than year before applying for the patent. The program was directed to similar functionality. Sales of the program would invalidate the patent claims for anticipation if, but only if, the program had a particular feature (a "metacode map"), which the later patent claims required. Direct evidence of what the software contained was missing because the "source code" had been lost before the infringement suit was filed. At trial to a jury, the inventors testified that the sold program lacked the metacode map feature. The patent owner's own expert testified that it was "impossible to know" whether the program contained the feature. Based on the court's instructions, which required the accused infringer Microsoft to prove invalidity by clear and convincing evidence, the jury found the patent claims not invalid.

On appeal, the Federal Circuit upheld the verdict.

Notably, in patent law, it is well-settled that an inventor's testimony that she or he previously invented something as of a particular date must be corroborated. In *i4i*, the Federal Circuit rejected the accused infringer Microsoft's argument that similar corroboration should be required for inventors' testimony about their alleged, in other word.

> "We know of no corroboration requirement for inventor testimony asserted to defend against a finding of invalidity by pointing to deficiencies in the prior art. Accordingly, we hold that corroboration was not required in this instance, where the testimony was offered in response to a claim of anticipation and pertained to whether the prior art practiced the claimed invention."

5.0 Assignment of Rights to Future Inventions

5.1 *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*; Pending Supreme Court Review. The Supreme Court granted review in *Board of Trustees of Stanford University v. Roche Molecular Systems, Inc.*, 583 F.3d 832 (Fed. Cir. 2009), *cert. granted*, 131 S. Ct. 502 (2010). The issue presented is:

> "Whether a federal contractor university's statutory right under the Bayh-Dole Act in

inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor's rights to a third party."

5.2 Federal Circuit's Decision; Standing; Assignment Agreements Providing for Present Assignment of Future Inventions: Co-Inventorship and Co-Ownership. Under Federal Circuit case law, an accused infringer may defeat a patent owner's infringement suit by establishing that there is an non-joined party who is, in fact, a co-owner of the patent by virtue of an assignment from a person who was, or should have been named, as a co-inventor. See *Int'l Nutrition Co. v. Horphag Research Ltd*., 257 F.3d 1324, 1331 (Fed. Cir. 2001); *Isr. Bio-Eng'g Project v. Amgen Inc*., 475 F.3d 1256, 1264-65 (Fed. Cir. 2007); *Ethicon, Inc. v. U.S. Surgical Corp*., 135 F.3d 1456, 1467 (Fed. Cir. 1998). The ostensible patent owner is said to lack "standing" to sue for infringement because of a rule that all co-owners of patent must join. Naturally, a co-owner will not join a suit against itself.

Such a nullification by lack of standing occurred in *Stanford v. Roche*. A complicating factor in *Stanford v. Roche* is the question whether state or federal law governs assignments. Generally state law does. However, federal patent law may govern the question of the effect of a state law agreement on standing. Further, in *Stanford*, the

ostensible patent owner, Stanford University, claimed that federal law governed the particular assignment question, to wit, the Bayh-Dole Act, which applies to university ownership of inventions arising from research funded by the United States government.

5.3 Facts and Holding. The complex facts and holding can be summarized (not so briefly) as follows.

The three patents at issue concerned use of polymerase chain reaction (PCR) to measure RNA (ribonucleic acid) from HIV (human immunodeficiency virus) and assess antiretroviral drug effectiveness. The patents named as inventors Stanford University researchers Holodniy, Merigan, Katzenstein and Kozal.

Stanford, as assignee of the patents, sued Roche, alleging infringement of the patents. Roche asserted ownership of the patents as a counterclaim, as an affirmative defense and as a challenge to Stanford's standing to sue. A district court rejected Roche's ownership claims but granted summary judgment that the asserted claims were invalid for obviousness. HELD: Stanford lacked standing and its infringement suit must be dismissed. The chain of title in a series of agreements with one named inventor, Holodniy, showed Roche's co-ownership. In a 1989 agreement with Roche's predecessor (Cetus) Holodniy made a present assignment of future inventions. Cetus thereby obtained equitable title to Holodniy's future inventions immediately and legal title

when the inventions were made. Stanford's assertion of superior ownership rights based on an earlier 1988 agreement failed because Holodniy had merely agreed to assign rights in the future. Stanford's assertion that it was a bona fide subsequent purchaser under 35 U.S.C. Section 261 by virtue Holodniy's later 1995 assignment to Stanford failed because Stanford had constructive notice of the 1989 transfer to Cetus. The four-year California statute of limitations barred Roche's counterclaim for ownership, but, nevertheless, Stanford's lack of ownership deprived it of standing to sue for infringement.

5.3.1. Stanford Research Fellow Consults with Biotech Company; Agreements with Both Stanford and Company. Roche's ownership claim was based on rights it allegedly obtained from co-inventor Holodniy.

In1988, Holodniy began work as a research fellow in co-inventor Merigan's laboratory at Stanford's "Department of Infectious Disease." Holodniy signed Stanford's "Copyright and Patent Agreement" (CPA). In the CPA, Holodniy acknowledged that Stanford entered into contracts and grants and that he "agree[d] to assign or confirm in writing to" Stanford rights in inventions as required by such contracts or grants.

In 1989, as directed by Merigan, Holodniy began regular visits to Cetus, which had developed PCR technology. Holodniy had no prior experience with PCR. Holodniy signed the Cetus "Visitor's Confidentiality

Agreement" (VCA). In the VCA, Holodniy did "hereby assign to" Cetus rights to inventions that he may devise "as a consequence of" his work at Cetus.

Also in 1989, Cetus collaborated with Merigan and Katzenstein on developing a separate HIV treatment. For the collaboration, Stanford and Cetus signed "Materials Transfer Agreements" (MTAs), which gave Stanford access to Cetus PCR-related materials and gave Cetus licenses to technology Stanford created using the materials.

Holodniy's research with Cetus produced a new PCR assay to measure HIV RNA. Holodniy published his findings with Cetus co-authors.

After concluding the Cetus visits, Holodniy continued research at Stanford with Merigan, Katzenstein and others. The researchers tested the new PCR assay and determined that HIV RNA was a drug efficacy "marker."

In 1991, Roche purchased the Cetus PCR business.

5.3.2. Stanford Patent; Bay-Dole Act. In 1992, Stanford filed a patent application based on the Holodniy, Merigan, Katzenstein work. The application led to the three patents: '730 in 1999, '705 in 2003, and '041 in 2006.

Because Stanford had received funding for the HIV work from the National Institutes of Health (NIH), its patent application was subject to the Bayh-Dole Act. 35 U.S.C. §§ 200-212. In 1992, Stanford filed an invention

disclosure with the NIH. In 1994, Stanford confirmed that the United States had a "nonexclusive, nontransferable, irrevocable, paid-up license" in the application. In 1995, Stanford elected to retain title to the inventions disclosed in the application.

5.3.3. Roche Refuses License; Infringement Suit. On April 6, 2000, a Stanford licensing associate made a presentation at Roche that asserted ownership of the HIV RNA assay drug efficacy invention and offered Roche an exclusive license.

On October 14, 2005, Stanford sued Roche for infringement in the Northern California district court.

On cross-motions for summary judgment, the district court ruled that Roche's ownership claims were barred by California statutes of limitation, laches, and the Bayh-Dole Act.

The Federal Circuit denied Roche's petition for a writ of mandamus on the ownership issue. *In re Roche Molecular Sys., Inc*., 516 F.3d 1003 (Fed. Cir. 2008).

After construing the claims, the district court granted summary judgment that the asserted claims were invalid for obviousness.

5.3.4. Lack of Standing; Error to Strike Defense; Laches and Statute of Limitations. On appeal, the Federal Circuit held that the district court erred by striking Roche's affirmative defense based on Stanford's lack of standing.

It noted that a defendant may plead ownership as both an affirmative defense and counterclaim. Rule 8(d)(2) allows parties to make alternative and hypothetical claims and defenses. A defense may be asserted even though it is based on matter that would be barred by the statute of limitations or laches if the matter were asserted as a basis for affirmative relief. It noted that "questions of standing can be raised at any time and are not foreclosed by, or subject to, statutes of limitation. *See Pandrol USA, LP v. Airboss Ry. Prods*., 320 F.3d 1354, 1367 (Fed. Cir. 2003)."

5.3.5 Chain of Title; Prior Stanford Agreement: Agreement to Assign Future Invention; Later Cetus Agreement: Present Assignment of Future Inventions. The chain of title of the co-inventor Holodniy's patent rights led to the accused infringer Roche and left Stanford "with defective title to the rights of all the inventors."

Federal Circuit law governs the question whether a patent assignment contract is "a present assignment of patent rights" or "an agreement to assign rights in the future." *DDB Techs., L.L.C. v. MLB Advanced Media, L.P*., 517 F.3d 1284, 1290 (Fed. Cir. 2008).

The 1988 CPA agreement by co-inventor Holodniy with Stanford was merely an agreement to assign, "not an immediate transfer of expectant interests." See *IpVenture, Inc. v. Prostar Computer, Inc*., 503 F.3d 1324, 1327 (Fed.

Cir. 2007). The agreement used the words "I agree to assign ...." That the agreement was only one to assign in the future was confirmed by Stanford's policies on patent rights, which was to allow patents rights to remain with an employee-inventor "if possible."

The 1989 VCA agreement by co-inventor Holodniy with Roche's predecessor Cetus was a present assignment of future inventions. See *Speedplay, Inc. v. Bebop, Inc*., 211 F.3d 1245, 1253 (Fed. Cir. 2000); *FilmTec Corp. v. Allied-Signal, Inc*., 939 F.2d 1568, 1572-73 (Fed. Cir. 1991). It used the words "do hereby assign." Under the VCA, Cetus immediately gained equitable title to Holodniy's future inventions. It gained legal title when the inventions were made, in this instance no later than the patent application filing date in 2005. Cetus did not need to take further action to transfer title because the transfer occurred by operation of law.

Stanford's arguments that the invention in the patent application was not covered by the VCA because it was not the "consequence" of Holodniy's work at Cetus lacked merit. The undisputed evidence showed that Holodniy took information and material from Cetus and used them to the develop the PCR assay for HIV RNA. Holodniy may have conceived and reduced to practice the invention after departing Cetus, but "his research was directly related to the collaboration with Cetus."

5.3.6. No Bona Fide Purchaser Defense;

Stanford on Constructive Notice of Cetus' Rights. Relying on 35 U.S.C. Section 261, Stanford claimed that it was a "bona fide purchaser" of the patent rights by virtue of Holodniy's1995 assignment to Stanford. The argument lacked merit because the bona fide purchase defense applies only when one purchases the patent in good faith and without notice. Notice includes "constructive or inquiry notice." Stanford was charged with notice of its employee Holodniy's assignment, which the employee made in the course of his employment.

5.3.7. Bayh-Dole Act. The Bayh-Dole Act "did not automatically void the patent rights that Cetus received from Holodniy." Stanford could claim "whatever rights were still available to it after the Government declined to exercise its option, including the rights of co-inventors Merigan, Katzenstein, and Kozal." Holodniy transferred his rights to Cetus long before Stanford elected to retain title.

6.0 Inequitable Conduct.

6.1 En Banc Review in *Therasense v. Becton*. On April 26, 2010, the Federal Circuit granted rehearing en banc in a case in which a patent had been held unenforceable for inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co*., 593 F.3d 1289 (Fed. Cir. 2010), *vacated and rehearing en banc granted*, 374 Fed. Appx. 35, 2010 U.S. App. LEXIS 9549 (Fed. Cir. 2010).

The court requested the parties to "file new briefs addressing the following issues:

> "1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
>
> "2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.,* 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). If so, what is the appropriate standard for fraud or unclean hands?
>
> "3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
>
> "4. Under what circumstances is it proper to infer intent from materiality? *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).

"5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

"6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context."

6.2. Reason for Comprehensive Review; Healing a Schism on Inferring Intent to Deceive; **2010 Inequitable Conduct Cases**. The court's call for briefs suggested that it intends to review comprehensively the law of inequitable conduct. The court did not state why, but a review of the 2010 Federal Circuit decisions, decided both before and after the April grant of en banc review and dealing with inequitable conduct, gives a strong indication of the reason why: the judges are deeply divided about issues on inequitable conduct, in particular on when the required intent to deceive may be inferred.

On the "schism": several of the Federal Circuit judges have aligned themselves with one or the other of two "schools" on inferring intent. Oversimplified, the "restricted inference" school leans to the view that intent can rarely be inferred and certainly not from materiality alone. Judge Linn, who dissented to the *Therasense* panel finding inequitable conduct, belongs to this school. See, for example, Judge Linn's opinion in *Lazare Kaplan International, Inc. v. Photoscribe Technologies, Inc*., 628 F.3d 1359 (Fed. Cir. 2010). See also Judge Lourie's

opinion in *Cancer Research Technology Ltd. v. Barr Laboratories, Inc.*, 625 F.3d 724 (Fed. Cir. 2010) and Judge Newman's opinion in *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313 (Fed. Cir. 2010). Cf. Judge Moore's opinion in *Ring Plus, Inc. v. Cingular Wireless Corp.*, 614 F.3d 1354, 2010 U.S. App. LEXIS 16296 (Fed. Cir. 2010).

The "permissible inference" holds that an inference is permissible (though not required) when the charging party establishes that a person knew of a "highly material" reference and of its materiality and provides no credible explanation for nondisclosure. Judge Prost showed adherence to this school, dissenting in *Cancer Research* concurring in *Optium*, and dissenting (and advocating summary judgment finding intent) in *Leviton Mfg. Co., Inc. v. Universal Security Instruments, Inc.*, 606 F.3d 1353 (Fed. Cir. 2010). See also Judge Mayer's opinion in *Taltech Ltd. v. Esquel Enterprises Ltd.*, 604 F.3d 1324 (Fed. Cir. 2010). Cf. Judge Dyk's opinion in *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, 614 F.3d 1367 (Fed. Cir. 2010).

Both schools acknowledge the dictate of *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008): "[T]he inference [of intent to deceive] must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn

from the evidence to meet the clear and convincing standard.' "

In *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817 (Fed. Cir. 2010), Chief Judge Rader, in a concurring opinion, urged that "absent extreme facts such as those found in the present case, this court should refrain from resolving inequitable conduct cases until it addresses the issue en banc" until the court spoke en banc in *Therasense*.

> "In *Therasense* this court has been asked to address the transformation of inequitable conduct from the rare exceptional cases of egregious fraud that results in the grant of a patent that would not otherwise issue to a rather automatic assertion in every infringement case. The exception has become the rule. Generally, I would hold inequitable conduct cases until after this court reexamines whether to put the doctrine back into the exception category."

6.3 Who Owes a Duty? Who Is "Substantively Involved" in Preparing or Prosecuting a Patent? *Avid Identification*. Who owes a duty of candor to the PTO such that a breach of the duty jeopardizes a patent's enforceability? PTO Rule 56(c) refers to an "individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor or assignee."

In *Avid Identification Systems, Inc. v. Crystal Import Corp.,* 603 F.3d 967 (Fed. Cir. 2010), the Federal Circuit applied Rule 56(c), holding that an individual, Stoddard, was "substantively involved" in patent's preparation and prosecution even though he was not a named inventor. He was the founder of the company to whom the patent was assigned. Stoddard breached the duty by withholding, with a specific intent to deceive the PTO, information on a demonstration at a trade show of a precursor of the patented product. The precursor was the closest prior art and, therefore, highly material to patentability even though a jury later found the patent's claims not invalid.

6.3.1 Evidence of Substantive Involvement. In *Avid*, the patent at issue concerned a radio frequency identification system that used implanted biocompatible chips to assist in the location of owners of lost pets. Stoddard founded the patent owner as a company to carry out his personal mission of developing and marketing an identification system. He hired the named inventors to reduce his idea to practice. He "did not contribute enough to the patentable features of the claims to be considered an inventor," but "the functionality of the system described in the '326 patent was his idea."

The district court found Stoddard was involved in "all aspects of the company's operation," including marketing and research and development. That involvement contributed to a "reasonable inference" that Stoddard was

involved in the preparation of the patent application, which concerned his "personal mission."

Two communications contributed to an inference of Stoddard's substantive involvement in "patent matters related to the identification chip system." First, Stoddard was one of two recipients of a communication by a named inventor that contained the content of a European application corresponding to the United States patent application for the patent at issue. Second, the named inventor sent a note to Stoddard, advising him to check with the company's European patent attorney before demonstrating technology that might affect patent rights in Europe.

The district court found that Stoddard's trial testimony was "suspiciously selective" and not credible. Stoddard's lack of credibility cast doubt on his assertion that he did not understand the technology of the patented invention and was not involved in the preparation of the application.

Stoddard "was personally responsible for the disputed prior art demonstrations."

Stoddard executed the small entity status affidavit for the application.

6.3.2 Intentional Deception by Types of Persons Most Likely to Have Knowledge of Section 102(b) Prior Art: Those on Commercial Side of Patented Product Development. The court noted that, to hold that "a person such as Dr. Stoddard owes no duty of

candor would allow intentional deception by the types of people most likely to have knowledge of § 102(b) prior art, i.e., those on the commercial side of patented product development."

6.3.3. No Automatic Extension of Candor Duty to Person Contacting One Inventor or Signing a Small-Entity Affidavit. The court cautioned that its "holding does not automatically extend the duty of candor to all individuals who contact one of the inventors or sign the small entity affidavit." "Nor does our holding extend the duty generally to all individuals on the commercial side of product development."

> "We simply hold that the district court may properly consider a variety of factors, such as an individual's position within the company, role in developing or marketing the patented idea, contact with the inventors or prosecutors, and representations to the PTO in deciding whether that individual is 'substantively involved' within the meaning of § 1.56(c)(3) and thus owes a duty of candor to the PTO."

Not surprisingly, Judge Linn, of the "restricted inference" school, dissented.

7.0. Obviousness; Refining the Standard After *KSR*; Mixed Messages from the Federal Circuit. Calendar year 2010 saw a large number of cases arising in a variety

of procedural postures: PTO rejections, district court decisions on summary judgment and judgments on jury verdicts. There were about 25 precedential decisions on obviousness and results were mixed.

7.1 Examples. For example, cases finding obviousness included *Western Union Co. v. MoneyGram Payment Systems, Inc.*, 626 F.3d 1361 (Fed. Cir. 24887 (Fed. Cir. 2010) (noting the line of cases holding obvious inventions that merely replace "older electronics" with computer technology), and Judge Paul Michel's last opinion on obviousness before he left the court at the end of May, *Dow Jones & Co., Inc. v. Ablaise Ltd.*, 606 F.3d 1338 (Fed. Cir. 2010) (holding patent claiming dynamically-generated Web pages obvious in view of a specific patent on user-preferred display of the text of faxes and "general knowledge in the field"). See also *Wyers v. Master Lock Co.*, 616 F.3d 1231 (Fed. Cir. 2010) (hitch pin locks securing a trailer to a vehicle; despite jury verdict, obviousness as a matter of law and of "common sense" in view of prior art; secondary considerations were not strong enough).

Cases finding nonobviousness despite close prior art included *Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010) (upholding a patent claiming a pharmaceutically-useful compound); *Spine Solutions, Inc. v. Medtronic Sofamore Danek USA, Inc.*, 620 F.3d 1305, 2010 U.S. App. LEXIS 18818 (Fed. Cir.

2010) (intervertebral implants; upholding jury verdict of nonobviousness even though all claim elements were in several prior art references);

7.2 Assessing *KSR*'s Impact; Chief Judge Rader's Views. Oscillation on obviousness among the Federal Circuit judges is not surprising. In its 2007 decision, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 405 (2007), the Supreme Court reversed a Federal Circuit decision on the obviousness standard of patentability, criticizing the lower court's rigid application of a teaching, suggestion or motivation (TSM) requirement.

Does *KSR International* substantially raise the bar for patentability? Or does it merely rein in an excessively technical requirement that shielded from rejection or invalidation patent claims to obvious modifications and combinations of prior art teachings?

Chief Judge Rader has subscribed to the view that *KSR* should be cabined and regarded as primarily altering aberrational holdings by the Federal Circuit involving "rigid" applications of the TSM rest and as adopting different language for discussing obviousness issues. For an early post-*KSR* Rader opinion, see *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). Rader opinions in 2010 reflect this view. For example, in *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 2010 U.S. App. LEXIS 18236 (Fed. Cir. 2010), the court upheld a group of patents covering therapeutic use of the drug Evista® in the face of

"close" prior art, which included the active ingredient compound itself. Prior tests of the ingredient showed concerns with its bioavailability. In language intermixing pre-*KSR* TSM words and *KSR* terminology, Chief Judge Rader noted that an accused infringer had pointed to no evidence from before the time of invention that would teach, suggest, motivate or supply any common sense reason for a person of ordinary skill in the art to reject the bioavailability concerns and routinely, simply, or easily arrive at the inventive result.

Chief Judge Rader applied this view to "low tech" inventions as well. *E.g., Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010). In *Media Technologies Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334 (Fed. Cir. 2010), two patents concerned a "memorabilia" sports trading card with an actual piece of an item in combination with a photograph of the famous figure depicted on the card. The majority, per Judge Mayer, held that a district court correctly granted accused infringers summary judgment that the patent claims were invalid as obvious in view of four prior art products, which were not sports-related items. The infringers met their burden of showing that "it would have been obvious to one skilled in the art to attach a piece of a sports-related item instead of those items attached in the prior art references."

The four products were (i) a trading card with a

celebrity (Marilyn Monroe) and an entire related item (a diamond), and (ii) three other nontrading-card celebrity items with pieces of memorabilia (authentic and nonauthentic) attached. The accused infringers presented evidence that trading card designers routinely looked to "other card industries" and could well have "sought, considered, and acted on" the four items "to develop 'crossover applications' for trading cards." The patent owner posed two responses. It argued that a skilled person would not have combined the references or applied them to sports cards because of "an inability to predict that a trading card would convey memorabilia authenticity." The argument lacked merit. Consumer acceptance came from the established trading card industry's credibility. The patent owner argued that "the trading card field contain[ed] an infinite number of identified and unpredictable solutions." The argument lacked merit. The patent claims concerned "content." "Content solutions are significantly limited by the theme and physical confines of the card, and the finite number of available solutions were predictable."

The patent owner's reliance on "secondary objective evidence" was not persuasive. The patent owner's argument for "long-felt but unsolved need" to stimulate demand was not persuasive. The patent owner offered erroneous and inconsistent definitions of "need" (stimulate demand generally) and "success" (stimulate demand only

as did accused infringing cards, not as did successful prior art nonmemorabilia cards). The patent owner's expert stated that he and other commentators originally and erroneously predicted that memorabilia cards would be "a short lived phenomenon." The record did not support the statement. Also, that critics decried the destruction of "valuable sports memorabilia" did not show that the trading card-memorabilia concept would fail. The patent owner established that the accused infringer's products were successful but did not establish a nexus between the claimed invention and the success. The accused infringers presented evidence that their cards entailed innovative manufacturing techniques and packaging that were essential to success but unrelated to the patented invention. The patent owner offered no response. Finally, the patent owner argued that an ordinarily-skilled person would not have expected the patented trading card's commercial success. This was merely a recycling of the groundless commercial success argument. Unexpected success, which "must arise from combining prior art elements," is distinct from commercial success.

Judge Rader dissented, arguing that the majority "substitutes its judgment on patentability for that of a jury" by "[r]elying on wholly irrelevant prior art and ignoring significant objective indicia of non-obviousness." The majority displays "a bias against non-technical arts."

An interesting Rader opinion in which patent claims

were held *not* valid is *Geo M. Martin Co. v. Alliance Mach. Sys. Int'l, LLC*, 618 F.3d 1294 (Fed. Cir. 2010). The decision relied, in part, on the near-simultaneous invention of another. Said Judge Rader:

> "Independently made, simultaneous inventions, made 'within a comparatively short space of time,' are persuasive evidence that the claimed apparatus 'was the product only of ordinary mechanical or engineering skill.' *Concrete Appliances Co. v. Gomery*, 269 U.S. 177, 184, 46 S. Ct. 42, 70 L. Ed. 222, 1926 Dec. Comm'r Pat. 284 (1925). *But see Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984) ('Because the statute, 35 U.S.C. § 135, (establishing and governing interference practice) recognizes the possibility of near simultaneous invention by two or more equally talented inventors working independently, that occurrence may or may not be an indication of obviousness when considered in light of all the circumstances.')."

7.3. Claim Construction and Validity. Claim construction is always a significant topic every year in Federal Circuit case law, and 2010 was no exception. E.g., *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010); *In re Suitco Surface, Inc.*, 603 F.3d 1255, 2010 U.S. App. LEXIS 7620 (Fed. Cir. 2010); *Trading Techs.*

Int'l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 2010 U.S. App. LEXIS 3914 (Fed. Cir. 2010).

Claim scope is critical in assessing infringement, but it is also central to determining validity. A recurring issue is whether a court should give a narrow interpretation to rescue a claim. The Federal Circuit's germinal claim construction decision, *Phillips v. AWH Corp*., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc), downplayed the traditional maxim that claims should be construed to upheld their validity.

Nevertheless, on occasion, decisions implicitly rely on the maxim. An example in which the court appeared to so, and also, arguably, read limitations into a claim from the specification, is *AstraZeneca LP v. Apotex, Inc.*, 2010 U.S. App. LEXIS 22660, 97 USPQ2d 1029 (Fed. Cir. 2010), twice discussed above. As noted, the claims recited a method of treatment for lung conditions by a once-daily administration of a "budesonide composition" or "budesonide." A prior art patent showed once-daily administration of budesonide for the same treatment, the budesonide being "entrapped" in liposomes. In granting a preliminary injunction against infringement of the patent's method claims, a district court construed "budesonide composition" and "budesonide suspension" as limited to budesonide in direct contact with a solvent. Based on that construction, the district court found that the patent owner would likely succeed in refuting the accused infringer's

invalidity defense based on the prior patent.

On appeal, a majority of a Federal Circuit panel affirmed. The majority noted that the patents' specification consistently described the budesonide compositions as suspended in a solvent. The specification did mention the use of liposomes, but the limiting construction did not exclude those embodiments. The construction only excluded budesonide in liposomes as described in the prior art patent ('528). In that patent, the liposomes separated the budesonide from the solvents. In the specification of the patent in suit, the liposomes were either excipients or encapsulated the budesonide in a solution or suspension in contact with the solvent.

The majority held that, in construing the claims as limited to budesonide in direct contact with the solvent, the district court correctly relied on the testimony of the patent owner's expert on how the invention worked. The expert testified that a "depot effect" made the claimed invention effective for once daily administration and that the depot effect required that the budesonide be in direct contact with the solution.

Judge Bryson dissented, arguing that the accused infringer had "raised a substantial question of invalidity" that rendered improper a preliminary injunction

In response, the majority disagreed with Judge Bryson's reliance on the patent specification, which stated that the "*proposed mechanism of action is exemplary; the*

invention is not limited by any particular mechanism of action." The majority noted that the specification disclosed no "mechanism" other than the depot effect. A court views with skepticism a proposed broad construction of a claim that would render the claimed invention inoperable. See *Talbert Fuel Sys. Patents Co. v. Unocal Corp*., 275 F.3d 1371, 1376 (Fed. Cir. 2002), *vacated and remanded on other grounds*, 537 U.S. 802 (2002).

To be contrasted with *AstraZeneca*'s emphasis on avoiding a construction that would render a claimed invention inoperable is *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776 (Fed. Cir. 2010), in which Judge Lourie brushed aside an argument that a construction apparently dictated by a claim's plain language would "yield an absurdity."

> "[W]e do not redraft claims to contradict their plain language in order to avoid a nonsensical result. *See, e.g., Elekta Instrument*, 214 F.3d at 1309. *Cf. Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp*., 587 F.3d 1339, 1348 (Fed. Cir. 2009) (holding that construing 'soluble calcium sulfate *anhydride*' to mean 'soluble *anhydrous* calcium sulfate' did not rewrite the claim but 'merely restate[d] its plain meaning' in light of the specification and the knowledge in the art)."