The Sedona Conference Journal

Volume 13 2012

The Past Year in Review: Supreme Court & Federal Circuit Case Law Update

James W. Morando & Julie Wahlstrand

Recommended Citation: James W. Morando & Julie Wahlstrand, *The Past Year in Review: Supreme Court & Federal Circuit Case Law Update,* 13 SEDONA CONF. J. 1 (2012).

For this and additional publications see:
https://thesedonaconference.org/publications

THE PAST YEAR IN REVIEW: SUPREME COURT & FEDERAL CIRCUIT CASE LAW UPDATE

James W. Morando & Julie Wahlstrand
Farella Braun + Martel, LLP
San Francisco, CA

I. THE SUPREME COURT IN AGREEMENT WITH THE FEDERAL CIRCUIT.[1]

Over the last several years, it has been realistic to assume that the Supreme Court's granting of *certiorari* in a patent case was the precursor to its reversing the Federal Circuit to correct what it sees as the Federal Circuit's error or misdirection. Many expected this year to be more of the same, and were surprised to see the Supreme Court upholding the Federal Circuit on multiple issues of patent law. Also of note, in departure from many other of the Supreme Court's recent patent decisions (*eBay* and *KSR*, to name a couple), the Supreme Court's patent decisions this term tended to lean in favor of affirming patent holders' rights. With both of these trends seemingly in direct contravention of past wisdom regarding the relationship between the Supreme Court and Federal Circuit, we are left wondering what surprises the Supreme Court has in store for us next term and, as always, we are also left grappling with how to apply the Supreme Court's latest rulings going forward.

We review the Supreme Court's decisions in patent cases since last year's The Sedona Conference®, along with their implications and the questions they raise, below:

A. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (decided June 09, 2011)

In an 8-0 decision, with an opinion authored by Justice Sotomayor, the Supreme Court affirmed that invalidity must be established by clear and convincing evidence, based on the presumption of validity written into the Patent Act, putting an end to thoughts that that the Court might lower the evidentiary standard for invalidity to combat issuance of what some argue are so many "bad" patents by the PTO. The decision, while perhaps not unexpected, is notable because both the Court's affirmance of the Federal Circuit and the decision's favoring of patent holders' rights were a departure from the trend of recent years.

The questions the decision left open, however, are fuel for discussion. Under the facts in *i4i*, the jury was presented with evidence regarding a prior art reference that was not before the Patent Office in any way (forming the basis for the argument that the presumption of validity should not apply in the case). After affirming the presumption, Justice Sotomayor suggested that, if prior art before the jury for consideration was not

1 This section does not address Supreme Court decisions regarding patentable subject matter, which are addressed separately below.

before the PTO, the jury should be so instructed. Thus, it seems that while the Court upheld the presumption, it may under certain facts recommend that the presumption be diluted by allowing the jury to consider the extent to which a reference was considered by the PTO. Because Microsoft had not requested such an instruction below, however, the Court addressed this only in *dicta*. Going forward, courts will need to wrestle with whether, and how, to apply this suggestion:

> Simply put, if the PTO did not have all material facts before it, its considered judgment may lose significant force. *Cf. KSR*, 550 U.S. at 427. And, concomitantly, the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain. In this respect, although we have no occasion to endorse any particular formulation, we note that a jury instruction on the effect of new evidence can, and when requested, most often should be given. When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent. When it is disputed whether the evidence presented to the jury differs from that evaluated by the PTO, the jury may be instructed to consider that question. In either case, the jury may be instructed to evaluate whether the evidence before it is materially new, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence. *Cf., e.g.*, *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1563-1564 (C.A. Fed. 1993); *see also* Brief for International Business Machines Corp. as Amicus Curiae 31-37. Although Microsoft emphasized in its argument to the jury that S4 was never considered by the PTO, it failed to request an instruction along these lines from the District Court. Now, in its reply brief in this Court, Microsoft insists that an instruction of this kind was warranted. Reply Brief for Petitioner 22-23. That argument, however, comes far too late, and we therefore refuse to consider it. *See Rent-A-Center, West, Inc. v. Jackson*, 561 U.S. ___ , ___ (2010) (slip op., at 12); *cf.* Fed. Rule Civ. Proc. 51(d)(1)(B).

Microsoft Corp. v. i4i Ltd. Partnership, 131 S. Ct. at 2251.

Determining just when such an instruction is warranted, and when the PTO had "no opportunity" to evaluate the reference before granting the patent, may prove a difficult task. As the Court itself noted in Footnote 10 of its opinion regarding the impracticality of "drop[ping] the heightened standard of proof where the evidence before the jury varied from that before the PTO," it is difficult to determine where to draw the line regarding what was "considered" by the PTO, as there is an entire spectrum of levels of consideration by the PTO. Although this footnote is regarding the standard of proof, it would seem to apply equally to the jury instruction issue:

> Not the least of the impracticalities of such an approach arises from the fact that whether a PTO examiner considered a particular reference will often be a question without a clear answer. In granting a patent, an examiner is under no duty to cite every reference he considers. We see no indication in §282 that Congress meant to require collateral litigation on such an inherently uncertain question.

Id. at 2250, n. 10 (citations omitted).

Indeed, the IBM amicus brief cited by Justice Sotomayor suggests giving jury instructions, but highlights the complicated nature of this task by noting four different situations along the spectrum of "consideration" by the PTO. The amicus brief proposes four different limiting instructions for the distinct example situations: (1) where the reference at trial was never presented to the PTO; (2) where more information was presented at trial than was before the examiner regarding a reference; (3) where the examiner was generally aware of a reference but did not explicitly note it in the file of the patent-in-suit; and (4) where there is a concurrent reexamination proceeding where the examiner has issued a non-final rejection based on the reference. It seems that a fifth situation is where the applicant or examiner has cited a prior art reference among a long list, but where the file history does not evidence that the examiner explicitly addressed or discussed that reference.

Which of these scenarios warrants an instruction and what should its content be? How will courts implement this suggestion moving forward? Where is the correct line for determining which prior art was before the PTO and which prior art was not before the PTO, warranting an instruction? Would the instruction also be appropriate if the prior art reference was part of a long list of references of which the PTO had constructive knowledge, but was not explicitly discussed or considered by the PTO? Does the fourth jury instruction proposed by IBM invite potential for unfair prejudice by allowing the jury to consider a non-final reexamination proceeding?

Additionally, how would instructing the jury regarding which art was not before the PTO square with precedent stating that courts and juries should not look behind proceedings at the patent office outside of the contexts of inequitable conduct or prosecution history estoppel? For example, how would jury instructions as Justice Sotomayor suggests reconcile with the Federal Circuit's holding in *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004), where the Court found that it was error for the district court to instruct the jury that "[ ]in determining whether Stryker ha[d] carried that burden [to overcome the presumption of validity by clear and convincing evidence] in this case, you may consider the proceedings before the examiner and the extent to which and the manner in which the prior art was considered by or before the examiner"?

It remains to be seen the extent to which and in what manner trial courts will follow Justice Sotomayor's suggestion. It will be difficult to apply this open suggestion uniformly, however, and the gray area will need to be sorted out in future opinions.

B. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (decided May 31, 2011)

In an 8-1 ruling, the Supreme Court examined the intent standard for inducement and affirmed the ruling by the Federal Circuit, which found that Global-Tech infringed by inducement.

The high Court ruled that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement, and applied a more stringent intent standard than the Federal Circuit, requiring "willful blindness" to satisfy this element in the absence of actual knowledge, and finding that "deliberate indifference," the standard applied by the Federal Circuit, was insufficient to support a finding of inducement. The Supreme Court agreed with the Federal Circuit, however, on a larger point: that a state of mind short of actual knowledge would suffice. Thus, the Court's finding of inducement in the absence of actual knowledge on balance appears to lean in favor of patent holders.

In *Global-Tech* the Court was faced with a question of statutory interpretation, determining what state of mind is required to find liability under Act § 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer."), and in particular whether induced infringement can be "active" if the defendant does not know of the particular patent. The main question presented was whether deliberate indifference was enough for inducement liability. The Court sought to require a state of mind far enough along the intent spectrum to protect innocent actors, while at the same time punishing culpable conduct. The Court settled upon "willful blindness," a standard imported from criminal law and analogizing to criminal statutes – "defendants cannot escape the reach of these [criminal] statutes by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances…." The Court then fleshed out the standard with two requirements: (1) that the defendant must subjectively believe that there is a high probability that a fact exists, and (2) that the defendant must take deliberate actions to avoid learning that fact, stating, "these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence."

One striking thing about this opinion is that the most critical portion appears to be the first three pages – the facts. The Court seemed driven to reach the same result as the Federal Circuit based on what it found to be egregious facts, the highlights being: (1) plaintiff SEB invented a design for a deep fryer, and obtained a U.S. patent for that design, selling practicing products in the U.S.; (2) Sunbeam Products, Inc., asked a wholly owned Hong Kong subsidiary of Global-Tech Appliances, Inc. to supply it with deep fryers to meet certain specifications; (3) the Global-Tech subsidiary purchased an SEB fryer made for sale in a foreign market (lacking U.S. patent markings) and copied everything except its cosmetic features; and (4) retained an attorney to conduct a right-to-use study without telling the attorney that it had copied SEB's design. The fourth fact, failure to tell its patent attorney that it had reverse-engineered a particular product from a particular source, especially stuck in Court's mind: "[W]e cannot fathom what motive [Global Tech's representative] could have had for withholding this information other than to manufacture a claim of plausible deniability in the event that his company was later accused of patent infringement."

The facts were so strong here in the Court's mind, that it found the evidence sufficient to find inducement under the newly minted "willful blindness" standard, affirming rather than remanding, even though the jury was not instructed on this standard, and this standard was not put forth at any stage in the litigation. The evidence cited as constituting willful blindness is: defendants' decision to copy reflected belief that SEB's fryer embodied technology that would be valuable in the U.S. market (although the implicit assumption here that valuable aspects are necessarily patented seems suspect), defendants' decision to copy a foreign model knowing it would not be marked with U.S. patent numbers, and, of course, defendants' decision not to tell its attorney that the product the attorney was asked to evaluate was based off of another company's fryer. Whether this rather circumstantial evidence truly establishes that Global-Tech subjectively believed that there was a high probability that the aspects of the fryer it copied were protected by valid patents is a matter of opinion.

Questions are left with from the *Global-Tech* decision include: How confined is the holding to the unique facts of the case? What other fact patterns satisfy the "willful blindness" standard? Given the facts of the case, might companies going forward be less likely to obtain opinions of counsel? Might companies also be incentivized not to look at competitors' patents and to remain ignorant of any potential infringement? Additionally, given the heightened intent standard (imported from criminal law no less), will a finding of

inducement by "willful blindness" also necessarily, *ipso facto* establish the requisite intent for willful infringement? Put differently, if an accused infringer is found to have been "willfully blind," can they avoid willful infringement? How would an accused infringer defend against an allegation of willful infringement after having been found to meet the "willful blindness" standard?

C. *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 131 S. Ct. 2188 (decided June 06, 2011)

In a 7-2 decision that is a combination of statutory interpretation and contract law, the Court affirmed the Federal Circuit and determined that patent ownership rights do not automatically vest in universities under the Bayh-Dole Act when the underlying research was federally funded. This is in keeping with the precedent in U.S. patent law that rights to an invention can be obtained only through assignment by the inventor. Chief Justice Roberts noted precedent establishing the general rule that "rights to an invention belong to the inventor," and although "an inventor can assign his rights in an invention to a third party," this assignment must be express; thus an employee "must expressly grant his rights in an invention to his employer if the employer is to obtain those rights." Contrary to Stanford's arguments, the Act does not expressly deprive inventors of their interest in federally funded inventions but instead provides that contractors ***may*** elect to retain title to an invention.

Under the facts in *Stanford v. Roche*, the inventor had made an initial agreement with Stanford, which the Court found to be only a promise to assign rights in the future, and thus Roche, to whom the inventor had assigned rights, had a valid ownership interest obtained through assignment by the inventor and could not be sued by Stanford on the patent.

The decision focuses on statutory interpretation, the Supreme Court noting that if Congress had intended to enact what Stanford proposed, it would have said so clearly, not obliquely through an ambiguous definition of "subject invention" and an idiosyncratic use of the word "retain." Moreover, the Court noted that the result of Stanford's proposed construction of the act would have been to allow title to vest in the University even if an inventor had conceived of the invention before becoming a University employee, and federal funds only supported the reduction to practice.

This appears to be a narrow holding, affecting only the presumption that rights are presumed to be the inventor's, not the university's.[2] As with most presumptions, the parties can easily contract around it through technology transfer agreements. The real-world result of the holding is that universities will be certain that their employment contracts with researchers clearly constitute a current, present assignment of all future rights to the university, rather than a promise to assign rights in the future. As the Court noted, however, these assignment contracts are already "common practice."

D. *Kappos v. Hyatt* 132 S. Ct. 1690 (decided Apr. 18, 2012)

In a 9-0 opinion by Justice Thomas (with a concurrence by Justice Sotomayor, joined by Justice Breyer), the Supreme Court once again affirmed the Federal Circuit, holding that there are no limitations on a patent applicant's ability to introduce new

2 Justice Breyer in dissent argued that the majority's opinion disregarded the principle that inventors be denied patent rights on inventions "for which the public has already paid," arguing that this should be the presumption under the Bayh-Dole Act.

evidence in a 35 U.S.C. § 145 proceeding beyond those already present in the Federal Rules of Evidence and the Federal Rules of Civil Procedure. If new evidence is presented on a disputed question of fact, the district court must make *de novo* factual findings that take account of both the new evidence and the administrative record before the Patent and Trademark Office.

An unsuccessful patent applicant has two possible paths available to seek redress. If a patent examiner rejects a patent application, the applicant may first appeal to the Board of Patent Appeals and Interferences (Board) at the U.S. Patent and Trademark Office (PTO). A patent applicant who is dissatisfied with the Board's decision may then appeal the decision by either proceeding in a § 141 action before the Federal Circuit, or in a §145 action (which have thus far been heard by the District Court for the District of Columbia, but following enactment of the America Invents Act will be heard in the Eastern District of Virginia). In a §141 action before the Federal Circuit, the patent applicant is not permitted to introduce new evidence that was not presented to the PTO.

In reviewing the Federal Circuit's *en banc* decision,[3] the Supreme Court addressed two questions presented:

> 1. Whether the plaintiff in a Section 145 action may introduce new evidence that could have been presented to the agency in the first instance.
>
> 2. Whether, when new evidence is introduced under Section 145, the district court may decide *de novo* the factual questions to which the evidence pertains, without giving deference to the prior decision of the PTO.[4]

The Federal Circuit below established new rules for a Section 145 action, reversing long-standing precedent and holding: (1) that a patent applicant is allowed to introduce new evidence in a Section 145 civil action filed to challenge a USPTO refusal to grant patent rights; and (2) that the issues implicated by the new facts must be considered *de novo*, because a Section 145 civil action is not an appeal, but rather a new, separate lawsuit filed to force the PTO to act.

The Supreme Court affirmed on both counts, holding that: (1) in a Section 145 proceeding, the applicant may present new evidence to the district court that was not presented to the PTO, and that there are no evidentiary restrictions on the introduction of such evidence beyond the restrictions already imposed by the Federal Rules of Evidence and the Federal Rules of Civil Procedure; (2) regarding the standard of review that should be applied when considering new evidence, the district court must make a *de novo* finding when the new evidence is presented on a disputed question of fact. In reaching its second holding, the Court reasoned that the district court must act as a factfinder and thus cannot apply a deferential standard:

> The district court must assess the credibility of new witnesses and other evidence, determine how the new evidence comports with the existing administrative record, and decide what weight the new evidence deserves. As a logical matter, the district court can only make these determinations de novo because it is the first tribunal to hear the evidence in question."

3 *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010) (*en banc*)
4 Order Granting Cert. (June 27, 2011).

Kappos v. Hyatt, 132 S. Ct. at 170.

The ruling means that an unsuccessful patent applicant can make a full evidentiary showing in Section 145 proceedings, utilizing the district court's ability to handle all types of evidence that could be introduced at trial, including expert testimony, demonstrations, and fact witness testimony (which the PTO is understandably unable to handle).

There are of course many questions going forward regarding the effect that *Hyatt* will have. Under the Federal Circuit's decision, Section 145 actions will likely be more attractive to patent applicants because they can bring new arguments and evidence to bear in a potentially more receptive forum (the Federal judges of the Eastern District of Virginia). Will the workload of the Eastern District of Virginia increase? If applicants choose § 145 actions instead of a § 141 actions so that they can introduce new evidence, will the Federal Circuit's workload be reduced? Will applicants bypass the slow process at the PTO and opt for Section 145 actions as soon as possible, receiving a final rejection and immediately appealing to the BPAI so that they can reach the Eastern District of Virginia?

Additional questions also remain concerning the impact of the new approach following the completion of Section 145 proceedings. Will a patent that has been issued as a result of a successful §145 action be blessed with more judicial deference as to the validity determinations in infringement litigation than one that had not been so tested? Will applicants be wary of the fact that all evidence presented would build a hefty prosecution record that could later be used to assert prosecution history estoppel?

There may also be inherent dangers in the fact that patent applicants will now be able to put on more and better evidence to the district court than would be possible before the PTO. Justice Thomas addressed this issue, expressing skepticism that this posed any real risk:

> The Director warns that allowing the district court to consider all admissible evidence and to make de novo findings will encourage patent applicants to withhold evidence from the PTO intentionally with the goal of presenting that evidence for the first time to a nonexpert judge. We find that scenario unlikely. An applicant who pursues such a strategy would be intentionally undermining his claims before the PTO on the speculative chance that he will gain some advantage in the § 145 proceeding by presenting new evidence to a district court judge.

Kappos v. Hyatt, 132 S. Ct. at 1700.

The Federal Circuit judges appear to have varying levels of concern as to the likelihood of the danger that applicants will withhold information from the first round before the PTO, saving it to bring before the district court. Judge Newman in concurrence-in-part stated:

> The PTO Solicitor and my colleagues in dissent argue that applicants will deliberately withhold evidence in their possession, in order to spring it on the district court under section 145. I share the view of the *amici curiae* that it is unlikely that applicants will withhold winning evidence from the examiner, in favor of a multi-year and expensive civil action in the district court.

Hyatt v. Kappos, 625 F.3d at 1341 n.1.

In contrast, Judge Dyk joined by Judge Gajarsa in dissent, showed much more concern:

> In my view today's majority decision reflects a remarkable departure from settled principles of administrative law. The majority holds today that a patent applicant may decline to present his evidence supporting a patent application to the Patent and Trademark Office ("PTO"), the expert agency charged by Congress with reviewing patent applications. Instead, he may elect to present that evidence to a district court in a de novo proceeding. As the majority itself states, "We hold that 35 U.S.C. § 145 imposes *no limitation* on an applicant's right to introduce new evidence before the district court, apart from the evidentiary limitations applicable to all civil actions...." Maj. op. at 1323 (emphasis added). Moreover, when the district court considers that new evidence, it owes no deference to the PTO's resolution of the fact issues. Rather, the district court makes de novo findings of fact.

Id. at 1341-42 (emphasis in original).

While perhaps the concern that applicants will actually withhold evidence from the PTO is unfounded, it is certainly true that the district court provides a forum to present additional types of evidence (for example, testimony from lay witnesses and experts) that are not available in the PTO proceedings. Applicants appealing a decision of the Board will have every incentive to present their case through a full evidentiary showing, while also gaining the benefit of a *de novo* standard when new evidence is presented.

The Supreme Court also noted that "[i]n deciding what weight to afford that evidence, the district court may, however, consider whether the applicant had an opportunity to present the evidence to the PTO." "Although we reject the Director's proposal for a stricter evidentiary rule and an elevated standard of review in § 145 proceedings, we agree with the Federal Circuit that the district court may, in its discretion 'consider the proceedings before and findings of the Patent Office in deciding what weight to afford an applicant's newly-admitted evidence.'" It remains to be seen whether this discretion to give less weight to newly presented evidence if the applicant had an opportunity to present the evidence to the PTO will be an exception that undermines the rule allowing presentation of new evidence. However, it may also provide an estoppel-like safeguard, allowing the district court to afford evidence less weight if the applicant had an opportunity to present it to the PTO and chose to withhold it.

Moreover, what is the nature of the opposition that applicants will be met with in Section 145 proceedings? The defendant will be the director of the PTO, represented by the Solicitor's Office, which has limited resources. Although the Solicitor's Office can likely also present new evidence (although this was not expressly addressed by the Federal Circuit), this may have little practical effect given the lack of available resources. Also, might third parties, such as competitors, offer support to the Solicitor's Office in opposing the applicant?

II. THE FEDERAL CIRCUIT WEIGHTS IN, *EN BANC*.

The Federal Circuit has had a very busy past year, which has included a number of significant *en banc* decisions, including:

A. *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869 (Fed. Cir. April 20, 2011) (*en banc*)

In an *en banc* decision authored by Judge Lourie, the Federal Circuit clarified the standard for contempt proceedings, a scenario encountered where after entry of an injunction, the accused infringer comes up with an alleged design-around that the patentee challenges by asserting contempt of the existing injunction. The Federal Circuit overturned the prior three-judge panel decision in *KSM Fastening Systems, Inc. v. H.A. Jones Co., Inc.*, 776 F.2d 1522 (Fed. Cir. 1985), firmly placing the decision whether to conduct a contempt proceeding in the trial court's discretion and also clarifying the standards for a contempt determination.

In the trial in *TiVo v. EchoStar*, the jury determined that the models of EchoStar receivers at issue literally infringed hardware and software claims of TiVo's patent claims relating to DVR technology. The trial court issued an injunction requiring EchoStar to: (1) stop making, using, offering to sell and selling the receivers that had been found to infringe by the jury; and (2) disable the DVR functionality in both existing receivers that had already been placed with EchoStar's customers and in new receivers that were yet to be placed with EchoStar's customers. When TiVo initiated a contempt proceeding, EchoStar argued that it had redesigned its receivers so that specific claim limitations were not met in the redesigned products.

The *en banc* Federal Circuit found that the district court did not abuse its discretion in initiating contempt proceedings. The Court also replaced the previous two-step process for seeking contempt, which required a threshold finding of whether the modified product is colorably different to determine whether a contempt proceeding should be initiated, prior to making a determination of whether contempt occurred. The Court removed the separate threshold step, giving district courts broad discretion in judging whether to hold a contempt proceeding so long as the injured party offers a detailed accusation alleging contempt:

> In recent times, we have required district courts to make a two-part inquiry in finding a defendant in contempt of an injunction in patent infringement cases. First, the court must determine whether a contempt hearing is an appropriate setting in which to adjudge infringement by the redesigned product. The court may do this by comparing the accused product with the adjudged infringing product to determine if there is "more than a colorable difference" between the accused product and the adjudged infringing product such that "substantial open issues with respect to infringement" exist. Where the court finds that to be the case, a new trial is necessary to determine further infringement and the court may not proceed with a contempt finding. Only in cases where the court is satisfied on the threshold inquiry of the appropriateness of a contempt proceeding can a court inquire whether the redesigned product continues to infringe the claims as previously construed. We conclude that KSM's two-step inquiry has been unworkable and now overrule that holding of KSM. KSM crafted a special rule for patent infringement cases, in that it required a threshold inquiry on the propriety of initiating a contempt proceeding. ***We recognize now that inquiry confuses the merits of the contempt with the propriety of initiating contempt proceedings.*** Moreover, as a practical matter, district courts do not separately determine the propriety of a contempt proceeding before proceeding to the merits of the contempt itself. As a result, ***we will telescope the***

> ***current two-fold KSM inquiry into one, eliminating the separate determination whether contempt proceedings were properly initiated. That question, we hold, is left to the broad discretion of the trial court to be answered based on the facts presented***. What is required for a district court to hold a contempt proceeding is a detailed accusation from the injured party setting forth the alleged facts constituting the contempt. As with appeals from findings of civil contempt in other areas of law, we will only review whether the injunction at issue is both enforceable and violated, and whether the sanctions imposed were proper. Allegations that contempt proceedings were improper in the first instance do not state a defense to contempt.

TiVo Inc. v. EchoStar Corp., 646 F.3d at 880-81 (internal citations omitted, emphasis added).

The Court made clear that it would review a trial court's decision to hold contempt proceedings under an abuse of discretion standard. It remains to be seen whether the broader discretion afforded will result in more contempt proceedings, which are arguably more efficient than the patent holder instituting new infringement actions.

The Court then went on to define the "more than colorable differences" test and correct application of it:

> We have previously interpreted that inquiry in patent cases as one of colorable differences between the newly accused product and the adjudged infringing product. Thus, the party seeking to enforce the injunction must prove both that the newly accused product is not more than colorably different from the product found to infringe and that the newly accused product actually infringes. We have stated the test for colorable differences as one that requires determining whether "substantial open issues with respect to infringement to be tried" exist. In some cases, that has misled district courts to focus solely on infringement by the newly accused devices in deciding contempt. That is the case here. Today, we reject that infringement-based understanding of the colorably different test. Instead of focusing solely on infringement, the contempt analysis must focus initially on the differences between the features relied upon to establish infringement and the modified features of the newly accused products. The primary question on contempt should be whether the newly accused product is so different from the product previously found to infringe that it raises "a fair ground of doubt as to the wrongfulness of the defendant's conduct." The analysis must focus not on differences between randomly chosen features of the product found to infringe in the earlier infringement trial and the newly accused product, but on those aspects of the accused product that were previously alleged to be, and were a basis for, the prior finding of infringement, and the modified features of the newly accused product. Specifically, one should focus on those elements of the adjudged infringing products that the patentee previously contended, and proved, satisfy specific limitations of the asserted claims. ***Where one or more of those elements previously found to infringe has been modified, or removed, the court must make an inquiry into whether that modification is significant***. If those differences between the old and new elements are significant, the newly accused product as a whole shall be deemed more than colorably

> different from the adjudged infringing one, and the inquiry into whether the newly accused product actually infringes is irrelevant. Contempt is then inappropriate.

Id. at 882-83.

In this first inquiry of a contempt proceeding, an infringement analysis is now clearly off-limits. Determining the contours of this standard may prove difficult for district courts going forward. For instance, how will courts determine whether there are colorable differences or whether a modification is "significant" without reference to an infringement analysis? That is, it seems difficult not to consider infringement at all in this stage, particularly given that differences between the current product and product previously found to infringe are not truly made in the abstract, but made in the context of whether the differences would matter with respect to the infringement analysis. For instance, knowing whether the change in an element is significant might require looking at the construction of that element below. The Federal Circuit seems to say that is off-limits, however it is unclear whether consideration of the infringement analysis or reasoning of the previous infringement finding is allowed, provided the district court does not undertake an element-by-element infringement analysis at this phase. How courts will truly avoid an infringement analysis in determining whether there are colorable differences will present a challenge going forward.

Additionally, this delineation requiring analysis of the "colorable differences" test prior to the infringement analysis seems to leave open the possibility that, where in the underlying action literal infringement was found, products that may infringe under the doctrine of equivalents could be found to have "colorable differences" and thus not provide the basis for contempt. Of course, a separate action for infringement may be brought, but it is unclear whether these scenarios can fall under the contempt umbrella.

While the district courts are not to undertake an infringement analysis in determining whether there are "colorable differences," the Federal Circuit did import an obviousness analysis into the "colorable differences" test:

> The significance of the differences between the two products is much dependent on the nature of the products at issue. The court must also look to the relevant prior art, if any is available, to determine if the modification merely employs or combines elements already known in the prior art in a manner that would have been obvious to a person of ordinary skill in the art at the time the modification was made. [FN1]
>
> > FN1. We do not suggest that the law on obviousness is binding in contempt proceedings, where, in most cases, a single limitation that has been modified by an infringer is at issue. However, the innovative significance of the modification is best viewed in light of the existing art and from the perspective of one of ordinary skill in the art.
>
> A nonobvious modification may well result in a finding of more than a colorable difference. Where useful, a district court may seek expert testimony in making the determination. The analysis may also take account of the policy that legitimate design-around efforts should always be encouraged as a path to spur further innovation. But an assertion that

> one has permissibly designed around a patent should not be used to mask continued infringement. Determining the requisite level of difference is a question of fact.

Id. at 882-83 & 883 n. 1 (citations omitted).

The inclusion of this obviousness analysis may lead to confusion in determining the significance of a modification, and the potential need for expert analysis may add considerable cost to a contempt proceeding, assuming parties are not limited to prior expert reports. This analysis may impact the patentee's consideration of whether a contempt proceeding is preferable to initiating a new infringement action.

Under the new standard, if the changes are not "significantly different" and there is not "more than a colorable difference" the inquiry ends and there is no infringement analysis. If more than a colorable difference is not found, then courts are to undertake an infringement analysis, based on the previous claim construction, to determine whether the alleged design-around infringes such that contempt is appropriate.

> Conversely, when a court concludes that there are no more than colorable differences between the adjudged infringing product and modified product, a finding that the newly accused product continues to infringe the relevant claims is additionally essential for a violation of an injunction against infringement. Thus, the court is required to evaluate the modified elements of the newly accused product against the asserted claim, on a limitation by limitation basis, to ensure that each limitation continues to be met. In making this infringement evaluation, out of fairness, the district court is bound by any prior claim construction that it had performed in the case. The patentee bears the burden of proving violation of the injunction by clear and convincing evidence, a burden that applies to both infringement and colorable differences.

Id. at 883.

While this infringement determination must be based on the previous construction, it is unclear whether any additional term(s) can be construed at this stage if necessary to determine infringement. Additionally, is the patentee stuck with the infringement analysis applied at trial, or can it apply new theories? For instance, if literal infringement was found, can the patentee assert a doctrine of equivalents theory in this stage of contempt proceedings? Would new expert analysis be needed in this infringement phase of the determination?

The Federal Circuit also addressed EchoStar's arguments that the injunction was vague or unlawfully overbroad. Because these arguments were not brought at the trial stage, EchoStar had waived them and could not bring these arguments alleging lack of clarity in the injunction at the contempt stage. This ruling certainly underscores the need and importance for an enjoined infringer to raise issues of clarification or modification of the injunction at the time of entry of the injunction, as they cannot attempt to raise them for the first time in contempt proceedings.

B. *Therasense, Inc. v. Becton, Dickinson and Company,* 649 F.3d 1276 (Fed. Cir. May 25, 2011) (*en banc*)

The Court in a six-judge majority tightened the standards for inequitable conduct, cracking down on what is described as the "absolute plague" of inequitable conduct allegations in recent years:

> One study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct. Inequitable conduct "has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system." "[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps." Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on "the slenderest grounds," patent prosecutors constantly confront the specter of inequitable conduct charges. With inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value. "Applicants disclose too much prior art for the PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct." "This flood of information strains the agency's examining resources and directly contributes to the backlog." While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.

Therasense, Inc. v. Becton, Dickinson and Co., 2011 WL 2028255 at *8-*9 (citations omitted).

To remedy this plague, the *en banc* Federal Circuit held that evidence of a "deliberate decision" to deceive is required to satisfy the intent element for inequitable conduct, and that when such evidence is circumstantial, intent to deceive must be "the most reasonable inference." Importantly, the majority also held that evidence of "but-for" materiality is required (the party alleging inequitable conduct must establish that "but-for" the misrepresentation or omission, the patent would not have issued). The Court did, however, make one exception to the requirement of but-for materiality in the case of "affirmative egregious misconduct": "Although but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, this court recognizes an exception in cases of affirmative egregious misconduct… . When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material." Further, the Court made clear that intent and materiality are separate requirements, doing away with the "sliding scale" whereby strong evidence of either intent or materiality could theoretically fill in holes as to the other requirement; no longer can a showing of high materiality make up for a lower degree of intent, or vice versa.

It remains to be seen just how significant the impact of *Therasense* will be and the degree to which it will cut down on the "plague" of inequitable conduct claims. It would certainly seem that the *Therasense* holdings, particularly coupled with the pleading requirements set forth in *Exergen*, have the potential for a significant impact.

It will also be interesting to see if *Therasense* will really reduce the "bury[ing] of PTO examiners with a deluge of prior art references." It seems that under the heightened standards, demonstrating that a reference was disclosed would destroy but-for materiality, so that applicants may continue to throw in "everything but the kitchen sink" in deciding which references to disclose to the patent office. Perhaps if the numbers of inequitable conduct allegations are reduced, prosecutors' fear of inequitable conduct will dissipate, but it seems likely that for now over-disclosure may continue, as it appears to provide insulation from inequitable conduct allegations, in addition to serving other purposes. In addition, an open question seems to be whether, in determining but-for materiality, courts will need to examine the reference under the standard applied by the PTO (the broadest reasonable construction).

Once the new provisions providing for supplemental examination procedures under the recently enacted American Invents Act become effective, it would seem that there will now be even further opportunities for disclosures in connection with such proceedings in addition to reexamination proceedings, that should provide the ability to cure potential inequitable conduct issues during prosecution. That is, if the PTO determines that a reference or other information presented in the request for supplemental examination does not raise a "substantial new question of patentability," then the patent cannot be found unenforceable due to any failure to present that information in the first examination, even if the conduct was intentional, provided that there was not "material fraud." However, supplemental examination cannot be used where allegations of inequitable conduct were pled in litigation before the supplemental examination was filed.

III. PATENTABLE SUBJECT MATTER.

Perhaps the most notable trend in patent decisions issuing from the Supreme Court and Federal Circuit this past year was the sheer number of opinions on patentable subject matter in the wake of *In re Bilski*, 130 S. Ct. 3218 (2010). This trend was of the not-so-subtle variety, as patentable subject matter seemed to dominate a large portion of both Courts' attention.

The Federal Circuit's most recent § 101 decisions leading up to The Sedona Conference® left a question mark rather than a period at the end of the patentable-subject-matter sentence, reflecting the fractured views in the Federal Circuit post-*Bilski*. The Supreme Court has now weighed in with its decision in *Mayo Collaborative Services v. Prometheus Labs.*, which will hopefully lend clarity and continuity to the patentable subject matter landscape.

A. *Mayo Collaborative Services v. Prometheus Laboratories.*, 566 U.S. __, 132 S. Ct. 1289 (decided March 20, 2012)

The Supreme Court granted *certiorari* for the second time in *Mayo Collaborative Services v. Prometheus Laboratories*, having already vacated and remanded the case to the Federal Circuit last year for further consideration in light of *Bilski*. The Supreme Court has

now reversed the Federal Circuit's second opinion in this case, issued December 17, 2010.[5] The Court's March 20, 2012 opinion, issued by Justice Breyer, held that the process claimed in Prometheus's patents, described below, is not patent-eligible under § 101.

The patent claims at issue in *Prometheus* are medical method claims directed at administering a drug to treat autoimmune disorders, and determining whether the metabolite level of the drug falls within a range correlated with efficacy but not toxicity. Two patents are at issue:

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

- The '302 patent, which claims a method of optimizing therapeutic efficacy and reducing toxicity, comprising the steps of determining the level of metabolite, which will give an indication to either increase or decrease the amount of drug in light of the correlation, allowing for calibration proper dosage of drugs to treat autoimmune diseases in light of those correlations. The claims of the '302 patent largely match those of the '623 patent, just without the "administering" step.

The Federal Circuit in December, 2010 found for the second time that the methods in both patents were patentable subject matter, holding that the method claims recite an application of the naturally occurring correlations (i.e., specific treatment steps), and accordingly do not preempt all uses of the natural correlations; further, the Federal Circuit held that the method claims satisfied the "transformation" prong of the machine-or-transformation test because the human body changes the drug into a different state or thing (i.e., a metabolite), which is central to the purpose of the claimed process. 628 F.3d at 1355-56.

The question presented in *Prometheus* appeared to offer an opportunity for the Supreme Court to clarify the patentable-subject-matter analysis, and the interplay between the multiple tests for determining patentable subject matter (namely, the preemption test and the machine-or-transformation test).

In granting *certiorari*, the Supreme Court stated as follows:

> This case concerns whether a patentee can monopolize basic, natural biological relationships. The Court has twice granted certiorari on the question presented, without yet resolving the issue. Last year, it granted certiorari, vacated, and remanded in this case to allow the Federal Circuit to reconsider this question in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). And seven years ago it granted certiorari but dismissed the writ as improvidently granted in *Laboratory Corp. of America Holdings v.*

5 *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. Dec. 17, 2010).

> *Metabolite Laboratories, Inc.,* 548 U.S. 124, 135 (2006), because petitioner there had not adequately preserved the question.
>
> The question presented asks:
>
> Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve "transformations" of body chemistry."

Order Granting Cert., 131, S. Ct. 3027 (June 20, 2011).

A patent cannot monopolize a natural phenomenon or law of nature. Thus, a patent claim that covers all uses of a natural phenomenon or law of nature such that if enforced it would prevent all uses of the naturally occurring phenomenon violates § 101.

It is a likely scenario that the Supreme Court granted *certiorari* for a second chance at *Laboratory Corp.*, where the writ was dismissed as improvidently granted, but Justice Breyer, joined by Justice Stevens and Justice Souter, wrote a dissent addressing the merits. They addressed the § 101 challenge to the patents at issue, which as stated by the dissent claimed a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin consisting of using any test (whether patented or unpatented) to measure the level in a body fluid of an amino acid called homocysteine and then noticing whether its level is elevated above the norm. In no uncertain terms, the dissenting Justices in *Laboratory Corp.* stated that the patents improperly sought to claim a monopoly over a basic scientific relationship (the relationship between homocysteine and vitamin deficiency):

> [T]his case is not at the boundary. It does not require us to consider the precise scope of the "natural phenomenon" doctrine or any other difficult issue. In my view, claim 13 is invalid no matter how narrowly one reasonably interprets that doctrine. There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a "natural phenomenon." … The respondents argue, however, that the correlation is nonetheless patentable because claim 13 packages it in the form of a "process" for detecting vitamin deficiency, with discrete testing and correlating steps…. Why should it matter if the test results themselves were obtained through an unpatented procedure that involved the transformation of blood? Claim 13 is indifferent to that fact, for it tells the user to use any test at all. Indeed, to use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter.

548 U.S. at 135-38.

As predicted, the Court in *Prometheus* followed the dissent in *Laboratory Corp.* and denied patent eligibility. At the base of the patent claims at issue in *Prometheus* is the correlation between metabolite levels and toxicity or efficacy. This correlation (the relationship between concentrations of thiopurine metabolite levels in the blood and the dosage of thiopurine drugs that either are too low and therefore ineffective or too high and

therefore harmful) is a law of nature or natural phenomenon that cannot itself be patented. The Court in *Prometheus* determined whether the other portions of the patent claims, such as the step of administering the drug to a patient or calibrating the drug dosage after analyzing the metabolite level, were sufficient application steps such that the claims did not effectively preempt all uses of the natural correlation. What "something else" beyond the natural law is sufficient to avoid preemption and confer patent eligibility? The Court articulated the question as follows:

> The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe that the answer to this question is no. If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1297 (2012) (emphasis in original).

The Court held that the patent claims at issue "effectively claim the underlying laws of nature themselves" and that the additional portions of the claims were not sufficient to confer patent eligibility, stating: "We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable." In reaching this determination, the Court reviewed its precedent "warn[ing] us against upholding patents that claim processes that too broadly preempt the use of a natural law." Applying this principle to the claims at issue, the Court determined that there was no other use for the natural correlation beyond the methods patented, and accordingly the claims improperly attempted to monopolize a natural law itself:

> Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination [of steps in the process] amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients…. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature: any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Id. at 1298.

At bottom, the Court ruled that the natural correlation itself *is* the invention or discovery that *Prometheus* attempted to patent, and the steps applying the natural correlation were mere "post-solution activity" that was "conventional or obvious" and not sufficient to confer patent eligibility. "Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular

(unpatentable) laws of nature (which the claim sets forth) to calculate the toxicity/efficacy limits, and (3) reconsider the drug dosage in light of the law.

Id. at 1299.

The Court also reversed the Federal Circuit's determination that there was sufficient "transformation" under the machine-or-transformation test to confer patent eligibility. Referring back to *Bilski*, the Court stated: "[I]n stating that the 'machine-or-transformation' test is an '*important and useful clue*' to patentability, we have neither said nor implied that the test trumps the 'law of nature' exclusion. That being so, the test fails here." *Id.* at 1303 (emphasis added, internal citations omitted).

While the Court in *Prometheus* provided further guidance following *Bilski*, certain critical questions remain, which the Federal Circuit will need to address soon, as the Supreme Court has already remanded multiple cases to the Federal Circuit for further consideration in light of *Prometheus* (discussed below). First, the Court did not delineate or articulate the precise interaction between the "preemption test" and the "machine-or-transformation" test. Is the preemption test the dominant analysis, for which the machine-or-transformation test is merely informative as a "useful and important clue"? It seems that the preemption test, which embodies the policy underlying § 101 should be the dominant analysis, in that if a claim fails the preemption test, it runs afoul of the policy of the statute, which precludes the patenting of laws of nature, natural phenomena, and abstract ideas. If a claim fails the preemption test, is there any need for the machine-or-transformation test, which arguably should not be able to rescue a claim failing the preemption test? Is the machine-or-transformation test applicable in some contexts but not others? The Federal Circuit will have to grapple with these questions in the upcoming term, as will the PTO in developing policy regarding § 101 rejections.

Another question left in the wake of the *Prometheus* decision relates to the apparent importation of novelty or obviousness analysis into the § 101 inquiry invited by the Court's opinion. In finding that the application steps were not sufficient to confer patent eligibility, the Court stated examined the extent to which the steps (other than the natural correlation) were novel or well-known: "[T]he steps in the claimed processes (apart from the natural laws themselves) involve ***well-understood, routine, conventional activity previously engaged in by researchers of the field***." *Id.* at 1294 (emphasis added). Later in the opinion, the Court acknowledged: "We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap." *Id.* at 1304. Does this conflation of the § 101 and § 102/103 analyses create the potential for confusion? It remains to be seen how courts will apply this portion of the *Prometheus* opinion

B. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (Mar. 26, 2012)

On March 26, 2012, the Supreme Court vacated the judgment of the Federal Circuit below (*Association For Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. July 29, 2011)) and remanded the case to the Federal Circuit for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ——, 132 S. Ct. 1289 (2012).

In the now vacated opinion written by Judge Lourie,[6] the Federal Circuit addressed the holdings from the S.D.N.Y. regarding whether isolated gene sequences of the BRCA1 and BRCA2 genes, which are linked to breast cancer, and diagnostic method patents involving the BRCA genes, fall within patentable subject matter under § 101. The majority held that:

> (1) the district court erred in holding that composition of matter patents on isolated DNA sequences were invalid under § 101 because the isolated DNA exists in a distinctive chemical form from the native DNA found in the body, as the isolated sequences are manipulated (either cleaved or synthesized) and are thus markedly different molecules than those found in the body;
>
> (2) the district court correctly held that the method claims for comparing or analyzing gene sequences were invalid under *Bilski*, as the comparison of genes is simply an abstract mental process, and the limitation of the method to the BRCA field of use cannot rescue the claimed methods from invalidation under § 101: "Although the *application* of a formula or abstract idea in a process may describe patentable subject matter, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process claimed."
>
> (3) the district court erred in holding that Myriad's claims directed to screening potential cancer therapeutics via changes in cell growth rates were invalid, since the method claims involve the transformative steps, critical to the purpose of the claimed process, of growing host cells transformed (a term of art) with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic, determining the growth rate, and then comparing the host cells' growth rate; thus the process involves physical manipulation of the cells, not just the process of comparing two cells' growth rates (and thus is not simply an abstract mental process).

The result under the previous Federal Circuit opinion is that the composition of matter claims, arguably the broadest claims, are upheld as patentable. It s appears that the Federal Circuit will reexamine its analysis of the patentability of the composition of matter claims for isolated DNA sequences. Indeed, the Federal Circuit's order regarding briefing on remand[7] requests briefing on the following issues: "What is the applicability of the Supreme Court's decision in *Mayo* to Myriad's isolated DNA claims and to the method claim 20 of the '282 patent [the screening method]?"

It appears that the second holding regarding the method claims for comparing gene sequences, which lack any application step and have already been held unpatentable (because "the step of comparing two DNA sequences is the entire method claimed") will likely not be affected by the Supreme Court's holding in *Prometheus*.

6 Judge Moore concurred in part, opining that short isolated DNA segments are distinct from long DNA sequences and may not be patentable. Judge Bryson concurred in part and dissented in part, opining that isolated genes are not materially different from native genes, and just as there is no transformation in "snapping a leaf from a tree," there is no transformation in isolating DNA sequences.

7 2012 WL 1500104 (Apr. 30, 2012).

It is likely, however, that the Federal Circuit's third holding regarding the screening method claims will be critically scrutinized on remand. Are the application steps in the method screening claims sufficient to avoid a determination that the claim preempts all uses of an abstract mental process? Under *Prometheus*, an application step confers patent eligibility only if it sufficiently limits the abstract idea to avoid conferring monopoly on the idea itself. Are there other uses for the abstract idea outside of the method claimed? Given that simply adding a "wet lab" step no longer appears sufficient under *Prometheus* to confer patent eligibility, can clever drafting no longer reliably steer applicants clear of § 101?

C. *WildTangent, Inc. v. Ultramercial, LLC,* __S. Ct. __, 2012 WL 369157 (May 21, 2012)

On May 21, 2012, the Supreme Court vacated the judgment of the Federal Circuit (*Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. Sept. 15, 2011)) and remanded the case to the Federal Circuit for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ——, 132 S. Ct. 1289 (2012).

In the now-vacated Federal Circuit opinion, written by Chief Judge Rader, the Federal Circuit addressed a method claim for monetizing and distributing copyrighted products over the internet where the consumer receives the copyrighted product for free in exchange for viewing an advertisement and the advertiser pays for the copyright content. The Federal Circuit found this claim to be eligible for patent protection, reversing the district court, which had granted the accused infringer's motion to dismiss on § 101 grounds.

The Court previously reasoned, after placing the claimed invention in the "process" category, that the invention was not an unpatentable abstract idea but a patentable application of an abstract idea. This determination was not by virtue of the machine-or-transformation test, but because of the application of specific and complicated steps for applying the abstract idea; additionally, the finding of validity appeared in part due to the fact that the patent was an improvement patent:

> [I]nventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act." *Research Corp.*, 627 F.3d at 869. The '545 patent seeks to remedy problems with prior art banner advertising, such as declining clickthrough rates, by introducing a method of product distribution that forces consumers to view and possibly even interact with advertisements before permitting access to the desired media product. '545 patent col.2 ll.14–18. ***By its terms, the claimed invention purports to improve existing technology in the marketplace. By its terms, the claimed invention invokes computers and applications of computer technology***…. [T]he mere idea that advertising can be used as a form of currency is abstract, just as the vague, unapplied concept of hedging proved patent-ineligible in *Bilski*. However, the '545 patent does not simply claim the age-old idea that advertising can serve as currency. Instead the '545 patent discloses a ***practical application of this idea***. The '545 patent claims a particular method for monetizing copyrighted products…. Viewing the subject matter as a whole, the invention involves an ***extensive computer interface***. This court does not define the level of programming complexity required before a computer-implemented method can be

> patent-eligible. Nor does this court hold that use of an Internet website to practice such a method is either necessary or sufficient in every case to satisfy § 101. This court simply finds the claims here to be patent-eligible, in part because of these factors…. The digital computer may be considered by some the greatest invention of the twentieth century, and both this court and the Patent Office have long acknowledged that "improvements thereof" through interchangeable software or hardware enhancements deserve patent protection. Far from abstract, advances in computer technology – both hardware and software – drive innovation in every area of scientific and technical endeavor.

Ultramercial, LLC v. Hulu, LLC, 2011 WL 4090761 at *4-*6 (emphasis added).

Is the *Research Corp.* reasoning (that "inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act") applicable after the *Prometheus* decision? After *Prometheus*, is would also appear that the level to which a computer is required to perform the steps is no longer the correct line of distinction between patent-eligible claims and claims failing the patentable subject matter test. Rather, under the preemption doctrine applied in *Prometheus,* the relevant distinction is not whether application steps are purely mental or performed by a computer, but instead whether the application steps add enough to the abstract idea such that all uses of the abstract idea are not monopolized. It will be of interest to see how the Federal Circuit applies *Prometheus* in a different substantive area outside of the biology context, but it seems the Federal Circuit will need to apply the broad principles of *Prometheus*, and contend with the fact that the Court in *Prometheus* determined that physical application steps were not necessarily sufficient to confer patentability under § 101.

D. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. Aug. 31, 2011)

In *Classen*, a Federal Circuit panel addressed § 101 challenges to three patents that covered a wide range of infant immunization methods and schedules aimed at lowering the risk for development of a chronic immune-mediated disorder. This was the second time the Federal Circuit was presented with the question of whether these patents fell within patentable subject matter, being handed the case again after the Supreme Court vacated and remanded the decision following *Bilski*. While not an *en banc* decision, the Federal Circuit Judges' viewpoints on patentable subject matter presented in *Classen* encapsulate the § 101 debate and illustrate the fracture at the Federal Circuit.

The majority opinion, written by Judge Newman, carved a § 101 boundary dividing the three patents, finding that two of the patents (the '139 and '739 patents) met the requirements of § 101, while the third (the '283) did not. The difference discerned between the two patents found to fall within § 101 and the '283 patent was a tangible application step. In plaintiff's own words, the '139 and '739 patents covered uses where "a health care provider reads the relevant literature and selects and uses an immunization schedule that is of lower risk for development of a chronic immune-mediated disorder," while the '283 patent did not involve the step of selecting an immunization schedule, and thus could be infringed when someone merely reviews the relevant literature. The majority opinion found that although the '139 and '739 patents included a mental step, this was not fatal to § 101 eligibility because the claims of these patents also included a physical, real-

world step (a "specific, tangible application"). The '283 patent did not similarly include any tangible step and was invalidated.

Classen presents a question currently at the forefront of the § 101 debate: What about preemption? If the patent claims as drafted may effectively monopolize all uses of an abstract idea or natural phenomenon, should preemption preclude patentability? Is an abstract idea or mental step "plus" any tangible step enough to satisfy § 101, even if it allows monopoly on (preempts) all potential uses of the abstract idea or natural correlation? The absence of a preemption analysis in the *Classen* majority opinion is notable, particularly in light of *Classen's* overlap with *Prometheus*. Would the tangible application step in *Classen* pass muster under the Supreme Court's analysis in *Prometheus*? Can this holding somehow be squared with the *Prometheus* decision? Will this decision be challenged in light of the Supreme Court's decision in *Prometheus*?

Judge Moore previews this issue in dissent, opining that the claims of all three patents covered only abstract ideas or principles, which cannot be torn from the public domain, stating: "Having discovered a principle – that changing the timing of immunization may change the incidence of chronic immune mediated disorders – Classen now seeks to keep it for himself." The real-world immunization step, in Judge Moore's opinion, is mere post-solution activity that does not transform the unpatentable abstract idea or correlation into patentable subject matter by providing meaningful limits, as the patents involving the immunization step still improperly grant monopoly on the principle itself.

While Judge Moore agrees with the majority that this case is not analogous to *Prometheus*, as the now-vacated Federal Circuit opinion in *Prometheus* determined there was physical transformation in *Prometheus*, she notes the majority's lack of consideration of the preemption analysis at issue in *Prometheus*: "There is no consideration of the extent of preemption by these staggeringly broad and abstract claims." While the preemption line is difficult to draw, Judge Moore maintains that it is an important one, noting her disagreement with where the majority drew the line:

> While I confess the precise line to be drawn between patentable subject matter and abstract idea is quite elusive, at least for me, this case is not even close. In the '283 patent, Classen claims the scientific method as applied to the field of immunization. No limitations exist on the type of drug to immunize with, the schedules that should be used for the immunization, the type of chronic immune disorder to look for, or any limitation on the control group. It is hard to imagine broader claims. It is harder to imagine a more conceptually abstract claim in the immunization area. Classen's claims are directed to a thought apart from any concrete realities, specific objects or actual instances. This is very much like patenting $E=mc^2$. Compare any two schedules to determine which one has fewer instances of immune disorders. Compare two substances to determine which one tastes sweeter. Compare two cups of coffee to determine which one is stronger. Actually these examples are more concrete than the Classen claims in that I tell you what to look for – sweetness or strength. The Classen claims do not even specify which immune disorder should be studied. Likewise the representative claim from the '139 and '739 patents specifies no specific immune disease, drug, or schedule. These claims cover any kind of comparison between any two schedules, using any drugs and comparing the incidence of any chronic immune disease. After the user performs this completely abstract

> mental comparison, then the user should immunize the subject with the drug they choose on the schedule they deem lower risk.

Classen Immunotherapies, Inc. v. Biogen IDEC, 2011 WL 3835409, at *20.

Perhaps the most interesting portions of *Classen*, however, are the "additional views" presented by Chief Judge Rader, joined by Judge Newman (who authored the majority opinion), which take a step back from the § 101 debate and critique the existence of the debate itself. In short, Chief Judge Rader notes the "rising number of challenges under 35 U.S.C. § 101" brought before the Court, and urges the Court to decline future invitations to delve into § 101:

> Subject matter eligibility under section 101 has become the "substantive due process" of patent law – except that reading non-procedural requirements into the constitutional word "process" has more historical and contextual support than reading abstractness into the statutory word "process" because Title 35 already contains ample protections against vague claims. *See* 35 U.S.C. § 112. Indeed it is difficult to "invent" any category of subject matter that does not fit within the four classes acknowledged by Title 35: process, machine, [article of] manufacture, or composition of matter. This court should decline to accept invitations to restrict subject matter eligibility. In order to highlight some public policy reasons that the statute places few, if any, limits on subject matter eligibility, these additional views are offered. The patent eligibility doctrine has always had significant unintended implications because patent eligibility is a "coarse filter" that excludes entire areas of human inventiveness from the patent system on the basis of judge-created standards. For instance, eligibility restrictions usually engender a healthy dose of claim-drafting ingenuity. In almost every instance, patent claim drafters devise new claim forms and language that evade the subject matter exclusions. These evasions, however, add to the cost and complexity of the patent system and may cause technology research to shift to countries where protection is not so difficult or expensive.

Id. at *13.

Chief Judge Rader commented further on "claim drafting evasion," stating: "Eligibility then becomes a game where lawyers learn ingenious ways to recast technology in terms that satisfy eligibility concerns." While potential for skirting requirements with careful drafting, and a corresponding increase of cost and complexity in the patent system are valid concerns, how are §101 challenges different from other patentability requirements (§§ 102, 103, and 112) in this regard?

Also, how do litigants square Chief Judge Rader's criticism of an overabundance of patentable-subject-matter challenges with the traction § 101 appears to be gaining traction among the courts, including the Supreme Court?

Another interesting issue is the juxtaposition of two of the Court's recent cases against each other, as they represent different approaches and different precedent in different fields. The majority in *Classen* found that the claims of the '139 and '739 patents met the requirements of Section 101 simply because the physical step of vaccinating the

patient was added. However, in *CyberSource* (discussed next), the *Beauregard* claims applying an otherwise abstract idea to a computer readable medium were invalidated under Section 101.

E. *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. Aug. 16, 2011)

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

The Court held that under the machine-or-transformation test, the claim as written does not require use of a machine or a physical transformation to a different state or thing. The method comprises the rather abstract processes of a) obtaining information about other transactions that have utilized an Internet address that is identified with the credit card transaction; b) constructing a map of credit card numbers based upon the other transactions, and; c) utilizing the map of credit card numbers to determine if the credit card transaction is valid. The Court invalidated under *Bilski*, finding that the data gathering steps were insufficient to overcome § 101, and that mention of the internet did not rescue the otherwise ineligible subject matter. The Court looked beyond the machine-or-transformation test, considering the broader policy behind § 101 that mental processes untethered to real-world applications are not patentable, and finding the method to be a mental process because it can be performed "by a human using a pen and paper." "[T]he application of human intelligence to the solution of practical problems is not in and of itself patentable."

The *Beauregard* claims met a similarly decisive end, the *CyberSource* Court finding the different form was "nothing more than a computer readable medium containing program instructions for executing the [method claim the Court invalidated]." Tying the method claim to software, and the storage device for the software (a "computer readable medium" which CyberSource argued is directed at a man-made article and *per se* patentable) did not render it patentable just by placing the invention in a different category, as the underlying invention does not meet the requirements of § 101:

> Regardless of what statutory category ("process, machine, manufacture, or composition of matter," 35 U.S.C. § 101) a claim's language is crafted to literally invoke, we look to the underlying invention for patent-eligibility purposes. Here, it is clear that the invention underlying both claims 2 and 3 is a method for detecting credit card fraud, not a manufacture for storing computer-readable information.

CyberSource Corp. v. Retail Decisions, Inc., 2011 WL 3584472 at *7.

If the method can be performed with a paper and pencil, claiming to perform the mental task on a computer or over the internet or storing it on computer readable media will not make it patent eligible. The result, that an abstract idea or purely mental process (that could be performed without the use of a computer) is unpatentable even when restricted to a computer, seems to be the right one. However, going forward, how are courts to apply the "underlying invention" analysis? Or is this analysis superseded by *Prometheus*?

IV. COMING ATTRACTIONS

Federal Circuit En Banc Rehearing Granted in *Akamai v. Limelight (en banc rehearing petition granted April 2011)* and *McKesson Technologies (en banc rehearing petition granted May 2011). Oral argument was heard in both cases in November, 2011.*

Akamai and *McKesson*, which will soon be decided *en banc*, deal, at least in part, with the issue of direct infringement of method claims and joint infringement. Joint infringement is of course a species of direct infringement, which is a strict liability "offense" with no level of knowledge or intent required. Indirect infringement, on the other hand, requires some level of knowledge or intent for a finding of liability.

To be liable for direct infringement of a method claim, the accused infringer must generally perform each element or step of the claimed method. Similarly, to establish inducement of a method patent, there still needs to be the prerequisite of direct infringement by the induced party, which for a method patent requires performance of each step by a single actor. The only previously recognized exception to this was where an agency or contractual relationship existed such that another party was performing steps on behalf of the accused infringer, essentially acting as a single actor under agency principles. (For example, this exception was recognized in the now-vacated opinion in the Federal Circuit's first decision in *Akamai*, at 629 F.3d 1311).

The Federal Circuit will likely be striving to strike the correct balance between finding liability for infringing activity, while still protecting innocent actors. To protect innocent actors, should a high degree of control should be required, or should perhaps an intent requirement be added? As the Patent Act makes no reference to liability for direct infringement by multiple actors or parties, this is uncharted territory.

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

> If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?

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

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

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

Akamai and *McKesson* pose the following questions: Under what circumstances, if any, can a method claim be directly infringed if separate entities perform separate steps of the method claim? If liability exists when no single party has performed every step of a method claim, to what extent would each of the joint infringers be liable? Under what circumstances should an alleged infringer or third party be liable for inducing infringement or contributory infringement when separate entities perform separate steps of a method claims? What level of control should be required to find inducement?

One interesting note is Judge Newman's dissent in the first *McKesson* opinion, where she expresses concern that "interactive" methods cannot be adequately protected absent findings of infringement of method claims by multiple actors, stating:

> Today's holding, and the few recent cases on which it builds, have the curious effect of removing from patent eligibility the burgeoning body of interactive computer-managed advances. A patent that cannot be enforced on any theory of infringement, is not a statutory patent right. It is a cynical, and expensive, delusion to encourage innovators to develop new interactive procedures, only to find that the courts will not recognize the patent because the participants are independent entities.

McKesson Technologies Inc. v. Epic Systems Corp., —- F.3d —- (Fed. Cir. Apr. 12, 2011), slip op. at 17.

What is the proper balance between protecting innocent actors, and avoiding the issue Judge Newman points out? Additionally, might the solution be in drafting the claims differently, such as drafting a mixture of systems and method claims?