

Top Ten Patent Cases*

Harold C. Wegner

1. *Microsoft v. i4i* – Invalidity Standard of Proof
2. *Costco v. Omega* – International Exhaustion
3. *Prometheus v. Mayo* – Diagnostic Method Patent-Eligibility
4. *Therasense* – Inequitable Conduct
5. *TiVo v. Echostar* – Contempt Infringement
6. *Myriad* – § 101 Patent-Eligibility
7. *Arkansas Carpenters (Cipro®)* – “Reverse Payments”
8. *Hyatt v. Kappos* – § 145 Presentation of New Evidence
9. *Global-Tech v. SEB*: Inducement to Infringe
10. *In re Jung* – PTO Board Presumptions
 - In re Tanaka* – Reissue “Error”
 - Classen v. Biogen* – Metabolite déjà vu
 - SRI v. Internet Security* – Statutory Presumption of Validity
 - Slattery v. United States* – En Banc CFC Appeal

* Harold C. Wegner is solely responsible for this list. The author is a former Director of the Intellectual Property Law Program and Professor of Law at the George Washington University Law School and is currently a partner in the international law firm of Foley & Lardner LLP. Any opinions or characterizations expressed in this paper represent the personal viewpoint of the author and do not necessarily reflect the viewpoint of any colleague, organization or client thereof.

This revision September 23, 2010.

Top Ten No. (1) *Microsoft v. i4i* – Invalidity Standard of Proof

In *Microsoft Corp. v. i4i Ltd.*, Supreme Court No. 10-290, Petitioner questions the ‘clear and convincing’ standard to establish invalidity where the prior art has not been considered by the examiner. The opinion below is *i4i Ltd. v. Microsoft Corp.*, 589 F.3d 1246 (Fed. Cir. 2009)(Prost, J.), vacating prior panel opinion, 598 F.3d 831 (Fed. Cir. 2010)(Prost, J.).

Status: Respondent’s opposition to the petition for review is due October 29, 2010 (once extended). Decision whether to grant review expected late Fall. (The first dates open for argument at the Court are in 2011.)

Question Presented: “The Patent Act provides that ‘[a] patent shall be presumed valid’ and that ‘[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.’ 35 U.S.C. § 282. The Federal Circuit held below that Microsoft was required to prove its defense of invalidity under 35 U.S.C. § 102(b) by ‘clear and convincing evidence,’ even though the prior art on which the invalidity defense rests was not considered by the Patent and Trademark Office prior to the issuance of the asserted patent. The question presented is:

“Whether the court of appeals erred in holding that Microsoft’s invalidity defense must be proved by clear and convincing evidence.”

Discussion: Petitioner suggests a conflict between the Federal Circuit and the regional circuits and also points to the Supreme Court *dicta* in *KSR* concerning the presumption of validity where the best prior art has not been cited:

“In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), ... this Court expressed a far more pragmatic view of the statutory presumption of validity. There, the Court ‘th[ought] it appropriate to note that the rationale underlying the presumption – that the PTO, in its expertise, has approved the claim – seems much diminished’ where an invalidity defense rests on evidence that the PTO never had an opportunity to consider. *Id.* at 426. That observation was in accord with the conclusion reached by *all twelve* regional circuits before the Federal Circuit assumed jurisdiction of most patent matters in 1982. *See, e.g., Futorian Mfg. Corp. v. Dual Mfg. & Eng’g, Inc.*, 528 F.2d 941, 943 (1st Cir. 1976) (affirming an instruction that the jury could find invalidity by a preponderance of the evidence

Wegner's Top Ten Patent Cases [September 23, 2010]

because ‘to the extent patent office attention has not been directed to relevant instances of prior art the presumption of validity arising from the issuance of a patent is eroded’).”

(2) Costco v. Omega – International Exhaustion

In *Costco Wholesale Corp. v. Omega, S.A.*, Supreme Court No. 08-1423, *opinion below, Omega S.A. v. Costco Wholesale Corp.*, 541 F.3d 982 (9th Cir. 2008)(Smith, Jr., J.), the question of international exhaustion of intellectual property rights is raised in the context of copyright law.

International exhaustion involves the principle that the intellectual property rights holder who places goods on sale outside the United States “exhausts” his patent right so that a purchaser is free to import into and use and sell purchased goods in the United States.

Status: Oral argument is scheduled for 10:00 AM on Monday, November 8, 2010. A decision is expected Winter 2011 but in any event before the end of June 2011.

Question Presented: “Under the Copyright Act's first-sale doctrine, 17 U.S.C. § 109(a), the owner of any particular copy ‘lawfully made under this title’ may resell that good without the authority of the copyright holder. In *Quality King Distribs., Inc. v. L'Anza Research Int'l, Inc.*, 523 U.S. 135, 138 (1998), this Court posed the question presented as ‘whether the ‘first sale’ doctrine endorsed in § 109(a) is applicable to imported copies.’ In the decision below, the Ninth Circuit held that *Quality King* (which answered that question affirmatively) is limited to its facts, which involved goods manufactured in the United States, sold abroad, and then re-imported. The question presented here is:

“Whether the Ninth Circuit correctly held that the first-sale doctrine does not apply to imported goods manufactured abroad.”

Discussion: This is one of several cases implicating international patent exhaustion; they are considered in detail in Harold C. Wegner, *International Patent Exhaustion: Whither the Supreme Court?*, available at www.GrayOnClaims.com/hal.

(3) *Prometheus v. Mayo* – Diagnostic Method Patent-Eligibility

In a case that could best be described as “Metabolite déjà vu”, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, Fed. Cir. 2008-1403, upon grant of certiorari, vacation and remand from the Supreme Court in light of *Bilski v. Kappos*, ___ U.S. ___ (2010), prior opinion, 581 F.3d 1336 (Fed. Cir. 2009)(Lourie, J.), the Federal Circuit is *explicitly* invited to reconsider their prior decision based upon Supreme

Status: Supplemental briefing by *both* parties is simultaneously due October 14, 2010.

The *Prometheus* panel on remand: Normally, where the same case is heard the second time at the Federal Circuit the same panel is assigned to hear the argument. Here, one member of the panel has resigned his commission, leaving the author of the first opinion, Lourie, J., and a Visiting Judge, Clark, J. It remains to be seen which regular member of the Court will join the panel and whether the Visiting Judge will remain on the panel.

The author of the first opinion will be the presiding judge in this case to assign authorship (if in the majority) unless the panel includes the more highly seeded Chief Judge (Rader, C.J.) or the longer serving regular member of the court (Newman, J.).

Prometheus Claim 1 in Controversy:

1. A method of optimizing therapeutic efficacy for treatment of an immune mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder wherein the levels of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the levels of 6thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently

administered to said subject.

Thus, claim 1 is infringed if a physician (or any other health care provider) gives a patient a particular drug and then measures the blood level of that drug in the patient against a fixed concentration, thereby learning whether subsequent dosages should be raised or lowered.

The District Court, *Metabolite déjà vu*: “[T]he fact that the inventors have framed the claims as ‘treatment methods’ does not make the claims patentable. Indeed, ‘one can reduce any process to a series of steps. The question is what those steps embody.’ *Lab. Corp. of Am. Holdings v. Metabolite, Inc.*, 548 U.S. 124, 126 S.Ct. 2921, 165 L.Ed.2d 399 (2006) (Breyer, J., dissenting from dismissal of certiorari) (emphasis in original); *see also In re Grams*, 888 F.2d 835, 839 (Fed.Cir.1989) (explaining that the critical question is: ‘What did applicants invent?’) (quoting *In re Abele*, 684 F.2d 902, 907 (C.C.P.A.1982)).

“Here, a careful review of the claims of the patents-in-suit reveals that the steps embody only the correlations themselves. First, the ‘administering’ and ‘determining’ steps are merely necessary data-gathering steps for any use of the correlations. However, an ‘unpatentable principle’ will not transform into a ‘patentable process’ simply by adding conventional method steps. *Flook*, 437 U.S. at 588-90; *accord Meyer*, 688 F.2d at 794 (‘[data-gathering] step[s] cannot make an otherwise nonstatutory claim statutory’). Thus, the Court must look to the third step to determine what the applicants claim to have invented. However, as construed, the final step—the ‘warning’ step (i.e. the ‘wherein’ clause)—is only a mental step. That is, the ‘warning’ step does not require that dosage be adjusted, or any other action. Indeed, contrary to Plaintiff’s assertion, the ‘warning step’ does not require that the doctor (or any person) ‘provide’ a warning. *See* Doc. No. 528 at 14. Rather, it is the metabolite levels themselves that ‘warn’ the doctor that an adjustment in dosage may be required.”

The First Federal Circuit Opinion, Daring the Court to Issue a GVR: The first panel opinion acknowledged that the trial court had relied upon the dissent in *Metabolite*: “In reaching its conclusion [that the claimed subject matter lacks patent-eligibility under 35 USC § 101], the district court relied heavily on the opinion of three justices dissenting from the dismissal of the grant of certiorari in [Metabolite].” *Prometheus v. Mayo*, 581 F.3d at 1346 n.3. Indeed, the notes that the trial judge “discuss[ed] the dissent in [Metabolite] at length and stat[ed] that although the dissent ‘does not have precedential value, the Court finds Justice Breyer’s reasoning persuasive’”. *Id.* (quoting trial court opinion). While *Metabolite* case is *factually* on all fours with the instant case, the panel dismissed

Wegner's Top Ten Patent Cases [September 23, 2010]

the factual relevance of the *Metabolite* case because the *Metabolite* case “involved different claims from the ones at issue here.” *Id.*

As to “Justice Breyer's reasoning [which the trial court found] persuasive”, the panel nowhere chose to dignify the Supreme Court opinion with a rebuttal anywhere in the body of its opinion. Indeed, the primary reason given by the panel as to why no discussion of the *Metabolite* case is necessary is because the Breyer “dissent is not controlling law[.]” *Id.*

Question Presented at the Supreme Court Leading to the GVR: “The Federal Circuit, reversing the district court, upheld Prometheus’s patent claims covering a process for correlating the level of certain chemicals in a patient’s blood with the patient’s health. By those claims, Prometheus seeks to monopolize the use of blood tests in the research, diagnosis, and treatment of disease, such that a physician violates the patent merely by thinking about the correlation between the test results and the patient’s health or treatment. This Court granted certiorari to determine whether basic scientific relationships may be monopolized in this way in *Laboratory Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 135 (2006) [], but dismissed the writ for lack of adequate issue preservation. Dissenting from dismissal, Justices Breyer, Stevens, and Souter explained that such patents are invalid under this Court’s precedents, and that resolving the issue presented in [*Metabolite*] was of great importance to innovative scientific inquiry and effective medical research and treatment. The question presented is as follows:

“Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between patient test results and patient health, so that the claim effectively preempts all uses of these naturally occurring correlations.”

What Does *Bilski* have to do with *Prometheus*? Indeed, this is a matter for the Federal Circuit to now decide, given that the Supreme Court has issued a “GVR” to send the case back to the appellate tribunal to rethink the case in light of *Bilski*. (This does not mean that the Federal Circuit must issue a decision differing from its first opinion, but if it does do so then presumably the Federal Circuit will explain why *Bilski* does not control the facts of the case to compel a different conclusion. See *The “GVR” in Patent Law, “Bergy déjà vu”* (page 3).

(4) *TheraSense* – Inequitable Conduct

“In *TheraSense*[, *Inc. v. Becton, Dickinson & Co*, Fed. Cir. No. 2008,] th[e] 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.” *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, ___ F.3d ___, ___ (Fed. Cir. 2010)(Rader, C.J., concurring).

The deep split within the Court over inequitable conduct is highlighted in the panel dissent, 593 F.3d, 1289, 1312 (Fed. Cir. 2010)(Linn, J., dissenting in part).

Status: An *en banc* oral argument is scheduled for November 9, 2010.

The En Banc Panel: *Therasense* will be argued before Chief Judge Rader with anywhere from eleven to thirteen members making up the *en banc* panel that will include Circuit Judge Friedman (because he sat on the panel). Whether either or both of the newly nominated members of the Court are confirmed in time for this decision is an open question; even if confirmed after the argument, the new members of the Court could choose to participate in the *en banc* decision.

The Ten Questions of the En Banc Order: In six numbered paragraphs (with paragraphs two and three each being broken down into three questions) there are a total of ten questions raised for briefing, perhaps only some of which are necessary to a decision in the particular case involved:

“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.”\

(5) *TiVo v. Echostar* – Contempt Infringement Proceedings

In *Tivo, Inc. v. Echostar Corp.*, Fed. Cir. No. 2009-1374, the Court has granted rehearing *en banc* to consider standards for contempt proceedings to block infringement by an adjudged infringer producing a *new* product marketed as a design around the patent. The vacated panel opinion is reported at 2010 WL 724807 (Fed. Cir. 2010)(Lourie, J.).

Status: An *en banc* oral argument is scheduled for November 9, 2010.

Discussion: The following questions have been presented by the Court for consideration:

a) Following a finding of infringement by an accused device at trial, under what circumstances is it proper for a district court to determine infringement by a newly accused device through contempt proceedings rather than through new infringement proceedings? What burden of proof is required to establish that a contempt proceeding is proper?

b) How does “fair ground of doubt as to the wrongfulness of the defendant’s conduct” compare with the “more than colorable differences” or “substantial open issues of infringement” tests in evaluating the newly accused device against the adjudged infringing device? See *Cal. Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609, 618 (1885); *KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1532 (Fed. Cir. 1985).

Wegner's Top Ten Patent Cases [September 23, 2010]

c) Where a contempt proceeding is proper, (1) what burden of proof is on the patentee to show that the newly accused device infringes (see *KSM*, 776 F.2d at 1524) and (2) what weight should be given to the infringer's efforts to design around the patent and its reasonable and good faith belief of noninfringement by the new device, for a finding of contempt?

d) Is it proper for a district court to hold an enjoined party in contempt where there is a substantial question as to whether the injunction is ambiguous in scope?

Discussion: A divided panel sharply split on when a court may use contempt proceedings in lieu of a new trial to adjudicate an attempt to design around a patent following an injunction. The majority sustained a contempt ruling of infringement, sharply distinguishing the test laid down in the leading case, *KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1530-32 (Fed.Cir.1985).

Normally, even after an infringement injunction, the accused infringer is free to seek to design around the patent and should not be punished for such a design around unless found guilty of infringement in a second proceeding.

If the infringer makes essentially no change at all – a more “colorable variation” – then the court may exceptionally find infringement as part of *contempt* proceedings in the original action, which is precisely what occurred in *Tivo v. Echostar*.

More than a “Mere ‘Colorable Variation’”: The dissent opens with two key paragraphs:

“Contempt ... is not a sword for wounding a former infringer who has made a good-faith effort to modify a previously adjudged or admitted infringing device to remain in the marketplace. Rather, the modifying party generally deserves the opportunity to litigate the infringement question at a new trial, ‘particularly if expert and other testimony subject to cross-examination would be helpful or necessary.’ “ *Arbek Mfg. Inc., v. Moazzam*, 55 F.3d 1567, 1570 (Fed.Cir.1995) (quoting *KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1531 (Fed.Cir.1985)). Citing a broad injunctive provision and a substantially-altered accused design, this court today punishes a good faith design-around effort.

Wegner's Top Ten Patent Cases [September 23, 2010]

The test laid down in the *KSM* case denies contempt proceedings against a design around which is more than a mere “colorable variation” of what had been judged to be an infringement in the prior proceedings. The dissent points out that, here, “[a] full examination of the disputed claim shows little similarity between the former infringement proceedings and the issues now before this court. The accused structures are different. The theories of infringement are different. The pertinent claim constructions apply in ways that are different. The parties' positions have flip-flopped. The modified method operates in a significantly different way from the old. Indeed, the only thing that is not different is the identity of the parties themselves. These differences deserve a trial, not a summary contempt proceeding.”

View from Abroad: An authoritative British source notes that "the English House of Lords faced exactly the same problem in 1957 in *Multiform v Whitmarley* [1957] RPC 260. The Defendants had altered their product from the one which had previously been held to infringe. The patentees said it still infringed and brought contempt proceedings. The House of Lords did not like that but said contempt proceedings were legitimate though a fresh action would have been better. ... [T]he re-design was held not to infringe. It was (and is) bad tactics to go by contempt proceedings when there is a genuine re-design as opposed to a colourable variation, for standards of proof are higher and the court may think the patentee is a bit oppressive so Defendant gets a sympathy vote."

Broad Injunctive Reliefs Leads to Overbroad Patent Protection: A leading British jurist noted that “[t]he practical effect of a broad injunction and the threat of contempt proceedings is that most defendants will steer well clear of the patent.

The result is that at least in respect of that defendant the patentee secures a wider monopoly than this patent should entitle him to.” *Coflexip SA v. Stolt Comex Seaway MS Ltd*, 1999] 1 All ER 593, ¶ 29 (High Court 1999)(Laddie, J.)

(6) *Myriad* – § 101 Patent-Eligibility

The *Myriad* case, *Association for Molecular Pathology U.S. Patent and Trademark Office*, Fed. Cir. App. No. 2010-1426, is an appeal from the summary determination that certain biotechnology product claims to DNA sequences and parallel method claims are lack patent-eligibility under 35 USC § 101, ___ F.Supp.2nd ___ (S.D.N.Y. 2009)(Sweet, J.).

In the District Court opinion, the court invalidated the biotechnology product claims in suit on the basis that they lacked patent-eligibility under 35 USC § 101. *See* § V-C, *The Composition Claims are Invalid under 35 U.S.C. § 101* (pp. 102-135). Method claims were also held to lack patent-eligibility under 35 USC § 101. *See* § V-D, *The Method Claims are Invalid under 35 U.S.C. § 101* (pp. 135-149).

Status: Appellant's brief is due October 22, 2010.

(7) *Arkansas Carpenters (Cipro[®])* – “Reverse Payments”

A Supreme Court petition is expected in the case of *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, ___ F.3d ___ (2d Cir. 2010)(per curiam), *reh'g en banc den.*, ___ F.3d ___(2d. Cir. 2010), which reached the conclusion that the Cipro[®] “reverse payment” ANDA settlement was not an antitrust violation, the same conclusion reached on the same factual circumstances in *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 544 F.3d 1323, 1333 (Fed. Cir. 2008)(Prost, J.).

Status: A petition for *certiorari* is due December 6, 2010.

Discussion: The Second Circuit panel reached its conclusion on the basis of binding precedent, the *Tamoxifen* case, *Joblove v. Barr Labs., Inc.*, (*In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187, 208-12 (2d Cir. 2005):

“[A]s long as *Tamoxifen* is controlling law, plaintiffs' claims cannot survive. Accordingly, we AFFIRM the judgment of the district court. However, we believe there are compelling reasons to revisit *Tamoxifen* with the benefit of the full Court's consideration of the difficult questions at issue and the important interests

at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc.”

(8) *Hyatt v. Kappos* – § 145 Presentation of New Evidence

Rehearing *en banc* has been ordered in *Hyatt v. Kappos*, Fed. Cir. App. No. 2007-1066, *vacated panel opinion, Hyatt v. Doll*, 576 F.3d 1246 (Fed. Cir. 2009)(Michel, C.J.). The *en banc* rehearing provides a vehicle to reopen the door to the presentation of evidence in a trial *de novo* under 35 USC § 145.

Status: Awaiting decision (en banc argument was held July 8, 2010).

PTO Difficulties with § 145 Actions: The Solicitor's Office has been experiencing problems dealing with Section 145 actions which is manifested by the statutory change in 1999 that was slipped into an omnibus patent reform measure that stripped away at least certain reexaminations from this route and as further manifested by the “Manager's Amendment” that has been proposed to Leahy S.515 that would further erode the rights of patent applicants in a Section 145 action. This case is a further manifestation of the attempts by the PTO to limit the rights of patent owners in Section 145 actions.

Status: Oral argument *en banc* is scheduled for July 8, 2010 at 2:00 PM.

The Split (now Vacated) Panel Opinion: The panel majority followed the view of the Solicitor taking a hard line on the presentation of new evidence at a § 145 trial. The exclusion of new evidence by the panel majority was criticized in the dissent that succinctly summarizes the traditional view of the law:

“[T]he majority blurs the line between an appeal pursuant to § 141 and the civil action of § 145. The admissibility of new evidence is exactly what distinguishes § 145 from § 141. “We must be vigilant to preserve to patent applicants the alternative procedures that the law provides, and to preserve the historical distinction between them.” *Fregeau [v. Mossinghoff]*, 776 F.2d 1034, 1041 (Fed.Cir.1985)(Newman, J., concurring-in-part). The legislative history and Supreme Court precedent make clear that the hallmark distinction is the admissibility of ‘all competent evidence,’ ‘to build up a new record,’ ‘to start *de novo* in court,’ ‘and file testimony bringing in evidence that they could have brought in before [the PTO] but did not bring in before.’ This evidence, admissible in this civil action, should be governed as the Supreme Court indicated by ‘equity practice and procedure,’ i.e., the Federal Rules of Evidence and Civil Procedure.

Wegner's Top Ten Patent Cases [September 23, 2010]

“Since only the presence of new evidence invokes the *de novo* standard of review (otherwise the district court will give the Board fact findings substantial evidence deference, *see Fregeau*, 776 F.2d at 1038), the majority's decision in this case makes the § 145 action virtually indistinguishable from an appeal under § 141. This version of a ‘civil action’ under § 145 is contrary to Congressional intent and to the Supreme Court's rulings. While it is sound policy to encourage full disclosure to administrative tribunals such as the PTO, we are not the body that makes the decision of how best to do this. Congress held numerous hearings over this legislation, considered the concerns over permitting a civil action, and decided to enact the legislation despite these concerns.” *Hyatt v. Doll*, 576 F.3d 1289-90 (Moore, J., dissenting).

Issues: The Court asks the parties to identify limitations on the admissibility of evidence in section 145 proceedings:

“(i) Does the Administrative Procedure Act require review on the agency record in proceedings pursuant to section 145?

“(ii) Does section 145 provide for a *de novo* proceeding in the district court?

“(iii) If section 145 does not provide for a *de novo* proceeding in the district court, what limitations exist on the presentation of new evidence before the district court?”

PTO Attempt to Severely Limit New Evidence: The PTO for some time has been attempting to squelch patent applicants and patentees from taking the § 145 route to review decisions of the Office. *See Dennis Crouch, Appealing BPAI Rejections in Ex Parte Reexaminations*, Patently O (February 10, 2010)(discussing the work of Charles Miller). The writer was involved in a § 145 case where the principal attack by the Office was not on the evidence presented but on whether evidence could be admitted. *Takeda Pharmaceutical Co., Ltd. v. Dudas*, 511 F.Supp.2d 81, 86-87 (D.D.C. 2007)(Hogan, C.J.), *subsequent proceedings on other grounds sub nom Takeda Pharmaceutical Co. v. Doll*, 561 F.3d 1372 (Fed. Cir. 2009).

(9) *Global-Tech v. SEB: Inducement to Infringe*

In *Global-Tech Appliances Inc. v. SEB S.A.*, opinion below, *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360 (Fed. Cir. 2010), Petitioner challenges the Federal Circuit ruling that inducement to infringe may be established without actual knowledge of the patent through a showing of a “deliberate indifference” to a risk that the patent does in fact exist

Question Presented: “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 ‘purposeful, culpable expression and conduct’ to encourage an infringement.”

Status: The Court is scheduled to take this case up for a decision whether to grant *certiorari* at its Conference on September 27, 2010. If *certiorari* is granted, the decision could be announced September 28, 2010; otherwise the decision is expected October 4, 2010.

(10) *In re Jung – PTO Board Presumptions*

In *In re Jung*, Fed. Cir. App. No. 2010-1010, *proceedings below*, *Ex parte Jung*, 2008 WL 4974150 (PTO Bd. App. & Int. 2008)(Timm, APJ), *reh’g den.*, 2009 WL 1995983 (2009), several premises of recent PTO Board opinions are challenged that deal with the standard of “reversible [Examiner] error” and prima facie obviousness.

On March 9, 2010, PTO Director David Kappos announced that the Board had *overruled* the standard of “reversible error” in *Ex parte Frye*, an expanded *per curiam* precedential panel opinion that included both Under Secretary Kappos and Deputy Under Secretary Sharon R. Barner as well as leaders of the Board.

Status: Briefing stage; awaiting briefing by the PTO as appellee (due date was May 17, 2010).

Third Issue: “Did the Board err by applying a standard of review on appeal that required [appellant] to ‘identify reversible error in an examiner’s finding’ rather than by applying a standard of review that properly put the burden on the examiner to properly support his rejections?”

In re Tanaka – Reissue “Error”

In re Tanaka, Fed. Cir. 10-1262, *proceedings below*, *Ex parte Tanaka*, j2009 WL 5819322 (Bd.Pat.App. & Interf. 2008), deals with “error” under the reissue statute, 35 USC § 251.

Issue: Per the Board’s opinion, “the issue before [the Board] is whether the reissue declaration can satisfy the error required under 35 U.S.C. § 251 when the Appellant is only adding a narrower dependent claim by reissue to the existing patented claims simply as a hedge against possible invalidity of the original claims.”

Status: Awaiting argument.

Classen v. Biogen – Metabolite déjà vu

In *Classen Immunotherapies, Inc. v. Biogen IDEC*, Fed. Cir. 2006-1634, *on remand from the Supreme Court upon Order granting, vacating and remanding in light of Bilski*, ___ U.S. ___ (2010), *earlier Federal Circuit opinion*, 304 Fed.Appx. 866 (Fed. Cir. 2008)(Moore, J.), a clone is presented of the fact pattern of both No. (1) *Prometheus v. Mayo* and the *Metabolite* case. The trial court opinion is reported at 381 F.Supp.2d 452 (2005).

Status: As of August 23, 2010, the Pacer docket sheet for this case did not give any indication of any order by the court for new briefing in light of the Supreme Court decision granting, vacating and remanding the case in light of *Bilski*.

One of the Shortest Merits Opinions in History: The panel opinion consists of less than 100 words: “In light of our decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither ‘tied to a particular machine or apparatus’ nor do they ‘transform[] a particular article into a different state or thing.’ *Bilski*, 545 F.3d at 954. Therefore we *affirm*.”

This case is expected to be considered in parallel with No. (3) *Prometheus v. Mayo*.

SRI v. Internet Security – Statutory Presumption of Validity

In *SRI International, Inc. v. Internet Security Systems, Inc.*, Fed. Cir. App. No. 2009-1562, the accused infringer-appellant Internet Security challenges a jury verdict sustaining patent validity where preliminary negative reexamination results were not presented to the jury and where, following *dictum* in *KSR*, a clear and convincing should not have been followed.

Prior Proceedings: Previously, several patents had been held invalid under 35 USC § 102(b), a split panel reversed on the basis that the prior publication was not prior art, *SRI International, Inc. v. Internet Security Systems, Inc.*, 511 F.3d 1186 (Fed. Cir. 2008)(Rader, J.), over a vigorous dissent, *SRI v. Internet Security*, 511 F.3d at 1198 (Moore, J.).

Status: Corrected Reply Brief was due April 29, 2010.

Second Issue (per Appellant Internet Security): “[W]hether Defendants are entitled to a new trial because the district court erred by admitting one and only one side of the evidence concerning the PTO's consideration of the prior art and by failing to instruct the jury to consider the presumption of patent validity in light of the PTO's findings on reexamination.”

Third Issue (per Appellant Symantec): “Did the district court err by denying a new trial after (a) refusing to instruct the jury regarding the preclusive effect of this Court's prior decision regarding *Emerald 1997*, (b) excluding adverse reexaminations decisions while allowing SRI to mislead the jury, and (c) requiring Defendants to prove invalidity by “clear and convincing evidence” in the face of a related invalidity judgment and adverse reexamination decisions?”

Discussion (per Internet Security): Somewhat different approaches were used by the two legal teams. The following discussion is taken from the brief from former Solicitor General Paul Clement:

“[§ II-]B. The District Court Should Have Instructed The Jury That The Presumption Of Validity Must Be Considered In Light Of The Reexaminations.

“... Defendants' proposed jury instructions would have informed the jury that ‘it may consider the PTO's decision to declare re-examinations and initially reject the

Wegner's Top Ten Patent Cases [September 23, 2010]

claims-in-suit when determining whether or not Defendants have rebutted the presumption of validity' A550-51. The court should have given that instruction for the same reasons it should have admitted evidence of the reexaminations.

“More fundamentally, the district court erred in instructing the jury that it had to find invalidity by clear and convincing evidence. By statute, a patent is presumed to be valid. 35 U.S.C. § 282. This Court has erroneously interpreted that presumption to require accused infringers to prove invalidity by clear and convincing evidence *in all cases*. See *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984). The Court need not reach this issue to order a new trial in this case because the relevant evidence was not even admitted. But if this Court were to uphold the district court's insistence on giving the jury a wholly misleading view of the facts, the impropriety of applying a heightened presumption of patent validity in the circumstances of this case would come to the fore.

“The Supreme Court ‘presume[s]’ that the preponderance of the evidence standard, rather than the clear and convincing one, applies in disputes between private parties. *Grogan v. Garner*, 498 U.S. 279, 286 (1991). By contrast, the clear and convincing standard applies only in two narrow circumstances: when Congress has expressly required it; and in certain rare civil cases where important liberty interests are at stake, such as deportation or denaturalization. See *Addington v. Texas*, 441 U.S. 418, 424 (1979); *Thomas v. Nicholson*, 423 F.3d 1279, 1283 (Fed. Cir. 2005). Neither of those circumstances is present here.

“The statutory presumption of validity does not provide a basis for a clear and convincing evidence standard. Numerous other statutory presumptions are overcome by only a preponderance of the evidence, including: the presumption of validity for copyrights, *Medforms, Inc. v. Healthcare Management Solutions, Inc.*, 290 F.3d 98, 114 (2d Cir. 2002); the Lanham Act provision that registration constitutes a prima facie case that a trademark, or service mark is valid, see *Online Careline, Inc. v. Am. Online, Inc.*, 229 F.3d 1080, 1087 (Fed. Cir. 2000); the presumption that decisions of the Customs Service are correct, *St. Paul Fire & Marine Ins. Co. v. United States*, 6 F.3d 763, 768-69 (Fed. Cir. 1993); and the ‘presumption of service connection for [veterans'] injuries that occur during active duty,’ *Thomas*, 423 F.3d at 1282.

Wegner's Top Ten Patent Cases [September 23, 2010]

“The Supreme Court has consistently held that such traditional principles govern in patent cases. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). Here as in *eBay*, ‘[n]othing in the Patent Act indicates that Congress intended ... a departure’ from traditional principles in setting a standard of proof for patent validity. *eBay*, 547 U.S. at 391-92.”

“Moreover, as the Supreme Court recently observed, ‘[t]he rationale underlying the presumption’ is ‘that the PTO, in its expertise, has approved the claim.’ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). That rationale cannot support the application of a clear and convincing evidence standard in at least two circumstances: when the PTO has rejected the patent on reexamination and when the PTO did not consider some of the relevant art in issuing the patent. Especially where, as here, *both* of those circumstances are present, the clear and convincing evidence standard cannot be justified by the respect and deference due to the PTO’s expertise, because the heightened standard serves to *prevent* due deference to the PTO’s actual actions, a complete corruption of its purpose. If deference has any meaning at all, courts and juries owe deference to *all* PTO decisions, not only to the PTO’s *first* decision or to those decisions that favor patentees.”

Slattery v. United States – En Banc CFC Appeal

Slattery v. United States, Fed. Cir. App. No.2007-5063 has been scheduled for *en banc* oral argument immediately after *Hyatt v. Kappos*, *supra*.

Status: Awaiting decision (en banc argument July 8, 2010).

[The case has not been analyzed.]