

**Wegner's Top Ten Patent Cases**  
[January 1, 2010\*]

***Happy New Year!!!***

**This Top Ten List was prepared in December as the final version for 2009.**

- (1) *Ariad v. Eli Lilly* – § 112, ¶ 1 “Possession”  
awaiting decision (argument December 7, 2009)
- (2) *Microsoft v. Lucent*: Preponderance Standard  
cert. petition expected
- (3) *Bilski v. Kappos* – Patent-Eligibility/Software Methods  
awaiting decision (argument November 9, 2009)
- (4) *i4i v. Microsoft*: Damages  
Awaiting decision (argument Sept.23, 2009)
- (5) *Costco v. Omega* – International Exhaustion  
awaiting S.G.’s CVSG *amicus* brief
- (6) *Mayo v. Prometheus* — “*Metabolite déjà vu*”; *Bilski!*  
cert. petition due December 15, 2009
- (7) *Arkansas Carpenters II* – “Reverse Payments” (Cipro<sup>®</sup>)  
2nd Cir. parallel to Federal Circuit Cipro<sup>®</sup> case
- (8) *Princo v. ITC* –Anticompetitive Patent Misuse  
*en banc* argument March 3, 2010
- (9) *Cardiac Pacemakers v. St. Jude* – § 271(f) *Microsoft* Conflict  
certiorari briefing stage
- (10) *Astellas v. Lupin* – product-by-process infringement **←New**  
certiorari decision expected January 11, 2010

**[Beyond the Top Ten \(see page 2\)](#)**

To facilitate requests for access to the *Top Ten List* and other documents of this writer, the cooperation of Justin Gray is acknowledged with appreciation: His blog website, [www.GrayOnClaims.com/hal](http://www.GrayOnClaims.com/hal), provides selected current documentation of this writer.

About the authorship and this List, *see* page 3.

\*This Revision prepared December 10, 2009.

**Beyond the Top Ten**

- Ferguson v. Kappos* – *Bilski déjà vu*  
possible GVR after *Bilski* decision
- Nebraska Power v. U.S.*: Limitations on D.C. Circuit  
awaiting decision (*en banc* argument September 18, 2009)
- AsymmetRX v. Biocare* – Implied License  
awaiting decision (argument August 4, 2009)
- Trading Technologies v. eSpeed* – Twelve Issues  
awaiting decision (argument August 4, 2009)
- In re Chapman* – Obviousness  
briefing stage
- In re Medicis* – Obviousness  
awaiting decision (argument December 10, 2009)
- Encapsulation Technology* – Obviousness  
Argument December 10, 2009
- Suitco Surface* – Reexamination Claim Construction  
argument January 6, 2010
- In re Arvinmeritor* – Unexpected Results  
awaiting decision (argument December 9, 2009)

### *About the authorship and interest in cases reported*

This paper has been prepared by Harold C. Wegner, former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School. Partner, Foley & Lardner LLP.

The views expressed re personal to the author and do not necessarily reflect the views of any colleague, organization or client thereof. The author acknowledges representation of an amicus party in *State Street Bank*, central to No. (3) *Bilski v. Kappos*, but has no current client relationship with that amicus party.

### *About the Top Ten List*

Top Ten List is solely prepared by Harold C. Wegner and is designed to focus upon cases which may challenge important concepts of patent law. Because a case is *commercially* important is not at all relevant, other than where there is an interesting legal issue the fact of great commercial importance may give greater prominence to the legal issues involved in the case.

**(1) *Ariad v. Eli Lilly* – § 112, ¶ 1 “Possession”<sup>1</sup>**

The Federal Circuit will decide *en banc* whether the judicially legislated “possession” requirement of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed.Cir.2002)(Lourie, J.); and *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed.Cir.2004)(Lourie, J.), finds basis in the statute.

**Status:** Awaiting decision (argued *en banc* December 7, 2009). A decision is expected by May 31, 2010, when the incumbent Chief Judge retires from the Court. (He will not be eligible to consider the final disposition of this case after May 31, 2009, because he has not taken senior status but rather resigned his commission.)

**Issues before the En Banc Court:** “a. Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

“b. If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?”

**Capstone to the Twenty Year Career of Judge Lourie:** Perhaps by April 6, 2010 – his twentieth anniversary on the Federal Circuit – we will reach the culmination of Circuit Judge Alan David Lourie’s one man crusade to engraft standards of patentability tailored to the perceived public policy needs of the major biotechnology and pharmaceutical industries. The capstone of his career is the crafting of a unique “written description” requirement that he has judicially read into United States patent law. This is a remarkable achievement, if successful, but in any case testimony to his perseverance to create special industry-based standards.

**The Argument:** With a vacancy caused by the senior status of Judge Schall, and with four members of the court clearly on record either for a separate “written description” requirement (Newman, Lourie, JJ.)(for) and two against (Rader,

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<sup>1</sup> *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, \_\_ F.3d \_\_ (Fed. Cir. August 21, 2009)(order) (en banc)(granting petition for rehearing en banc), *panel opinion*, 560 F.3d 1366 (Fed. Cir. 2009)(Moore, J.), *opinion below*, 529 F.Supp.2d 106 (D. Mass. 2007)(Zobel, J.).

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Linn, JJ.)(against), the controversy boils down to which side can gain four votes from amongst Michel, C.J., Mayer, Bryson, Gajarsa, Dyk, Prost, Moore, JJ.

Appellee's counsel, Associate Dean John Whealan of the George Washington University Law School, made the point that there *is* a "written description" requirement *and* an "enabling disclosure" requirement in 35 USC § 112, ¶ 1, *but that they are both linked together*: The "written description" must be for enabled disclosure for the full scope of what is claimed.

As the argument has developed with the help of briefing both by the parties and numerous amici, there is a general consensus that most situations where there has been a "written description" denial of patentability occur *where there is also a failure to provide an enabling disclosure for the full breadth of a generic claim*. Judge Bryson pointedly asked whether it was sufficient to apply the enablement standard of 35 USC § 112, ¶ 1, to deny patentability for inadequately disclosed inventions that did not show enablement for the full scope of the claimed invention.

Judge Lourie, who created the current "possession"/"written description" requirement apart from enablement argued that even though there may be redundancy, "judicial efficiency" was a solid basis for maintaining a separate "written description"/possession ground to deny patentability. Circuit. Judge Newman helpfully recalled the old days of chemical inventions when she was a practitioner in support of a separate "written description" requirement.

### **(2) *Microsoft v. Lucent*: Preponderance Standard<sup>2</sup>**

The Supreme Court is expected to be asked to review the current Federal Circuit standard that obviousness of a patented invention under 35 USC § 103(a) is under a "clear and convincing" evidence test, whereas petition is expected to argue that the standard should be a "preponderance" of the evidence as at the PTO in

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<sup>2</sup> *Microsoft Corp. v. Lucent Technologies, Inc.*, Supreme Court petition expected, *opinion below*, *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009)(Michel, C.J.).

reexamination and as per various regional circuit courts of appeal and other authorities.

The petition for rehearing *en banc* builds upon a critical argument in *KSR Int'l Co. v. Teleflex Inc.*, 560 U.S. 398 (2007), made by Professor John Fitzgerald Duffy that was *not* necessary for the decision in that case. (Professor Duffy's argument in *KSR* is reproduced in part below.)

**The Likely "Question Presented:** The following question was raised in the petition for rehearing *en banc*: "Where the validity of a patent is challenged on the basis of prior art that was not considered in the original prosecution, should the standard of proof for a finding of invalidity be a preponderance of the evidence?"

**Status:** The *certiorari* petition is due February 21, 2010.

**Parallel PTO Proceeding under a Preponderance Standard:** Making *Microsoft v. Lucent* a witches brew of circumstances that favor the petitioner, the prior art relied upon in the litigation – that failed to establish obviousness under the "clear and convincing" standard" – *has* been found in the preliminary PTO reexamination proceedings to establish unpatentability under the lower preponderance standard.

**Factors Favoring Grant of *Certiorari*:** Microsoft's petition is an obvious preliminary to a *certiorari* petition that is keyed to a suggestion in *KSR* as well as an allegation of a conflict with circuit court opinions and a conflict with opinions of a government agency as well as scholars. Insofar as the *KSR* case is concerned, the petition states that "Microsoft ... argued that ... the jury had been improperly instructed to apply the clear and convincing evidence standard that, in accordance with the suggestion in *KSR Int'l Co. v. Teleflex Inc.*, 560 U.S. 398, 426 (2007), a preponderance instruction should have been given instead."

*The remainder of the discussion of this case is based upon the Top Ten discussion of this case prior to the panel decision of the court below which outlines the argument likely to be raised by the Court:*

**Microsoft's Potential Supreme Court Challenge – Standard of Review ...**

In its Reply Brief (prior to the panel decision), Microsoft paves the way for a *certiorari* petition that challenges the standard of review in the case of a validity challenged keyed to prior art not considered by the PTO. Noting that its position

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may conflict with binding precedent – which it indeed does – Microsoft acknowledges that “[i]t is then up to the panel to ‘decide whether to ask the regular active judges to consider hearing the case en banc.’” Reply Brief, p. 20, quoting Fed. Cir. R. 35(a)(1)). Microsoft says “[t]hat course of action would be appropriate here.” *Id.*

The standard of review in the case of prior art that was not cited by the Examiner was introduced at the Federal Circuit in a single paragraph of *dictum* in *Connell v. Sears*:

“The [trial court] ... says that when ‘any relevant’ non-considered [prior] art is introduced, the burden upon the patent challenger is thereby changed from a requirement for clear and convincing proof to one of proof by a mere preponderance. Proof, however, relates not to legal presumptions, but to facts. The patent challenger may indeed prove facts capable of overcoming the presumption, but the evidence relied on to prove those facts must be clear and convincing. Thus, the introduction of [prior] art or other evidence not considered by the PTO does not change the burden and does not change the requirement that that evidence establish presumption-defeating facts clearly and convincingly.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983)(Markey, C.J.):

To the extent that Microsoft loses its appeal at the Federal Circuit, its inclusion of a challenge against the standard of review, *here*, may leave the door open to a Supreme Court challenge that focuses upon this issue.

Perhaps the leading patent academic scholar with Supreme Court experience, Professor John Fitzgerald Duffy, has laid out his argument making the exact challenge now voiced by Microsoft in the *KSR* case:

### **Prof. Duffy's Challenge of the “Clear and Convincing” Standard of Review:**

In the merits briefing of *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), Professor John Fitzgerald Duffy of George Washington University Law School argues that the that the standard of review for validity based upon an obviousness challenge should be a preponderance of the evidence and not the clear and convincing standard of the Federal Circuit. This argument was not considered

in the opinion rendered in *KSR*. The arguments, here, are quoted directly from Prof. Duffy's merits briefing of *KSR*.

### Establishment of the Preponderance Standard

[*KSR* Merits Petitioner's Opening Brief, p. 10 n.10]

“In 1983 the Federal Circuit announced, without citation of authority, that *any* facts proffered to support *any* defense of invalidity under 35 U.S.C. § 282(2) must be ‘proven’ in *every* instance by ‘clear and convincing evidence.’ *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983) (‘the evidence relied on to prove those facts must be clear and convincing’) (dictum) (emphasis added). This openly expressed preference for patentees over accused infringers is without basis in the Patent Act or any patent precedent of this Court, and in fact is antithetical to applicable precedents of this Court. *See Herman & McClean v. Huddleston*, 459 U.S. 375, 387-90 (1983) (noting that, outside the context of ‘particularly important individual interests or rights’ such as parental rights or deportation, the Court does not ‘depart from the preponderance-of- the-evidence standard generally applicable in civil actions’).”

### Prof. Duffy's Argument

[*KSR* Merits Reply Brief, pp. 18-20, § B, *Invalidity Under Section 103(a) May Be Proven by a Preponderance of the Evidence*, pp. 18-20. Citations have been omitted in part. Footnote 15 is indicated as ‘[15]’ with the text integrated in brackets.]

“35 U.S.C. § 282 provides in part: ‘The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.’ The statute says nothing whatever about ‘clear and convincing evidence.’ In numerous cases, this Court has determined the merits of patent invalidity defenses without subjecting such defenses to a ‘clear and convincing evidence’ burden of proof.

“Prior to the creation of the Federal Circuit, regional Circuits had held, following this Court's precedents, that in the ‘usual’ patent case, ‘a preponderance of the evidence is sufficient to establish invalidity.’ *Dickstein v. Seventy Corp.*, 522 F.2d 1294, 1297 (6th Cir. 1975); *accord Rains v. Niaqua, Inc.*, 406 F.2d 275, 278 (2d Cir. 1969) (‘[I]n the usual case a preponderance of the evidence determines the

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issue’). The contrary position of the Federal Circuit below traces to dicta in a 1983 Federal Circuit panel decision that gave no reasoning and cited no authority whatsoever.

“Respondents cite *Radio Corp. of America v. Radio Engineering Laboratories, Inc.*, 293 U.S. 1 (1934), for the broad proposition that ‘the clear and convincing evidence standard is well founded because the expert patent examiner has considered the question and deemed the invention non-obvious’. In fact, *Radio Corp.* involved an attempt to re-litigate an issue of inventorship that had previously been determined in a contested adversarial proceeding among the rival claimants. 293 U.S. at 3-6. Such a situation could not be further removed from a case like the present one, where the asserted patent was procured *ex parte* and the facts relied upon to establish invalidity (e.g., the disclosure of the Asano patent) were never the subject of any prior administrative or judicial consideration.

“Issued patent claims are ‘presumed valid.’ 35 U.S.C. § 282. But this presumption has nothing to do with substantive evidentiary burdens and cannot reasonably be read as calling for a blanket imposition of a ‘clear and convincing evidence’ burden of proof with respect to any and all historical facts that might be presented in support of any and every defense of invalidity under 35 U.S.C. § 282(2). See U.S. Federal Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition & Patent & Policy*, chap. 5, at 28 (2003) (‘[T]here is no persuasive reason why the level of that burden should be clear and convincing evidence.’)<sup>[15]</sup>

“ [Contrary to Respondents’ suggestion the burden of proof applicable to historical facts – the probability that a fact is true – is an entirely distinct concept from the probability that a legal conclusion (e.g., patent invalidity) follows from established historical facts. Questions of law are argued, not ‘proved.’ Thus, regardless of whether the invalidity of claim 4 of the Engelgau patent follows more directly from the disclosure of the Asano patent than from the ‘Rixon ’183 system’ cited by Respondents, the burden of proving historical facts in a patent case should not depart from the usual preponderance of the evidence standard in the absence of an explicit legislative command, as exists for example in 35 U.S.C. § 273(b)(4) and various other federal statutes.]

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“ ‘Because the preponderance of the evidence standard results in a roughly equal allocation of the risk of error between litigants, we presume that this standard is applicable in civil actions between private litigants unless ‘particularly important individual interests or rights are at stake.’ *Grogan v. Garner*, 498 U.S. 279, 286 (1991) (quoting *Herman & MacLean v. Huddleston*, 459 U.S. 375, 389 (1983)).

“Congress clearly knows how to specify a ‘clear and convincing evidence’ burden of proof when that is its intention. *See, e.g.*, 35 U.S.C. § 273(b)(4) (‘A person asserting the defense under this section shall have the burden of establishing the defense by clear and convincing evidence.’). It clearly did not do so in 35 U.S.C. § 282. *Cf. KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111, 118 (2004) (where Congress uses language in one section of a statute but not in another, the omission is presumed to be intentional).”

***Federal Circuit, an Invitation for En Banc Consideration:*** This case being so obviously poised for a Supreme Court petition through the combined efforts of Microsoft and *amici*, the advocates manifest an obvious implicit suggestion to the Federal Circuit that it seize the moment to provide *en banc* guidance over the important issues raised in the appeal.

Indeed, the Chief Judge of the Federal Circuit at a recent Harvard Conference noted the *certiorari* petitions to the Supreme Court, but complained about the absence of attempts by leading members of the profession attending this conference to seek *en banc* review at his court. Harvard Law School Conference on Intellectual Property Law *Address of Chief Judge Paul R. Michel*, Cambridge, Massachusetts, pp. 6-8, September 9, 2008. He concluded his remarks by speaking to the patent experts assembled at Harvard, challenging them to seek *en banc* review of important cases: “You in the room know the problems better than anyone. Why not raise them? Then, we can and will act.” *Id.* at 7-8.

The Chief Judge prefaced this conclusion with the observation that his court “ha[s] the expertise and the will to resolve doctrinal problems. What we lack is mainly the opportunity. Why for example did it take a full decade to revisit *State Street*? Because no one asked us to until recently. The same can be said of the central issue decided in *KSR*. It was never simply presented to us in a petition for *en banc* treatment. Oddly, we receive over a hundred a year. Yet few raise such

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fundamental issues as eligible subject matter under § 101, or the Teaching-Suggestion-Motivation test, or the proper methodology for assessing requests for the permanent injunction, or barring them, future damages.

“I doubt that the advocates consider our court lacking diversity of views and backgrounds. Surely, we have in-depth knowledge of the patent doctrine, especially its more problematic areas. Surely, we have the responsibility. Surely we have the will as in recent en bancs such as *Phillips*, *Seagate*, *Egyptian Goddess*, and *Bilski*.

“Why than do we so rarely get these sorts of issues presented in en banc request? I don't know the answer. But I submit to you all that if such petitioners were more strategic and more imaginative, our court could do its part to make the patent law better for everyone.

“What are the gaps? Well, most petitions allege conflicts in the law without real analysis beyond convenient quotes from past decision, which we derisively refer to as ‘cite bites’. Most challenge our result more than our reasoning. Few plumb the depths of the Supreme Court precedent. Almost none discuss practical impacts, empirical evidence or public policy. It is almost as if advocates assume every rule, test, and standard ever articulated even in dicta is both binding and are immutable. But they are not.” *Id.* at pp. 6-7.

***Patent Reexamination Sloth:*** The present case appears to be one that could have been and should have been disposed of through reexamination. In fact, although the first litigation was filed in 2002, it was not until May 2007 that one of the patents in suit was subjected to *ex parte* reexamination. If the “special dispatch” provision of the statute had been complied with, that reexamination would have been *concluded* by now. It remains a major point for PTO reform that the PTO devote sufficient resources to patent reexamination to make the system work: With a \$ 2.1 billion annual budget, the PTO spends relative pennies on reexamination, whereas the instant litigation carries a damages price tag on the order of \$ 500,000,000.00.

Reexamination sloth and the failure to prioritize obviously important cases is manifested by the fact that in this extremely important case it took the PTO nearly

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three (3) full months to issue its latest Office Action, a Final Rejection dated March 26, 2009.

Furthermore, despite the manifestly more efficient electronic filing of correspondence, the PTO in its outstanding Final Rejection has *invited* the use of electronic filing, but not compelled such filing.

### **(3) *Bilski v. Kappos* – Patent Eligibility<sup>3</sup>**

**Status:** Awaiting decision, likely first quarter 2010 (argument November 7, 2009).

***Main (First) Question Presented:*** “Whether the Federal Circuit erred by holding that a ‘process’ must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing (‘machine-or-transformation’ test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court’s precedent declining to limit the broad statutory grant of patent eligibility for ‘any’ new and useful process beyond excluding patents for ‘laws of nature, physical phenomena, and abstract ideas.’”

***What’s in Doubt:*** There is hardly any doubt about the outcome with virtually everyone saying that the decision below will be affirmed. The principal question in doubt is whether the sweeping machine-or-transformation test of the *en banc* court below will be followed or whether a narrower affirmance will be focused merely upon the invention in question being to an abstract (and therefore patent-ineligible) idea.

***The Court’s Absurd Hypothetical Examples:*** In an exercise of *reductio ad absurdum* several members seemingly had a contest to set forth the most extreme example of an unpatentable invention seemingly within petitioner’s ambit of patent-eligible subject matter. Justice Scalia was the obvious winner with his suggestion that a nineteenth century horse whisperer’s training techniques were patent-eligible under the *Bilski* patent-eligibility umbrella. Runners up were methods to “buy low and sell high” (Chief Justice), speed dating (Justice Sotomayor) and law school teaching (Justices Breyer and Ginsburg).

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<sup>3</sup> *Bilski v. Kappos*, Supreme Court No. 08-964, *certiorari* granted June 1, 2009, *opinion below*, 545 F.3d 943 (Fed. Cir. 2008)(*en banc*)(Michel, C.J.)

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Petitioner refused to say that any of these far-fetched were in any way unpatentable. For a summary, see Kevin Noonan, *Supreme Court Bilski Argument*, Patent Docs (November 9, 2009), <http://www.patentdocs.org/2009/11/supreme-court-bilski-argument.html>.

[Further details of the case are found in the November 17th *Top Ten* discussion at pp. 5-7, available at [www.GrayOnClaims.com](http://www.GrayOnClaims.com).]

### **(4) *i4i v. Microsoft: Damages*<sup>4</sup>**

Along with *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009)(Michel, C.J.), this case involves the review of a massive damages award for what appears to be, at most, a minor infringement by Microsoft for inclusion on its Windows® software of a minor component that had at most minor use by the public and which was not basis for the purchasing public's choice to purchase Windows®.

**Status:** Awaiting decision; argument September 23, 2009 (Prost, Schall, Moore, JJ.).

**Discussion -- Is statutory damages reform necessary?** Is statutory damages reform as proposed in the current Congress necessary or desirable? *Lucent v. Gateway* prior to decision and the instant *i4i* case represent poster child exhibits for why damages reform is necessary.

But, why not apply the *existing* damages test of *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F.Supp. 1116 (S.D.N.Y.1970)? Indeed, in both *Lucent v. Gateway* and the trial court opinion in *Cornell University v. Hewlett-Packard Co.*, 2008 WL 2222189 (N.D.N.Y. 2008)(Rader, J.), there were successful applications of the *Georgia-Pacific* test.

But, both *Lucent v. Gateway* and *Cornell v. Hewlett-Packard* manifest the opinions of two of the most senior patent experts on the judiciary, the current Chief Judge and his successor on the Federal Circuit each with more than twenty years of

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<sup>4</sup> *i4i Limited Partnership v. Microsoft Corp.*, Fed. Cir. No. 2009-1504.

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judicial experience. The idea that even the most brilliant and experienced trial judge *without significant patent experience* could readily navigate the waters of *Georgia-Pacific* is contrary to actual reality. The answer could and should be that all patent trials should be before patent-experienced members of the judiciary.

***Appellant's Statement of the Issue:*** Whether the district court erred in holding that Prometheus's patents-which claim methods for individually calibrating the appropriate dosages of synthetic drugs for treatment of patients with various autoimmune diseases-are merely unpatentable 'natural phenomena.'”

***Appellee's Argument; Reply Brief:*** The latest briefs available from Westlaw are limited to the principal brief of appellant and amici in support of appellant or neutral.

***Amici Briefs:*** Briefs have been filed either supporting appellant or neutral by the Biotechnology Industry Organization (BIO), self-styled Interested Patent Law Professors, Novartis and Myriad Genetics.

***Biotechnology Industry Organization:*** The BIO summary of the argument states:

“In *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), this Court endorsed a ‘machine or transformation’ test for assessing patent subject matter eligibility for process claims. This test provides a useful conceptual framework for the technology context in which it arose, but it is problematic and raises significant questions when applied to scientific and technological advances in the field of biotechnology. These questions have particular importance for research and development efforts in emerging disciplines such as ‘personalized’ and preventative medicine, crop science, and modern animal husbandry. These disciplines focus significantly on deducing complex interrelationships within biological systems, and then applying that knowledge to develop new and useful methods of diagnosis, treatment and prevention of disease, plant selection and breeding, and livestock production, among others.

“If this case and others establish broad exclusions of technological subject matter without fully considering the consequences of those exclusions, significant and important sectors of the biotechnology industry could be denied participation in the U.S. patent system, with attendant negative effects on incentives for innovation in these sectors. Promising innovative products that could benefit patients and consumers would be developed abroad, or not at all.

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“The claims of the Prometheus patents involved in this appeal are not directed to a ‘fundamental principle’ ( *i.e.*, a law of nature, natural phenomenon, or abstract idea) that is ‘part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none.’ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). The court below erred in concluding that they were. In addition, the reasoning the court employed to reach its conclusion that the claimed methods were patent-ineligible could call into question the patent eligibility of many claims to processes that make use of ‘data’ obtained by measuring or evaluating the operation of biological systems. The district court committed significant error by failing to consider the patent claims as a whole, and instead assessed the effect of only certain limitations in isolation. Moreover, the claims define a process that would satisfy the ‘transformation’ branch of the ‘machine or transformation’ test as this court has explained in *Bilski*.

“*Bilski* left several aspects of the application of the ‘machine or transformation’ test unanswered or insufficiently clear. BIO urges the Court to clarify the law in those aspects of the test that are implicated by its resolution of this case.”

***Interested Patent Law Professors***: The *amicus* brief of *Interested Patent Law Professors in Support of Neither Party* was filed by Professor Christopher M. Holman. The Interested Patent Law Professors argue:

“The district court erred in characterizing an entirely man-made biological correlation, which did not and could not exist absent human intervention, as an unpatentable ‘natural phenomenon’ under 35 U.S.C. § 101. This overly expansive definition of the term ‘natural phenomena’ is contrary to precedent, and the district court was incorrect in finding support for its decision in a dissenting opinion by Justice Breyer in *Laboratory Corp. of America Holding v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) ..., and in this Court's recent decision in *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007), *cert. denied*, 129 S. Ct. 70 (2008). Contrary to the district court's conclusion, the mere fact that the breakdown of a man-made, non-naturally occurring drug (*i.e.*, drug metabolism) involves natural processes in the body does not render the breakdown of the drug a natural process, nor does it render a correlation between these non-naturally occurring drug breakdown products (*i.e.*, drug metabolites) and the optimal dosage of the drug a natural phenomenon. There is a fundamental distinction between a *natural* metabolite, such as the homocysteine in [*Metabolite*], and a *drug* metabolite, which is the breakdown product of a drug, and thus no more a natural phenomenon than is the drug itself. If not reversed, the decision below could cast doubt on the patentability of many important innovations, particularly in the area of

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biotechnology and life sciences. Furthermore, a reversal of the lower court's expansive definition of natural phenomena to include man-made biological correlations would in no way impede the courts from invalidating a patent claim pre-empting a true natural phenomenon. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), did not obviate the necessity to accurately distinguish between non-natural and natural phenomena, and the instant case provides appropriate facts for this Court to provide critical guidance for future courts faced with this important inquiry.”

**BIO's Failure to Understand *Funk v. Kalo*:** The BIO *amicus* brief misunderstands the holding of *Funk v. Kalo*, instead *distinguishing* the case: “The claims of the Prometheus patents involved in this appeal are not directed to a ‘fundamental principle’ ( *i.e.*, a law of nature, natural phenomenon, or abstract idea) that is ‘part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none.’ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).” The BIO brief repeats the same mistake made by in the *certiorari* petition process by *amici* in No. (1) *Bilski v. Kappos*, discussed *supra*.

**Who's Afraid of Justice Stephen Breyer?** The opinion of the trial court follows the *procedural* dissent by Justice Breyer in *Metabolite* which is discussed under No. (3) *Bilski v. Kappos*, *supra*.

### (5) *Costco v. Omega – International Exhaustion*<sup>5</sup>

The Supreme Court decision on October 5, 2009, to defer a *certiorari* vote to obtain the views of the government through a CVSG order keeps the door open for a Supreme Court review of the question of “international exhaustion”. Although the context, here, is in the copyright context, spillover implications may exist for patents as well. The greater likelihood that international exhaustion in the patent context may eventually be reviewed by the Court is considered in more detail in Harold C. Wegner, *Post-Quanta, Post-Sale Patentee Controls*, 7 J. Marshall Rev. Intell. Prop. L. 682, 698 (2008).

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<sup>5</sup> *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.)

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**Status:** A *certiorari* vote awaits the filing of an invited *amicus* brief CVSG from the Solicitor General. The invitation, extended by order on October 5, 2009, has no time limit. Based upon the pattern of recent years, there may be a considerable time interval between the Order and the filing of the *amicus* brief. (The Office of the Solicitor General faces tight time deadlines for virtually all other matters.)

**Discussion:** 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.

*Costco v. Omega* raises the issue of international exhaustion in the context of copyright law, which may have implications as to the parallel considerations of international exhaustion in the context of *patent* law. “International exhaustion” for patents has been *denied* in the United States by the Federal Circuit in *Jazz Photo* and *Fuji Photo*. In “Quanta II”, *LG Electronics, Inc. v. Hitachi, Ltd.*, 2009 WL 667232 (N.D.Cal. 2009)(Wilkins, J.), a trial court has repudiated *Jazz Photo* and *Fuji Photo* on the basis that the decisions are inconsistent with the subsequent ruling in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S.Ct. 2109 (2008).

**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.”

**“Quanta II” – The *Costco* Petition for *Certiorari*:** At note 8 of the *certiorari* petition in *Costco v. Omega*, petitioner cites the “Quanta II” opinion, which is reproduced in pertinent part later in this paper as ‘Quanta II’. The petition in *Costco v. Omega* notes that “[i]n the analogous area of patent exhaustion, one court recently noted that ‘[d]rawing such a distinction between authorized domestic sales and authorized foreign sales would negate the Supreme Court's stated intent in

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*Quanta [Computer, Inc. v. LG Elecs., Inc., 128 S. Ct. 2109 (2008)]* to eliminate the possibility of a patent holder doing an ‘end-run’ around the exhaustion doctrine by authorizing a sale, thereby reaping the benefit of its patent, then suing a downstream purchaser for patent infringement.’ *LG Elecs.*, 2009 WL 667232, at \*10. Analogous concerns are present here.”

***Laser Dynamics:*** More recently in *LaserDynamics v. Quanta Storage America, Inc.*, \_\_ Westlaw \_\_ (E.D. Tex. 2009)(Ward, J.), the court *denied* the theory of international exhaustion. Citing the Federal Circuit opinions that had been distinguished by Judge Wilken in the “Quanta II” case, the court said that “the exhaustion doctrine does not apply to sales made overseas by the plaintiff’s licensees.”

***STMMicroelectronics:*** In *STMMicroelectronics*, the court found international exhaustion on the basis that there was a worldwide license so that the sale by the licensee in any country of the world exhausted the patent right:

“[D]oes the patent exhaustion doctrine apply where United States patents are covered in a world wide license even when the first sale occurs outside the United States? As a general rule, to invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent. *See Boesch v. Graff*, 133 U.S. 697, 701-703 (1890) (lawful foreign purchase does not obviate the need for a license from the United States patentee before importation into and sale in the United States). The *Jazz Photo* case does not stand for the proposition that only sales within the United States can trigger the doctrine when there is a valid license covering the products. [STMicroelectronics] gave Toshiba a license in all types of patents with respect to the licensed products *in all countries of the world*. All the countries of the world includes the United States of America. Therefore, Toshiba ... had the right to sale any of the licensed products under the United States Patents ... in the United States or anywhere in the world.” *STMicroelectronics, Inc. v. Sandisk Corp.*, 2007 WL 951655 (E.D.Tex. 2007)(Bush, Maj. J.).

### (6) *Mayo v. Prometheus* -- Metabolite déjà vu<sup>6</sup>

*Mayo v. Prometheus* considers anew the patent-eligibility of a medical treatment method; this case becomes extremely important in view of *Bilski v. Kappos*, as both cases relate to patent-eligibility under 35 USC § 101. Whether a medical diagnosis method is patent-eligible subject matter under 35 USC § 101 has been a subject of debate for several years, particularly once the Supreme Court had *dismissed* a case raising the issue but under the wrong statutory basis, *Lab. Corp. of Am. Holdings v. Metabolite, Inc.*, 548 U.S. 124 (2006) (Breyer, J., dissenting from dismissal of certiorari).

**Status:** *Certiorari* briefing stage (awaiting response to the petition).

**Question Presented:** “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) (“*LabCorp*”), 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 *LabCorp* 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.”

**The Majority Opinion – Declaring War on Justice Breyer’s Dissent:** Nowhere in the main text of the Federal Circuit panel opinion is there any discussion

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<sup>6</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, Supreme Court No. 09-\_\_\_\_\_, *opinion below*, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009)(Lourie, J.)

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whatsoever concerning the conflict between the panel's opinion and the procedural dissent of Justice Breyer in the *Metabolite* case.

Rather, the sole commentary is found in footnote 3 that simply states that Justice Breyer's "dissent is not controlling law and also involved different claims from the ones at issue here."

The entire footnote reads as follows:

"[T]he district court relied heavily on the opinion of three justices dissenting from the dismissal of the grant of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (Breyer, J., dissenting). See [*Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-CV-1200, 2008 WL 878910, at \*8 (S.D.Cal. Mar. 28, 2008)] (discussing the dissent in *Laboratory Corp.* at length and stating that although the dissent 'does not have precedential value, the Court finds Justice Breyer's reasoning persuasive'). That dissent is not controlling law and also involved different claims from the ones at issue here."

**Medical Treatment Method:** The claim is to –

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  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the levels of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

***Expected Attack from the Medical Community:*** The Federal Circuit opinion represents a frontal assault on the procedural dissent in the Supreme Court *Metabolite* case and has patent-eligibility issues under 35 USC § 101 that may depend upon the decision of the Court in *Bilski v. Kappos*. Indeed, the American Medical Association and several other *amici* jointly through the voice of New York University Law School Professor Katherine Strandburg have joined in the *Bilski* proceedings for the express purpose of arguing the *Prometheus* issue, a

preview of the likely Supreme Court petition in that case. Professor Crouch has made a copy of Professor Strandeburg's brief available at <http://www.patentlyo.com/08-964-bsac-the-american-medical-association.pdf>.

### **(7) *Arkansas Carpenters II* – “Reverse Payments” (Cipro<sup>®</sup>)<sup>7</sup>**

On June 22, 2009, the Supreme Court denied *certiorari* in the companion *Arkansas Carpenters* case that presented the same issue, where the Federal Circuit in the decision below had denied an antitrust violation, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008)(Prost, J.). The current “Arkansas Carpenters II” case is now before the Second Circuit to consider the same issue.

To the extent that the Second Circuit would reach the opposite conclusion from that of the Federal Circuit, this would naturally provide added impetus for a Supreme Court review of “reverse payments”.

***Department of Justice Amicus Brief at the Second Circuit:*** Whereas the Justice Department of the Bush Administration had supported reverse payment settlements, under Christine Varney the Obama Administration is now strongly questioning reverse payments. A strong *amicus curiae* brief has recently been submitted by the Department of Justice to the Second Circuit in this case.

***Question Presented in “Arkansas Carpenters I” (denied):*** “Are pharmaceutical ‘reverse payment’ agreements - whereby the manufacturer of a brand-name drug (and patent holder) pays a generic manufacturer (and alleged patent infringer) to not launch a generic version of the brand-name drug - *per se* lawful without regard to the amount of cash paid or the strength of the underlying patent challenge?”

***The United States View as Amicus Curiae:*** In the *Summary* of its brief *amicus curiae*, the United States states its position, the government “focus[es] on the narrow questions the Court posed with respect to settlements involving a payment from the patent holder to the alleged infringer in return for withdrawal of a validity challenge in the context of the Hatch-Waxman Act.

“The Patent Act... expressly grants patentees the right to enforce their patents through litigation but requires them to accept the risk of patent invalidation in

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<sup>7</sup> *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 2nd Cir. No. 05-2851-cv(L).

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exercising it. Although settlement of patent litigation is generally to be encouraged, settlements involving reverse payments substantially in excess of anticipated litigation costs may upset the balance Congress struck between the public interest in encouraging innovation and the public interest in competition. Reverse payments are scarcely essential to the voluntary settlement of patent disputes; to the contrary, they appear to be essentially unknown outside the Hatch-Waxman context.

“Private agreements that include reverse payments are properly evaluated under the antitrust rule of reason, which takes into account efficiency-related justifications as well as anticompetitive potential. The anticompetitive potential of reverse payments in the Hatch-Waxman context in exchange for the alleged infringer's agreement not to compete and to eschew any challenge to the patent is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act. Defendants may rebut that presumption by providing a reasonable explanation of the payment, so that there is no reason to find that the settlement does not provide a degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success.

“Whether this Court properly has jurisdiction over these appeals depends on the elements of a plaintiff's claim. A well-pleaded complaint requires no allegation regarding a question of patent law. Thus, in our view, this Court has jurisdiction over these appeals.”

**Discussion:** The viewpoint in favor of reverse payments has been expressed by Professor Christopher M. Holman, *Do Reverse Payment Settlements Violate The Antitrust Laws?*, 23 Santa Clara Computer & High Tech. L.J. 489 (2007), while the case against reverse payments has been made by Professor Mark A. Lemley, most recently in his brief for *amici* supporting the grant of the petition in *Arkansas Carpenters I*.

**Senate Legislation to Outlaw Reverse Payment Settlements:** In parallel with the ongoing Second Circuit litigation, the United States Senate now has before it legislation that would outlaw “reverse payment” settlements, Kohl, S. 369, *Preserve Access to Affordable Generics Act*. The bill has gone through the Senate Judiciary Committee in an amended form. It has not been scheduled for full Senate consideration.

**(8) *Princo v. ITC* –Anticompetitive Patent Misuse<sup>8</sup>**

The Court will reconsider *en banc* patent misuse issues as well as unrelated procedural questions in *Princo*. This will be the last *en banc* argument heard before Chief Judge Michel before he steps down from the Court on May 31, 2010. (If the case is not decided by that time, the opinion may be reassigned by new Chief Judge Rader. The incumbent has resigned his commission, as opposed to taking senior status and would not participate in a decision if the case remains pending through June 1, 2010.)

**Status:** Oral argument is scheduled for March 3, 2010.

**Issues:** The petition by Phillips raises two issues for *en banc* consideration, keyed to an alleged conflict with *Finnigan Corp. v. ITC*, 180 F.3d 1354, 1363 (Fed. Cir. 1999):

“1. Whether a supposed agreement, between developers of new technology and a new product standard, to license one of the resulting patents only for use under that standard, thus foreclosing the possibility that it might be used to create a competing standard, could be held anticompetitive without (i) defining a relevant market in which the standards compete and (ii) proving that the agreement injured or was likely to injure competition in that market.

“2. Whether such an agreement, even if deemed anticompetitive, would be a proper basis for invoking the doctrine of patent misuse to refuse enforcement of *different* patents used to practice the joint standard.”

A *separate* issue raised for *en banc* consideration is raised in the parallel petition of the International Trade Commission:

The ITC argues that “the panel majority decision is contrary to the decision of the Supreme Court of the United States in *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33 (1952), and consideration by the full court is therefore necessary to secure and maintain uniformity of the court's decisions.”

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<sup>8</sup> *Princo Corp. v. International Trade Com'n*, \_\_\_ F.3d \_\_\_, 2009 WL 3261589 (Fed. Cir. 2009)(en banc)(order), vacating panel opinion, 563 F.3d 1301 (Fed. Cir. 2009)(Dyk, J.).

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Explaining the alleged conflict with *L.A. Tucker Truck Lines*, “the panel majority misapprehended the arguments raised by the parties during the underlying administrative proceeding and misapprehended the Commission's final determination on the issues presented. As a result, the panel majority would require the Commission to address on remand a patent misuse defense not presented below. The panel majority's decision raises the possibility that the outcome of multi-year litigation would be decided on an issue for which the affected parties had no notice. The decision is contrary to *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952) (“[O]rderly procedure and good administration require that objections to the proceedings of an administrative agency be made while it has opportunity for correction in order to raise issues reviewable by the courts.”).

### **(9) *Cardiac Pacemakers v. St. Jude* – § 271(f) Microsoft Conflict<sup>9</sup>**

This case presents a conflict with *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437 (2007), which has sharply curtailed the extraterritorial scope of a patent under 35 USC § 271(f). Instead of a frontal assault on this two year old Supreme Court precedent, two *other* issues are first presented with the conflict with this Supreme Court precedent tucked away as a *third* Question Presented. Petitioner must be given credit for an imaginative strategy.

**Status:** Opposition to the *certiorari* petition is due December 17, 2009.

**Three Questions Presented:** “A widespread difficulty in patent litigation is the long period necessary to resolve a case. This case is about to enter its 14th year. In many instances, the delay is attributable to permitting the defendant upon remand to raise previously available but not previously asserted defenses. A first question is

“1. Should a defendant be permitted to use “the accident of a remand” to raise previously available but not previously asserted defenses?

“Patent protection is important for an economy heavily based upon technology. Although this Court recently held in one context that method and product inventions should be treated similarly (*Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S.Ct. 2109 (2008)), the Federal Circuit's *en banc* decision in another

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<sup>9</sup> *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, Supreme Court No. 09-596, *opinion below*, 576 F.3d 1348 (Fed. Cir. 2009)(*en banc*)(Lourie, J.).

context does not provide such similar treatment and significantly restricts protection for method inventions. Two additional questions are

“2. Where the value of a method invention is its availability for use if needed, should damages for infringement be restricted to actual use?”

“3. Should the maker of a product capable of performing a patented method be liable for products made here but sold abroad, *i.e.*, does 35 U.S.C. §271(f) exclude method claims?”

***Skirting the Conflict with Microsoft:*** At first blush, it would appear that *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437 (2007), makes denial of *certiorari* a slam dunk. Yet, the artful wording of the *certiorari* petition that avoids *Microsoft* seeks to avoid this conclusion.

The petition dismisses *Microsoft* in a single paragraph: “The only intervening event of record [in the past four years] (for St. Jude) is this Court's decision in *Microsoft...*, but this Court specifically left for another day the issue whether ‘an intangible method or process’ can qualify as a ‘patented invention’ under §271(f). *Id.* at 452, n.13. Although this Court in *Microsoft* spoke of the presumption against extraterritoriality, the Federal Circuit in its decision gives this presumption little emphasis, regarding it as a resolver of ‘[a]ny ambiguity.’ ... [T]he reason for the Federal Circuit's reversal of its position in a less than four year period is not clear.”

***Mike Jakes brought in as Co-Counsel:*** Interestingly, counsel has enlisted for Supreme Court expertise the head of the appellate practice group the same lead counsel as in No. (3) *Bilski v. Kappos*.

### **(10) *Astellas v. Lupin* – Product-by-Process Infringement<sup>10</sup>**

The Supreme Court is asked to review the 8-3 split *en banc* ruling of the Federal Circuit that a product-by-process claim is infringed only when the product of that process is produced by the enumerated process. Rader, J., joined by Michel, C.J., Bryson, Gajarsa, Linn, Dyk, Prost, Moore, JJ. The other view is that a product-by-process claim is infringed when the same product is made by *any* process,

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<sup>10</sup> *Astellas Pharma, Inc. v. Lupin Ltd.*, Supreme Court No. 09-335, *opinion below*, *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009)(*en banc* in relevant part)(Rader, J.).

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including a process outside the scope of the process defined in the claim. Newman, Lourie, Mayer, JJ., dissenting. (The twelfth member of the Court, Schall, J., did not participate.)

**Status:** This case is scheduled for the January 8, 2010, Conference, which means that the Orders List for January 11, 2010, should include a decision as to whether *certiorari* is granted.

**Question Presented:** Whether the United States Court of Appeals for the Federal Circuit erred in ignoring the Court's binding precedent and finding product-by-process claims are not infringed by an identical product made by a different process?

**“[I]gnoring the Court's binding precedent...”:** The majority below pins its case on decisions from the Supreme Court as well as circuit courts of appeal. Insofar as Supreme Court precedent is concerned, the majority cites seven cases. *See Abbott v. Sandoz*, 566 F. 3d at 1291-92 (citing *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224 (1880); *Merrill v. Yeomans*, 94 U.S. 568 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884); *The Wood-Paper Patent*, 90 U.S. (23 Wall.) 566 (1874); *Plummer v. Sargent*, 120 U.S. 442 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938))

**Question discussed but NOT presented:** Whether the Federal Circuit improperly decided this case *en banc*, *sua sponte*, with no public notice?

This issue is prominently featured as an argument in the *certiorari* petition that focuses upon the fact that the Federal Circuit granted *en banc* review without notice to the public. It did so *sua sponte* and issued its decision as the first notice that *en banc* consideration had been given to the case.

This procedure is bluntly attacked in a sharp dissent by three members of the court in their dissent below as contrary to the Federal Rules of Appellate Procedure:

“The court has given no notice of this impending *en banc* action, contrary to the Federal Rules of Appellate Procedure and contrary to the Federal Circuit's own operating procedures. The *en banc* court has received no briefing and held no argument, although the Federal Rules so require.” *Abbott v. Sandoz*, 566 F. 3d at

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1301 (Newman, J., joined by Mayer, Lourie, JJ., dissenting from en banc Section III.A.2).

***Violation of the Federal Rules, Myth or Reality?*** The dissent, of course, provides an interpretation of the Federal Rules of Appellate Procedure that does not comport with reality. The Federal Circuit itself has chosen to issue an opinion *en banc* with no prior notice to the public, a practice which dates back twenty-seven years to the very first opinion of the court itself, *South Corporation v. United States*, 690 F.2d 1368 (Fed. Cir. 1982)(*en banc*)(Markey, C.J.).

Although Petitioner does not mention *South Corporation*, Petition does acknowledge various Federal Circuit cases that were decided *en banc* without any prior notice to the public of the *en banc* status, *Midwest Industries, Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) (*en banc* in part, *overruled on other grounds*), and *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (*en banc* in part); *In re Violation of Rule 50*, 78 F.3d 574 (Fed. Cir. 1996) (*en banc*).

### **Other Cases**

#### ***(Ferguson v. Kappos – Bilski déjà vu*<sup>11</sup>**

The legal underpinning for this decision is the *Bilski* opinion now on review at the Court, No. (3) *Bilski v. Kappos*.

**Status:** Awaiting conference for *certiorari* vote. (It is possible that the petition is being *held* until after a decision in *Bilski v. Kappos*. The electronic Supreme Court docket sheet (as of October 26, 2009) shows that the case was scheduled for Conference for September 29, 2009, but no decision on a *certiorari* vote was announced.)

**Questions Presented:** “(1) Are claims that recite business methods unpatentable per se when they are not tied to a machine and do not preempt any mathematical algorithm?

“(2) Is a claim properly unpatentable under 35 U.S.C. § 101 as being an abstract idea only because it does not come within the test of ‘machine or transformation’ set forth by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)?”

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<sup>11</sup> *Ferguson v. Kappos*, Supreme Court No. 08-1501, *opinion below*, *In re Ferguson*, 558 F.3d 1359 (Fed. Cir. 2009)(Gajarsa, J.).

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**A Possible GVR in 2010:** If the case is held until after a decision in *Bilski v. Kappos*, one option would be for the Court to then issue an order granting *certiorari*, vacating the opinion below and remanding the case to the Federal Circuit for further consideration in light of *Bilski v. Kappos*, a so-called “GVR” one line per curiam decision.

### ***Nebraska Power v. U.S.: Limitations on D.C. Circuit*<sup>12</sup>**

In *Nebraska Public Power*, the Federal Circuit considers whether a D.C. Circuit mandamus order violates the jurisdiction of the D.C. Circuit.

**Status:** Awaiting decision (*en banc* argument September 18, 2009).

**Issue:** In its *per curiam* order announcing the *en banc* status of the case, the court asks for briefing and argument on the following questions:

“Does the mandamus order issued by the [D.C.] Circuit in *Northern States Power Co. v. United States Dep’t of Energy*, 128 F.3d 754 (D.C. Cir. 1997)[,] preclude the United States from pleading the ‘unavoidable delay’ defense to the breach of contract claim pending in the United States Court of Federal Claims, and if so, does this order exceed the jurisdiction of the [D.C.] Circuit?”

**Discussion:** One circuit judging the jurisdictional limits of a sister circuit necessarily presents a touchy issue, one that could well attract the attention of the Supreme Court.

### ***AsymmetRX v. Biocare – Implied License*<sup>13</sup>**

This case considers whether there is an implied license under certain patents to use the technology of the agreement:

**Issues** (as stated by Appellant): “[1. W]here the accused infringer asserted an ‘implied license’ defense to defend against its sale of material covered by the asserted patents, did the District Court err as a matter of law in interpreting a provision in a Biological Materials License Agreement, which provided the

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<sup>12</sup> *Nebraska Public Power Group v. United States*, Fed. Cir. App. No. 2007-5083.

<sup>13</sup> *AsymmetRX, Inc. v. Biocare Medical LLC*, Fed. Cir. No. 2009-1094.

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underlying biological materials to the defendant and which expressly stated that '[t]he license granted by this Agreement does not include a license under *any* U.S. or foreign patents,' (emphasis added [by petitioner]) to exclude a license only to patents that were in existence at the time the Agreement was executed?

“[2. D]id the District Court err as a matter of law when it concluded on the summary judgment record before it that there was no material question of fact, and that the accused infringer had an implied license to the asserted patents -- despite the fact that the Biological Materials License Agreement which provided the underlying infringing material expressly included a statement that '[t]he license granted by this Agreement does not include a license under any U.S. or foreign patents' and despite other evidence that the licensor never intended to grant a patent license to the defendant, and the defendant understood that?”

**Issues** (as stated by Biocare): “In framing its issues for this Court, AsymmetRx advances issues that were ruled on by the lower court on an alternative basis - - *to wit*, whether the District Court erred in holding that Biocare has an implied license to use the patents at issue. ... In doing so, AsymmetRx completely side-steps the District Court's overriding analyses concerning interpretation of Biocare's License, and corresponding ruling that (1) the License was an unambiguous agreement that did not restrict Biocare's sales of the p63 antibodies to the life science research market; and, (2) that § 2.5 did not expressly exclude any rights covered by the '256 and '227 patents. ...

“Biocare reasons that if this Court were to find that the District Court erred in finding an implied license, it would not affect the lower court's ruling of an unambiguous agreement that does not restrict Biocare's right to use and sell the p63 antibodies – an issue not being appealed by AsymmetRx. .... Such ruling by this Court on the implied license issue would present a conflicting result inasmuch as Biocare would be free to sell the biological material in the commercial diagnostic market yet, when doing so, would be infringing on the patents-at-issue. As such, AsymmetRx's Appeal directed only at the implied license issue is illogical and must be dismissed.”

**Status:** Oral argument was held August 4, 2009 (Lourie, Rader, Clark, JJ.)

**Discussion:** Neither party has cited or briefed the relevance of *Quanta* to this case.

***Trading Technologies v. eSpeed – Twelve Issues***<sup>14</sup>

Best practices for an appeal dictates selection of a focused issue – or two – that can capture the interest of the appellate bench. In this case, appellant presents five (5) issues, trumped by his opponent who presents seven (7) issues.

**Status:** Oral argument was held August 4, 2009 (Lourie, Rader, Clark, JJ.)

**Five Issues** (appellant):

“1. Whether the district court erred in narrowly construing the claim term ‘static’ as requiring that the price levels:

*never* change positions [which the court defined as precluding ‘any movement’] unless by *manual* re-centering or re-positioning;

when ‘static’ is explicitly and broadly defined in the patent specification as requiring that the price levels:

do not normally change positions unless a re-centering command is received?

“2. Whether the district court erred in finding no literal infringement by the Dual Dynamic and eSpeedometer products when under the proper construction of ‘static,’ those products meet all of the limitations of the asserted claims?

“3. Whether the district court erred in barring TT from asserting DOE against eSpeedometer by ruling that ‘static’ (as construed by the district court) was narrowed by amendment during prosecution, when in fact there was no narrowing amendment?

“4. Whether the district court erred in barring TT from asserting DOE against Dual Dynamic by ruling that doing so would vitiate the ‘static’ claim term, when there is only a subtle difference of degree between the ‘static’ claim term (as construed by the district court) and Dual Dynamic?

“5. Whether the district court erred in granting JMOL overturning the jury's verdict of willful infringement because of its mistaken belief that there was no evidence

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<sup>14</sup> *Trading Technologies International, Inc. v. eSpeed, Inc.*, Fed. Cir. 2008-1392.

that the infringing products were sold after the patents-in-suit issued, when in fact there is substantial evidence in the record that eSpeed continued selling its infringing product after the patents issued?

***Espeed's Seven Issues:***

“1. Did TT's sale of custom software embodying the invention to Brumfield before its earliest possible critical date, March 2, 1999, constitute an on-sale bar?

“2. Were the Patents-in-Suit entitled to the benefit of the filing date of TT's provisional application, March 2, 2000, as was necessary to antedate Brumfield's commercial use of the custom software that began in March 1999, where the provisional contained no written description supporting the limitation ‘single action of a user input device’ as broadly construed by the court?

“3. Was the following information, which TT failed to disclose to the PTO, material to prosecution of the Patents-in-Suit: (a) that TT sold custom software embodying the invention to Brumfield, then one of the world's highest-volume futures traders, before March 2, 1999, TT's earliest possible critical date; and/or (b) that Brumfield commercially used the custom software to do his proprietary futures trading between March 2, 1999 and the critical date of TT's non-provisional application, June 9, 1999, and thus it was ‘intervening’ art that would have required the PTO to make a priority date determination?

“4. Is the limitation ‘single action of a user input device,’ as construed by the court, indefinite?

“5. Is the limitation ‘static display of prices’ correctly construed as ‘a display of prices comprising price levels that do not change positions unless a manual re-centering command is received’ in light of the claim language, specification, and prosecution history.

“6. Should the summary judgment that automatically re-centering price displays do not infringe the ‘static display of prices’ limitation by equivalents be affirmed on any of three alternative grounds: (a) no proof of equivalency-in-fact; (b) claim vitiation; and/or (c) prosecution history estoppel?

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“7. Was there sufficient evidence for a reasonable jury to find that continued use by customers of software that was launched by eSpeed before the Patents-in-Suit issued, for four-to-five months after issue, was a willful infringement?”

### ***In re Chapman – Obviousness*<sup>15</sup>**

Yet again, another example of the difficulty for an *ex parte* appellant winning an obviousness challenge at the Federal Circuit is manifested by this case.

**Status:** Briefing stage.

**Issue:** “Whether the Board erred as a matter of law in finding the subject matter of [the claims] obvious over U.S. Patent No. 6,025,158 (“Gonzalez”) alone or in combination with U.S. Patent No. 5,435,154 (“Barbanti”) where the Board  
“a) misinterpreted the scope and content of Gonzalez;  
“b) erred in finding a lack of teaching away by Gonzalez; and  
“c) employed impermissible hindsight.”

### ***In re Medicis -- Obviousness*<sup>16</sup>**

A reexamination proceeding raises a question of obviousness, while an underlying question of anticipation is left unanswered.

**Status:** Awaiting decision (argument Dec. 10, 2009 (Rader, Plager, Prost, JJ.))

**Issues:** “1. Whether the Board ...erred by finding patent claims related to medicated rinse-off skin cleansers containing 10% sodium sulfacetamide and 5% sulfur, and having a pH from about 6.5 to about 8.1, to be obvious in light of medicated leave-on lotions containing 10% sodium sulfacetamide and 5% sulfur, where there was no evidence before the Board that one of ordinary skill in the art would expect sodium sulfacetamide and sulfur to effectively treat skin conditions if rinsed off the skin within a few minutes of application.

“2. Whether the Board erred in finding that it would be obvious to one of ordinary skill in the art to adjust the pH of a skin cleanser containing sodium sulfacetamide to the pH of blood, based on prior art teachings related to sodium sulfacetamide's solubility in and absorption into blood.”

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<sup>15</sup> *In re Chapman*, Fed. Cir. 2009-1270.

<sup>16</sup> *In re Medicis Pharmaceutical Corp.*, Fed. Cir. No. 2009-1291.

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*Discussion:* It appears that claim 1 is directed to a new use for an old composition:

“A composition suitable for topical application to human skin or hair, comprising: Sulfur at about 5 % by weight; Sodium sulfacetamide at about 10 % by weight; and a pharmaceutically acceptable carrier; wherein the carrier is a cleanser and the composition has a pH from about 6.5 to about 8.1.”

But, the question of anticipation is not raised in the Board's decision.

### ***Encapsulation Technology – Obviousness***<sup>17</sup>

*Status:* Oral argument is scheduled for December 10, 2009.

*Statement of the Issues (per Appellant):* “Every pending claim in the present case includes a limitation similar to that of claim 1 which requires the introduction of a fog into the process area to coat the surfaces of the process area and encapsulate and adhere particulates against the surfaces with the fog’ (sometimes referred to herein as the ‘coating, encapsulation and adhering’ limitation). In affirming the examiner's rejection of all pending claims in the case, the Board of Patent Appeals and Interferences ignores this claim language limitation. The language of this limitation is not superfluous to the claimed invention. Indeed, it goes to the core of the claimed invention. The prior art cited by Board and the examiner neither discloses nor suggest the invention as claimed in any of the pending claims. As such, the Board's decision is not supported by the type of substantial evidence that a reasonable mind might accept as adequate to support the decision. Therefore, this Court should reverse the rulings of the Board and remand this application with instructions to allow all pending claims.

“This appeal raises the following issues:

“1. Whether the Board of Patent Appeals and Interferences erred in its obviousness analysis of all pending claims by failing to consider a limitation appearing in all pending claims which requires the introduction of a fog into the process area to coat the surfaces of the process area and encapsulate and adhere particulates against the surfaces with the fog.

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<sup>17</sup> *In re Encapsulation Technology, LLC*, Fed. Cir. App. No. 2009-1377.

“2. Whether the Board of Patent Appeals and Interferences erred in its obviousness analysis of claims 2 and 42 when it required Appellant to point out where *Grawe* teaches or suggests that associating contaminants with a solid-state matrix *excludes* adhering the contaminants to the matrix.”

*The PTO's Statement of the Issues:* “Encapsulation claims a method of using an aerosolized ‘capture liquid’ to encapsulate and adhere hazardous particles to contaminated surfaces. The method has two basic steps: (1) generating a ‘fog’ or ‘aerosol fog’ from a ‘capture liquid’; and (2) introducing the fog into a process area to ‘encapsulate and adhere’ contaminants to surfaces. *Grawe* teaches all of the limitations of the claimed method except the use of an aerosol fog, which is taught by Mitsui and disclosed by Castronovo to be ‘arguably the most effective method of treating an enclosed space.’ The issue on appeal is whether substantial evidence supports the Board's finding that Castronovo would motivate one of skill in the art to combine *Grawe* and Mitsui to achieve the claimed invention.”

### ***Suitco Surface – Claim Construction in Reexamination*<sup>18</sup>**

In *Suitco Surface*, the reexamination patentee-appellant challenges the broad claim construction used by the PTO that permits the claims to read on unpatentable subject matter; the reexamination patentee argues that the judicially determined narrower definition should govern.

**Status:** Oral argument January 6, 2010.

The Board in the proceedings below defended its use of the broadest reasonable claim construction under binding precedent including most recently *Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

**Necessity to Request *En Banc* Reconsideration of Precedent:** *From a standpoint of practical reasoning* the appellant’s position may be reasonable that the same claim construction as used in court should be used at the PTO. But, this overlooks the fact that cases such as *American Academy* represent the binding precedent of the court. The appropriate way to challenge binding precedent is to ask the Court to consider the case *en banc*.

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<sup>18</sup> *In re Suitco Surface, Inc.*, Fed. Cir. No. 2009-1418, *proceedings below*, *Ex parte Suitco*, 2009 WL 798895 (PTO Bd. App. & Int. 2009)(Song, APJ).

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(To be sure, the patentee seeks to distinguish *American Academy* on the basis that “[i]n *American Academy of Sciences*, unlike in this proceeding, claim construction had not been the subject of appellate review at the time the district court stayed the infringement proceeding.”)

Even though appellant did not in its brief ask the Federal Circuit to overrule its prior precedent through an *en banc* ruling, the rules leave the door open for making this request at oral argument. Fed. Cir. Rule 35(a)(1), *Arguing to a Panel to Overrule a Precedent* (“[A] party may argue, in its brief *and oral argument*, to overrule a binding precedent without petitioning for hearing *en banc*. The panel will decide whether to ask the regular active judges to consider hearing the case *en banc*.”).

### ***In re Arvinmeritor* – Obviousness, Unexpected Results<sup>19</sup>**

*Arvinmeritor* represents yet another example of a reexamination appeal involving an obviousness rejection – and the challenges facing appellant at the Federal Circuit.

**Issues:** “1. Whether the Board ... erred in failing to conclude that claims 1-9 of the Wilkes patent are not obvious over the proposed combination of the Kagiya and Tuckey references.

“2. Whether the Board erred in failing to conclude that claims 1-9 of the Wilkes patent are not obvious over the proposed combination of the Kagiya and Coquiote references.”

“3. Whether the Board erred in failing to conclude that claims 1-9 of the Wilkes patent are not obvious over the proposed combination of the Noel and Tuckey references.

“4. Whether the Board erred in failing to conclude that claims 1-9 of the Wilkes patent are not obvious over the proposed combination of the Noel and Coquiote references.

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<sup>19</sup> *In re Arvinmeritor, Inc.*, Fed. Cir. No. 2009-1287, *proceedings below, Ex parte Arvinmeritor, Inc.*, 2008 WL 2781987 (PTO Bd. App. & Int. 2008), *on reconsideration*, 2008 WL 5376656 (2008).

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“5. Whether the Board erred in failing to give any weight to the evidence of non-obviousness.”

**Status:** Awaiting decision (argument Dec. 10, 2009) (Mayer, Plager, Dyk, JJ.)

***Failure to Present Market Share Evidence to Establish Commercial Success:***

The patentee justified its failure to present evidence on the share of the market in connection with its commercial success on the basis that, “[o]f course, in all cases in the Patent Office, an Appellant does not have access to the Federal Rules or Civil Procedure, and thus would have difficulty proving overall market share. While this patent was initially the subject of federal litigation, the litigation was dismissed prior to extensive discovery such with the parties could pursue this re-examination. As such, Appellant has no evidence of market share.” *Ex parte Arvinmeritor*, decision on reconsideration (quoting Appellant). The Board responded: “Be that as it may, under [*In re Huang*, 100 F.3d 135, 139-40 (Fed. Cir. 1996),] evidence of sales is insufficient to establish commercial success in *ex parte* proceedings before the USPTO in the absence of market share evidence.” *Id.*