#### **TOP TEN SUPREME COURT PATENT CASES\***

[updated March 9, 2006]

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- (1) The eBay Injunctive Relief Case: eBay, Inc. v. MercExchange, LLC, No. 05-130. Argument March 29, 2006; decision by June 2006
- (2) The KSR Obviousness Case: KSR Intern. Co. v Teleflex Inc., No. 04-1350: CVSG invited.
- (3) MedImmune Broadening of Lear: MedImmune, Inc. v. Genentech, Inc., No. 05-608: briefing stage; argument October/November 2006
- (4) The Schering-Plough Reverse Payments Antitrust Case: Federal Trade Comm'n v. Schering-Plough Corp., No. 05-273: CVSG invited.
- (5) The Metabolite Patent Piñata: Lab. Corp. of Am. Holdings v. Metabolite Labs, Inc., No. 04-607. Argument March 21, 2006
- (6) Microsoft v. AT & T Patent Extraterritoriality: Microsoft Corp. v. AT & T Corp., No. 05-1056. Cert. response due March 23, 2006
- (7) Empresa Cubana "Charming Betsy" Issue: Empresa Cubana Del Tabaco v. Gen'l Cigar Co., Inc., No. 05-417 CVSG invited.
- (8) SmithKline Inherent Anticipation Case: SmithKline Beecham Corp. v. Apotex Corp., No. 05-489. CVSG invited.
- (9) Phillips Claims Issues: Nystrom v. TREX Co., Inc., No. 05-950
- (10) Phillips Claims Issues: Izumi Products Co. v. Koninklijke Philips Electronics N.V., Supreme Court No. 05-961

#### What's Next this Term

By far the most important patent case that will be decided this term is the *eBay* case (no. 1) which will be argued March 29, 2006; a decision is expected in June 2006. It is entirely possible that *eBay* and will be the *only* pure patent case decided this term on the merits. The *Metabolite* case (no. 5) could well be dismissed for the improvident grant of *certiorari* at some point after the March 21, 2006, oral argument, perhaps in April or May.

#### **Cases Coming to and Leaving the Court**

[Soon] Shell v. Union Carbide Patent Extraterritoriality: Shell Oil Co. v. Union Carbide Chemicals & Plastics Technology Corp. petition expected

[Soon] LizardTech "Possession": Lizardtech, Inc. v. Earth Resource Mapping, Inc. petition expected by April 6, 2006

[Delayed] Tamoxifen Reverse Payments Antitrust Case: In re Tamoxifen Citrate Antitrust Litigation, \_\_ F.3d \_\_, 2005 WL 21 864654 (2nd Cir. 2005). This case mirrors the issues in Schering-Plough. This case has been taken off the Top Ten list because it remains bottlenecked in the Second Circuit awaiting a decision on rehearing en banc. If the Second Circuit denies such a rehearing, a certiorari petition is inevitable. To the extent that certiorari is granted in Schering-Plough, it is likely t hat the certiorari petition would be deferred consideration until after a decision in Schering-Plough.

[Finished] The Unitherm Patent Fraud Case: Unitherm Food Systems, Inc. v. Swift Eckrich, Inc., \_\_ U.S. \_\_, 126 S.Ct. 980 (2006)(rev'g Federal Circuit on procedural issue unrelated to patent law)

[Finished] The Illinois Tool Market Share Case: Illinois Tool Works, Inc. v. Independent Ink, Inc., \_\_ U.S. \_\_, 2006 WL 468729 (2006)("The question presented to us today is whether the presumption of market power in a patented product should survive as a matter of antitrust law despite its demise in patent law. We conclude that the mere fact that a tying product is patented does not support such a presumption.")

[Finished] BlackBerry Extraterritoriality Case: Research In Motion, Ltd. v. NTP, Inc., certiorari den., 126 S.Ct. 1174 (2006), opinion below, NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).

[Finished] Lemelson Prosecution Laches Case: Lemelson Med., Ed.. & Res. Found. v. Symbol Technologies. The anticipated petition was never filed.

[Finished] AWH v. Phillips Claim Construction Deference: AWH Corp. v. Phillips, \_\_ U.S. \_\_, 2006 WL 386393 (2006)(cert. denied).

#### The Supreme Court Certiorari and Appeal Process

Until quite recently, it was extremely rare for the Supreme Court to *accept* for review *any* patent case. For example, in the case of the bread and butter issue of the standard of obviousness under what is today 35 USC § 103(a), it was only in 1965 that *certiorari* was granted to review this "new" patent law from 1952 – thirteen years earlier. The latest review of the obviousness standard for patentability from the Court was in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976), which is thirty (30) years ago, and six (6) years *before* the creation of the Federal Circuit.

The last major eruption of patent activity at the Court took place in 1965 – over forty (40) years ago. In that year, stimulated by both a patent antitrust and patent misuse case as well as two patent preemption cases in the previous two years – all with rulings against the intellectual property rights holder – the Court granted *certiorari* in seven (7) patent cases, including the *Walker Process* patent fraud case as well as six cases involving interpretation of the 1952 Patent Act – *Adams Battery, Graham v. Deere, Calmar v. Cook, Colgate-Palmolive v. Cook, Hazeltine v. Brenner* and *Brenner v. Manson*.

#### The Battle for Certiorari and the One (1) Percent Chance of

<u>Grant</u>: Each year, the Court carefully restricts its intake of appeals to about eighty cases that can all be given oral argument – generally one hour per case – and all decided in the period from the start of the term on the first Monday of October (when oral arguments are first heard for the Court's year) until the Court goes into its summer recess – generally at the end of the following June. *Every* case that is argued during the term is decided in that same term, leaving nothing on the Court's docket for a decision: In the rare

situation that a case may not be decided in a term, then the case is *reargued* in the following October and starts anew.

To winnow the approximately 8,000 petitions that are filed each year down to the eighty cases where review is given, there is a *certiorari* process of a petition and response. The Court then schedules a Conference (usually on a Friday) where the specific case is considered. The secret result is generally announced in an Order given down on the following Monday. (The electronic docket sheet available on the Court's website posts the date of the conference; a calendar is also posted which shows the next session of the Court after that conference, which is generally the day that the Order is given.)

The CVSG before the Vote: Several times each year – and surprisingly often in recent patent cases, the Court has not taken a vote on *certiorari* but instead issued an Order that invites the Solicitor General to provide the views of the United States whether to grant certiorari. This is the so-called "CVSG" – the *certiorari* views of the Solicitor General. There is no time limit for the government to issue its opinion that is given in the form of a brief. Therefore, since the Solicitor General is extremely busy during the full term of the Court with briefs and arguments where there *are* time deadlines, generally the CVSG briefs are deferred until late Spring or Summer. Then, the Court will consider the views of the United States in determining whether to grant *certiorari*. The Court does *not* always follow the views of the United States: For example, a CVSG brief in the *Metabolite* case argued *against* grant of *certiorari*, yet the Court nevertheless *did* vote for review.

The Legal Battle over a Single "Question": The certiorari petition identifies and frames a specific "question" – an issue of law or procedure that the Court needs to resolve. Only the specific question that is asked should be answered. (Plural questions may be asked.) For example, in the Metabolite case that is to be argued on March 21, 2006, there are some predictions that the Court will rule on patent-eligibility under 35 USC § 101, perhaps even implicating business method patents. But, this is not a question that is before the Court and has nothing to do with the question on which certiorari was granted.

The Critical Importance of the Certiorari Petition: A major reason that patent cases have not been accepted for appeal is due to the quality of the certiorari petition. Recently, the very top Supreme Court appellate counsel have become more involved in patent petitions which is one of the reasons for grant of certain cases and not others. For example, the RIM petition on extraterritoriality in the BlackBerry case was easily predicted by experts as not standing a chance for review because of the unfocused nature of the certiorari petition. Yet, in the more recent Microsoft certiorari petition that was filed on February 17, 2006, an outstanding brief by the former Solicitor General of the United States gives this particular case a much stronger chance of certiorari being granted.

Open Access to the Supreme Court Process: The worldwide public has open and free access to almost everything in the Supreme Court process *except* for the possibility to attend the oral argument. The Supreme Court has a free and easy to navigate website, <a href="http://www.supremecourtus.gov">http://www.supremecourtus.gov</a>. To find out the latest status of a case, click on "Docket", type in the name of either party, and a list of the cases with that party's name is given. Then, the docket is easily clicked open with all relevant information *except* the "Question" for cases prior to the grant of *certiorari*. The easiest access to the "Question" is from the petitioner's brief which is available on line on Westlaw on the SCT-BRIEFS database.

For cases where *certiorari* has been granted, PDF copies of briefs of the important cases are made available by Dennis Crouch on his Patently-O blog.

The Court as a general rule only issues opinions on days that it is in session. These days are identified on the Supreme Court calendar (also on its website).

Attendance at Oral Arguments: Members of the Supreme Court bar are given open access to a certain number of seats for each session; overflow seating is provided for members of the Supreme Court bar in a separate attorneys' room which has an audio feed. Others, including tourists, may attend *several minutes* of an argument by waiting in a line for the public. (A few passes are given to each party for the session when their case is heard.)

#### The Big Five: eBay, KSR, MedImmune Schering-Plough, Metabolite

The *eBay* case (no. 1) may be the most important patent case in quite some time. For the pharmaceutical field, it is the single most dangerous case of all, either where *certiorari* has been granted or amongst any on the horizon. It opens the door wide to the Court throwing out its nearly one century old standard of injunctive relief as the virtually automatic result of a patentee's successful patent infringement case. The case will be argued March 29, 2006, and decided by the end of June 2006.

It may be assumed that one of the goals of petitioner in the *eBay* case is that injunctive relief should be denied to a "patent troll". The "patent troll" indication has been coined to describe the patent owner who has no plan to practice the invention but only hold up manufacturers for high royalties at the threat of an injunction to shut down commercial operations. Indeed, petitioner's stance is completely antithetical to *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 423 (1908), and to the position taken by the United States in the creation of the Trade Related Aspects of Intellectual Property (TRIPS). The *eBay* case is analyzed in detail in a separate paper, Wegner, *Injunctive Relief: A Charming Betsy Boomerang*, 1st Annual Northwestern Journal of Technology and Intellectual Property Symposium: IP Litigation in the 21st Century, Northwestern University, February 24, 2006 [51 pp.] [available at www.foley.com]

Insofar as substantive patent law is concerned, the *KSR* case (no. 2) would pack the biggest punch of any of the cases, by far, *if certiorari is granted*. Perhaps by May or June, the Solicitor General will file his brief *amicus curiae* responsive to the Supreme Court's order which invites the views of the United States whether to grant *certiorari* – the CVSG.

If the CVSG brief is filed early enough, it is conceivable that a *certiorari* vote could still be taken in June so that briefing would occur in the summer, followed by an October 2006 argument; otherwise, the *certiorari* vote will take place at the end of September so that the earliest an argument would be scheduled would be late 2006. *KSR* reopens the split between the Federal Circuit and the Supreme Court that happened more than twenty years ago when the lower court in the *Stratoflex* case *sub silentio* abrogated the Supreme Court *Anderson's-Black Rock* and *Sakraida* case law line. If a

tough patentability standard under *Anderson's-Black Rock* is imposed by the Court, this would represent a seismic shock to the current *status quo* of the patent system. To the extent that the *KSR certiorari* petition is denied, this would not end the matter. To the extent that the Federal Circuit in an *en banc* ruling were to clarify its standard of obviousness *taking into account and rationalizing it with Supreme Court case law*, then it is conceivable that *certiorari* would be avoided in a future *KSR*-like case.

Beyond the combination claim issue of the *KSR* case itself, undoubtedly the petition in this case will stimulate a challenge to the biotechnology patentability standards. While the spotlight on obviousness standards in *KSR* is currently on "combination" claims, in the biotechnology area the criticism of *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), by Circuit Judge Rader as well as numerous scholars such as Professor Dan Burk make it a certainty that the Court will eventually need to consider whether the low standard of patentability in *Deuel* is correct. *Deuel* will surely be raised by *amici* if the Court grants *certiorari* in *KSR* – which is presently awaiting the views of the Solicitor General responsive to a CVSG invitation. Even if *certiorari* is denied in *KSR*, the *KSR* certiorari petition strategy provides a blueprint for a like petition in a *Deuel*-like case.

MedImmune (No. 3) revisits the right of a patent licensee to challenge validity of a patent under Lear v. Adkins, 395 U.S. 653 (1969), where the Court opened the door to patent challenges by a licensee under public policy grounds that licensee challenges of patents are needed to weed out invalid patents. In recent years, the Federal Circuit has taken a restrictive view of Lear as a case with "tones that echo from a past era of skepticism over intellectual property principles[.]" In MedImmune, the Federal Circuit dismissed a declaratory judgment challenge to validity because the licensee was continuing to pay royalties and operate under the patent license. The narrow question is whether a licensee in this situation is entitled to seek declaratory judgment relief, but more broadly the case will demonstrate where the Court remains in an "era of skepticism over intellectual property principles[.]"

Schering-Plough (No. 4) would rank No. 1 in any normal year: After the Solicitor General weighs in with his amicus brief in Schering-Plough responsive to the CVSG invitation of the Court, it is expected that the Court will grant certiorari. It will then be briefed and argued in the October 2006 term that runs through June 2007. Schering-Plough raises the antitrust

implications of the "reverse payment" settlement agreement where a pioneer pays a generic many millions of dollars to terminate an "ANDA litigation and thereby permit continued exclusivity for the patentee for some period of time. The "reverse payment" practice was stimulated by a 1993 vacatur of an inequitable conduct patent unenforceability ruling in *Imperial Chemical* Industries, PLC v. Heumann Pharma GmbH & Co., 991 F.2d 811 (Table), 1993 WL 118931 (Fed. Cir. 1993) (Michel, J.). What breathes great life into the *certiorari* petition is that the reverse payments system has the potential to cost elderly America that seeks the purchase of generic drugs potentially billions of dollars in added health costs, a point that is stressed in the certiorari petition. Less than six months ago the Supreme Court was given an education at oral argument in the *Merck* case about the importance of new research in the search for cancer cures which was clearly an underlying basis for the sweeping reversal of the Federal Circuit in Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 2372 (2005), as discussed in Wegner, Post-Merck Experimental Use and the "Safe Harbor", 15 Fed. Cir. Bar. J. 1 (2005).

Metabolite (no. 5) has dropped from the top spot. The argument is set for March 21, 2006: Lowering of the ranking is based upon the excellence of Respondent's brief that greatly enhances the possibility that after the oral argument, the Court will conduct a further vote on *certiorari* and "DIG" the case – dismiss the grant of *certiorari* on the basis of an improvident grant; or, the chance that the highly controversial issue of patent-eligibility under 35 USC § 101 will be reached has also been diminished by the procedural arguments made by Respondent.

The *Metabolite* case is a "patent piñata", both for the surprisingly large number of issues that *could* be reached as well as for the synergistic impact it will have on *other* cases, in particular, the *KSR* case (no. 2). The segue to *KSR* is that because *Metabolite* includes attacks on a low standard of patentability that resonates quite well with the challenge in *KSR*. Indeed, if *certiorari* is granted in *KSR*, in hindsight one may then view *Metabolite* as having played a significant role in garnering the necessary four votes for review.

# "Low" Patentability Standards

A common them for *all* of the top five cases (other than *Schering-Plough*) is the argument that there is a low standard of patentability that the Court must address. This is a theme that will never go away despite whatever Court actions are taken because the root causes for the bad patents that are coming out of the Patent and Trademark Office are not addressed by standards of patentability: No matter what the Court does, there will be little difference in what the approximately 4000 patent examiners do as part of their daily examination tasks. Only when there is an *inter partes* post-grant review process instituted in Alexandria is there any hope to address the quality and standard issues.

#### **Phillips Claim Construction and De Novo Deference**

Already, there have been three *certiorari* petitions that have raised issues in the wake of *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir.2005) (*en banc*) concerning either or both of claim construction narrowing and/or *de novo* review.

First, *certiorari* was *denied* in the attempt to seek review of the *de novo* review standard in the *Phillips* case itself, *AWH Corp. v. Phillips*, \_\_ U.S. \_\_, 2006 WL 386393 (2006)(cert. denied). Now, two further petitions have been filed, *Nystrom v. TREX* (case no. 9), and *Izumi v. Philips* (case no. 10).

But, yet to appear is a blockbuster *certiorari* petition that focuses upon *either* claim construction or the *de novo* standard of claim construction review; it is anticipated that when that does happen, there is a strong likelihood of grant of *certiorari*. Just as the unfocused attack on extraterritoriality failed in the RIM petition in the *BlackBerry* petition earlier this year, it is not expected that despite the importance of the *Phillips* issues that either of the two pending petitions will be granted.

#### (1) The *eBay* Injunctive Relief Case:

*eBay, Inc.* v. *MercExchange, LLC*, Supreme Court No. 05-130, *proceedings below sub nom MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1338-39 (Fed. Cir. 2005)(Bryson, J.).

Issue raised in the certiorari petition (granted): "Whether the Federal Circuit erred in setting forth a general rule in patent cases that a district court must, absent exceptional circumstances, i ssue a permanent injunction after a finding of infringement."

Issue added by the Court in the order granting certiorari: "Whether this Court should reconsider its precedents, including Continental Paper Bag Co. v. Eastern Paper Bag Co, 210 U.S. 405 (1908), on when it is appropriate to grant an injunction against a patent infringer."

*Importance*: This may be the single most important patent case in several years. The fight between big pharma and the electronics and software industries that had been center stage before Congress now shifts immediately to a judicial solution. In June 2006, after the Court issues its opinion, there may be continued efforts to overrule existing case law as part of the patent reform debates now taking place in the Congress.

**Status:** The briefs of the many *amici* supporting the current standard will be due March 10, 2006. The Court has scheduled the oral argument for March 29, 2006; a decision is expected in June 2006.

**Analysis and Outcome:** The *eBay* case is analyzed in detail in a separate paper, Wegner, *Injunctive Relief: A Charming Betsy Boomerang*, 1st Annual Northwestern Journal of Technology and Intellectual Property Symposium: IP Litigation in the 21st Century, Northwestern University, February 24, 2006 [51 pp.]. The paper is available at www.foley.com.

#### (2) The KSR Obviousness Case

KSR Intern. Co. v. Teleflex Inc., Supreme Court No. 04-1350, opinion below sub nom Teleflex Inc. v. KSR Intern. Co., 119 Fed.Appx. 282 (Fed. Cir. 2005)(Schall, J.)(non-precedential), appeal from trial court opinion, 298 F.Supp.2d 581 (E.D.Mich. 2003).

*Issue:* The Court has before it a petition for *certiorari* to review the issue of the standard of patentability for a combination claim: Does a combination claim survive a validity challenge where the invention is nonobvious in the sense that there is no teaching, suggestion or motivation to create the combination, but where the invention does not meet the test of synergy in *dictum* in *Sakraida*.

Importance: For inventions which reside in a combination of elements (i.e., many if not most inventions other than in chemistry and biotechnology) the KSR case has the potential to suddenly elevate the standard of nonobviousness by an order of magnitude. This would be a serious setback for individual inventors of mechanical combinations but welcomed by major electronics and software concerns. KSR is ranked high on the list of cases because even if certiorari is denied, the KSR case has drawn immense attention to the issue: It is certain to spark further petitions for review in future terms of the Court. Should certiorari be denied, it will be of great interest to see whether the Federal Circuit, for the first time, attempts to reconcile its body of case law with the Supreme Court precedent cited in the certiorari petition.

*Status*: On October 3, 2005, a CVSG Order was issued, that invites the Solicitor General to express the views of the United States whether to grant *certiorari*. If *certiorari* is granted, the appeal would be heard in the October 2006 term which runs through October 2007.

*Outcome:* A decision whether to grant *certiorari* may be influenced by whatever position the Solicitor General takes in his brief *amicus curiae*.

*Implications*: (1) Even though *certiorari* may well be denied, the petition and filings of *amici* present a blueprint for future petitions to the Court for every combination patent where the Federal Circuit sustains patent validity; (2) absent a Federal Circuit exposition of the law of obviousness that fully

deals with *Sakraida*, it may be expected that at some point in the next few years review *will* be granted in a *KSR*-like petition; (3) should the *dicta* from *Sakraida* become the law, this would move the United States closer to the synergy standard set by the House of Lords (Lord Hoffman) in the 2004 *SABAF* case; it would very sharply tighten up patent granting standards in the mechanical and electronics arts and threaten the validity of literally hundreds of thousands of existing patents still in force; and (4) as discussed in the following section, if *certiorari* is granted, mainstream research-based companies, particularly pharma and biotechnology, will surely weigh in against petitioner, yet – as was the case amongst the *amici* in the *Festo* briefing four years ago – a large segment of industry may be expected to part company, particularly in the heavy manufacturing and software fields.

An Open Door to Revisit the Deuel Biotechnology Holding: Should certiorari be granted in KSR, then amici in the biotechnology field will surely appear to attack – and defend – In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995). If certiorari is denied, review will surely be sought more directly in a Deuel-like setting, fueled by the fresh criticism of Circuit Judge Rader and some of the more influential academic scholars:

The standard of obviousness in biotechnology is singled out for criticism in the "Clockwork Lemon" piece by Professor Burk who equates the depth of reasoning in *Deuel* to "slogans for T-shirts and bumper stickers". Dan L. Burk, Biotechnology In The Federal Circuit: A Clockwork Lemon, 46 Ariz. L. Rev. 441, 443 (2004). He states that "[i]n cases like ...In re Deuel[, 51 F.3d 1552, 1558 (Fed. Cir. 1995)], the court applies this relationship to DNA sequences that code for a protein whose sequence was known in the prior art. There is a relationship between the DNA sequence and protein sequence, but the correspondence between codes is not one-toone; there is redundancy or degeneracy. Because of the degeneracy of the genetic code, the court held that the prior art lacked the degree of detail necessary for obviousness until actual discovery of the molecule--that is, the degree of detail necessary for conception. And so the cases produce a very stringent view of obviousness, what we might call obviousness in detail. The cases sum this up in more slogans for T-shirts and bumper stickers: 'What cannot be contemplated or conceived cannot be obvious.' Similarly, knowledge of a protein does not give one a conception of a particular DNA encoding it, because it does not provide the detailed structure of the genetic code." Id. at 442-43.

Professor Burk finds himself in the company of Circuit Judge Rader who focuses upon his disagreement with *Deuel* in *Fisher*: "The [Patent and Trademark] Office needs some tool to reject inventions that may advance the 'useful arts' but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement [under 35] USC § 101] to reject [biotechnology] research tools as contributing 'insubstantially' to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions. See In re Deuel, 51 F.3d 1552 (Fed.Cir.1995); Martin J. Adelman et al., Patent Law, 517 (West Group 1998) (commenting that scholars have been critical of *Deuel*, which 'overly favored patent applicants in biotech by adopting an overly lax nonobviousness standard.' (citing Anita Varma & David Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J.L. & Tech. 53 (1996))); Philippe Ducor, The Federal Circuit and In re Deuel: Does § 103 apply to Naturally Occurring DNA?, 77 J. Pat. & Trademark Off. Soc'y 871, 883 (Nov.1995) ('The Court of Appeals for the Federal Circuit could have formulated its opinion in only one sentence: '35 U.S.C. § 103 does not apply to newly retrieved natural DNA sequences.'); Philippe Ducor, Recombinant Products and Nonobviousness: A Typology, 13 Santa Clara Computer and High Tech. L.J. 1, 44-45 (Feb.1997) ('This amounts to a practical elimination of the requirement for nonobviousness for these products, even when all the information necessary to discover them is previously available.'); see also over fifty additional articles critical of Deuel in the 'Citing References' tab for *Deuel* on Westlaw. Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used world wide for such assessments (other than in the United States), namely inventive step or obviousness." In re Fisher, 421 F.3d 1365, 1381-82 (Fed. Cir. 2005)(Rader, J., dissenting).

# (3) MedImmune Licensee Validity Challenge

MedImmune, Inc. v. Genentech, Inc., S.Ct. No. 05-608, proceedings below, 427 F.3d 958 (Fed. Cir. 2005)(Newman, J.)

*Status*: Oral argument is likely to be scheduled in October or November 2006, with a decision likely Winter 2007 (but in any event by the end of the term in June 2007). Briefing is underway, with deadlines in the April-June 2006 time frame. Certiorari was granted February 21, 2006.

<u>Issue</u>: "Does Article III's grant of jurisdiction of 'all Cases ... arising under ... the Laws of the United States,' implemented in the 'actual controversy' requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?"

<u>Discussion – "Lear II"</u>: In *Lear v. Adkins*, 395 U.S. 653 (1969), the Court ruled that a patent licensee as a matter of public policy should be able to challenge the validity of a patent as part of the public function of patent litigation. In *MedImmune*, petitioner seeks to have a broader holding to include the right to challenge the validity of a patent *even if the challenger continues to pay royalties under the license and is thus not in breach of the agreement*.

A Narrow Federal Circuit Reading of *Lear*: As explained in by Judge Rader, "[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification. We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest...." *Studiengesellschaft Kohle, m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir. 1997)(Rader, J.)(quoting *Lear*, 395 U.S. at 670). Therefore, "in examining the interface between national patent policy and state contracts, the Supreme Court requires this court to consider 'whether overriding federal policies would be significantly frustrated" by enforcing the license." (*Id.*, quoting *Lear* at 670).

Lear is not an isolated case. In General Motors v. Devex it was pointed out that the Court has "noted the public function served by patent litigation." General Motors Corp. v. Devex Corp., 461 U.S. 648, 658 (1983)(Stevens, J., concurring) (citing Lear, 395 U.S. at 670). In Aronson v. Quick Point, the Court noted that "[i]n Lear..., we held that a person licensed to use a patent may challenge the validity of the patent, and that a licensee who establishes that the patent is invalid need not pay the royalties accrued under the licensing agreement subsequent to the issuance of the patent. Both holdings relied on the desirability of encouraging licensees to challenge the validity of patents, to further the strong federal policy that only inventions which meet the rigorous requirements of patentability shall be withdrawn from the public domain." Aronson v. Quick Point Pencil Co., 440 U.S. 257, 264 (1979)(citing Lear, 395 U.S. at 670-71).

Yet, the Federal Circuit reads *Lear* as representing an anachronistic view from an era having "skepticism over patents." Studiengesellschaft Kohle, 112 F.3d 1561 at 1567 (citing *Lear* as having "tones that echo from a past era of skepticism over intellectual property principles"). The Federal Circuit acknowledges distinguishing Lear again in Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220 (Fed.Cir.1988), and that "[i]ndeed, in several other settings, this court has distinguished Lear." Studiengesellschaft Kohle, 112 F.3d 1561 at 1567-68 (citing Foster v. Hallco Mfg. Co. 947 F.2d 469, 476-77 (Fed.Cir.1991); Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 991-93 (Fed.Cir.1989); Hemstreet v. Spiegel, Inc., 851 F.2d 348, 350-51 (Fed.Cir.1988)). More recently, the Federal Circuit has emphasized its narrow reading of *Lear* in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004)(Rader, J.). There, the Federal Circuit expressly stated that "[t]he *Lear* doctrine, however, does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent. In several instances, this court has declined to apply the *Lear* doctrine." Gen-Probe, 359 F.3d at 1381 (citing Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368-70 (Fed.Cir.2001)' Studiengesellschaft Kohle m.b.H. v. Shell Oil Co., 112 F.3d 1561, 1567-68 (Fed.Cir.1997); Foster v. Hallco Mfg. Co., 947 F.2d 469, 476-77 (Fed.Cir.1991); Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 991-93 (Fed.Cir.1989), overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed.Cir.1992); Hemstreet v. Spiegel, Inc., 851 F.2d 348, 350-51 (Fed.Cir.1988); Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220, 1224-25 (Fed.Cir.1988)).

The Unheard Message of Lear: The principal message of Lear is not skepticism over patents but rather that the patent system of the day -1969, nearly forty (40) years ago - did not have an effective way to weed out invalid patents, short of a full blown patent infringement litigation. That message remains unheeded by the patent community and the legislature even today, and, if anything, has become much more problematic for industry.

It is time for the patent community to come together to create a *legislative* answer to the problems raised in *Lear*. Both an effective post-grant administrative patent revocation procedure as well as the "Saris solution" to focus all patent trials on judges with experience and interest in patent cases must be implemented to moot the otherwise still unanswered criticism of the system from *Lear*.

The Second MedImmune Case: MedImmune, Inc. v. Centocor, Inc., S.Ct. No. 05-656, proceedings below, 409 F.3d 1376 (Fed. Cir. 2005)(Schall, J.). This case was considered at the same conference as the Genentech appeal, but no action was taken. Presumably, the case will remain on the docket of the Court until a decision is reached in the Genentech appeal, after which the Court may issue a "GVR" – it may then grant certiorari, vacate the decision below and remand for consideration in light of Genentech. The certiorari question is essentially the same, but worded slightly differently: "Does the 'actual controversy' requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a) require a material breach of a license agreement by a licensee prior to suit for declaratory relief for patent infringement, invalidity, or unenforceability?"

# (4) The Schering-Plough Reverse Payments Antitrust Case

Federal Trade Comm'n v. Schering-Plough Corp., Supreme Court No. 05-273, proceedings below sub nom Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1075 (11th Cir. 2005).

*Issue*: Whether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade.

*Importance:* If *certiorari* is granted, *Schering-Plough* may be the most important patent antitrust case in some time; it opens the door to antitrust challenges to the settlement of patent litigation that is an outgrowth of an early 1990's Federal Circuit practice of vacatur of trial court invalidity or unenforceability rulings where this is a condition of settlement.

*Status: Certiorari* grant is pending. On October 3, 2005, the Court issued its CVSG order inviting the Solicitor General to file a brief *amicus curiae* expressing the position of the United States whether to grant certiorari. If *certiorari* is granted, the appeal would be heard in the October 2006 term which runs through October 2007.

*Discussion*: In essence the case poses the question whether there be an antitrust violation where an accused infringer is paid tens of millions of dollars to drop a validity challenge to a patent and stay off the market for a period of time keyed to that payment? In the setting of pharmaceutical Abbreviated New Drug Application (ANDA) litigation, this is a "reverse payment" settlement that became popular when it was sanctioned by the Federal Circuit in *Imperial Chemical Industries*, *PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (Table), 1993 WL 118931 (Fed. Cir. 1993)(Michel, J.).

**Second Certiorari Question:** In addition to the main question (quoted above), a second question raised in the *certiorari* petition is "[w]hether the [Eleventh Circuit] grossly misapplied the pertinent 'substantial evidence' standard of review, by summarily rejecting the extensive factual findings of an expert federal agency regarding matters within its purview."

*Inter-Circuit Conflict*: The potential for the grant of certiorari is high because of the split amongst the several circuits. At one extreme is the Eleventh Circuit that has sanctioned the reverse payment of several tens of millions of dollars by a patentee to buy off a generic competitor from early entry into the market – whereas the Sixth Circuit at the other extreme has found a reverse payment settlement to be a *per se* antitrust violation.

*Merck v. Integra – Putting Flesh on the Antitrust Bones*: What breathes great life into the *certiorari* petition is that the reverse payments system has the potential to cost elderly America that seeks the purchase of generic drugs potentially billions of dollars in added health costs, a point that is stressed in

the *certiorari* petition. Less than six months ago the Supreme Court was given an education at oral argument in the *Merck* case about the importance of new research in the search for cancer cures which was clearly an underlying basis for the sweeping reversal of the Federal Circuit in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372 (2005), as discussed in Wegner, *Post-Merck Experimental Use and the "Safe Harbor"*, 15 Fed. Cir. Bar. J. 1 (2005). The remarkable reactions of the members of the Court to the policy aspects of the argument underscore the generational reaction to patent policy concerns relating to pharmaceuticals. This past Spring, the Court was faced with the policy concerns relating to *encouraging research* while the current *certiorari* petition focuses upon the health care costs that result if patents are not challenged.

Federal Circuit Case Law - Genesis for the "Reverse Payment": The Schering-Plough, "reverse payments" scenario stems from the early 1990's vacatur practice of the Federal Circuit where settlement of patent disputes was given a status of priority in *Philips Corp.* v. Windmere Corp., 971 F.2d 728 (Fed. Cir. 1992). The ultimate extension of *Phillips v. Windmere* led to vacatur of an unenforceability ruling based upon inequitable conduct where the settlement involved the reverse payment of over \$ 20,000,000.00 from the patentee to the generic market entrant. See *Imperial Chemical Industries, supra*)("The parties to the district court proceeding have entered into a settlement agreement resolving the entire dispute. They ask us to vacate and remand in accordance with their agreement and this court's practice. See Smith International, Inc. v. Hughes Tool Co., 839 F.2d 663 (Fed.Cir.1988; U.S. Philips Corp. v. Windmere Corp., 971 F.2d 728 (Fed.Cir.1992), cert. granted."). Indeed, the Eleventh Circuit cited the tamoxifen settlement with approval. See Schering-Plough, 402 F.3d at 1075 (citing In re Tamoxifen Citrate Antitrust Litig., 277 F.Supp.2d 121, 133 (E.D.N.Y.2003)), which has now been affirmed and where a certiorari petition is expected – as discussed as the next case below. What has not been fully appreciated is that the Federal Circuit's policy of *Phillips v*. Windmere was overruled the following year in Cardinal Chemical Co. v. Morton Intern., Inc., 508 U.S. 83 (1993). Indeed, there had been an essentially unanimous voice in the scholarly community that had criticized the Federal Circuit practice. See *Cardinal Chemical*, 508 U.S. at 102 n.25.

**Related case:** In re Tamoxifen Citrate Antitrust Litigation, 429 F.3d 370 (2nd Cir. 2005) – is bottled up at the Second Circuit pending a decision on a request for rehearing *en banc*. This case is likely to wind up at the Court during the October 2006 term for a vote on *certiorari*.

# (5) The *Metabolite* Patent Piñata:

Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., Supreme Court No. 04-607, 125 S.Ct. 1413, 1413-14 (2005), opinion below, 370 F.3d 1354 (Fed. Cir. 2004Rader, J.).

**Issue:** "Whether a method patent ... directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."

**Status:** Briefs for respondent and supporting *amici* are due February 6, 2006. Oral argument is scheduled March 21, 2006; a decision is expected by the end of June 2006.

*Outlook: Metabolite* may provide the most far-reaching opportunity for change in the substantive patent law of any case at the Court for some time. Assuming that Justice Stevens is in the majority, it can be expected that he will assign the case to himself – and that the opinion will be a far-reaching limitation on the scope of patents. (Because the Chief Justice has recused himself from this case, Justice Stevens – as the senior member of the Court – would be expected to assign the opinion to himself.)

**Possible Dismissal without a Merits Decision:** Respondent's brief makes powerful arguments that *certiorari* was improvidently granted. The Court can have a *new* vote on *certiorari* at any time – even after the oral argument in the case has been completed. If the Court lacks four votes for *certiorari*, it can then dismiss the case based upon an improvident grant of *certiorari*, a "DIG".

A patent piñata effect on other cases: Much of the briefing paints a highly uncharitable view of the patent system of today and underscores the point of several *amici* that the standard of patentability is too low. Whether this is

due to the PTO granting patents on a method for painting using the bare bottom of a baby – as illustrated by one of the *amici* – or whether it is a standard at the Federal Circuit, the most immediate impact will be on the Court's vote on *certiorari* in the *KSR* case: If anything, the briefing in *Metabolite* is a red flag to the Court about patentability standards and should provide a further impetus to the Court to grant *certiorari* in *KSR*.

The scope of the patent piñata effect: Several of the teams of lawyers involved at the merits stage — including petitioner's — involve highly sophistical appellate teams. Petitioner's appellate team was until last October quarterbacked by the Chief Justice of the United States; it is comprised exclusively of Supreme Court appellate lawyers who take a decidedly different approach than would a "patent attorney". Amici briefs that may prove influential include one that has as a principal author the former Dean of Stanford University Law School; another of the amici features the work of a tenured professor from the Georgetown University Law Center; both add substantive clout to amici efforts beyond the content.

Respondent's legal team provides the highest level of appellate firepower. Supplementing the lead counsel-trial lawyer is an appellate team of partners that includes significant Supreme Court expertise; additionally, Professor Mark Lemley of Stanford was added to this team. To the extent that the case will be argued by one of the Supreme Court experts on the team, the lawyering skills of the two teams should be on a par.

Petitioner's Funk v. Kalo Challenge: Petitioner does not directly challenge patent-eligibility under 35 USC § 101 but does focus on Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948), which is an obviousness case (but uses the pre-1952 terminology of a patentable "invention"). The opening introduction paints a picture focused upon Justice Stevens and several other colleagues who may be most sympathetic to a reversal:

"The Court has granted certiorari to answer this question: whether a vaguely worded patent claim 'directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.' Pet. i. The answer to the question is no. As construed by the Federal Circuit, the patent claim at issue is infringed whenever any doctor tests a patient for a

level of homocysteine, a basic amino acid - regardless of how or why the test is performed - and then thinks in his or her mind that the result may signify a vitamin deficiency. The result has been millions of dollars in damages and an injunction prohibiting homocysteine testing by LabCorp for any reason and by any method.

"Upholding this patent claim would allow an effective monopoly over a scientific principle, in contravention of this Court's settled precedents. Correlations, like all natural phenomena and laws of nature, belong in the public domain because they are 'the basic tools of scientific and technological work.' *Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972). Allowing a vaguely worded 'correlating' claim to confer an almost unbounded private property right over doctors' thought processes and both past and future inventions would hinder both the practice of medicine and the goals of innovation and scientific progress that the patent laws were intended to promote."

The summary hones in on *Funk v. Kalo*: "No less than Einstein's famous formula E=mc<sup>2</sup> or Newton's description of the laws of gravity, the discovery of a natural relationship between homocysteine and vitamin deficiencies is a 'manifestation[] of laws of nature, free to all men and reserved exclusively to none.' *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Respondents cannot effectively assert proprietorship over this basic scientific fact."

**The Ghost of Funk v. Kalo:** Neither petitioner nor its supporting *amici* focus upon the *holding* of *Funk v. Kalo* but only deal in "cite bites" of quotable language:

In *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), while *holding* that certain software technology is patent-eligible under USC § 101, in *dicta* the Court cited to several earlier cases for the proposition that "[t]his Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." Among the cases cited is *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), which at first blush appears highly relevant to the present case. One finds in *Funk v. Kalo* the oft-quoted statement that "[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come

from the application of the law to a new and useful end." *Funk v. Kalo.* 333 U.S. at 130.

The statement is entirely *dictum* as the *holding* of the case was that the *composition of matter* of the Bond patent in litigation was *obvious* under what is today 35 USC § 103(a); or, under the terminology of the day, Bond's composition lacked "invention" under the standard of *Hotchkiss v. Greenwood*, 11 How. (52 U.S.) 248, 267 (1851), which was only codified as part of the 1952 Patent Act under the current obviousness statute. *See Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 279 (1976)(citing *Dann v. Johnston*, 425 U.S. 219 (1976))("It has long been clear that the Constitution requires that there be some '*invention*' to be entitled to patent protection.")(emphasis added); *id* (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)(The *Hotchkiss* "standard was enacted in 1952 by Congress in 35 U.S.C. § 103 'as a codification of judicial precedents . . . with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability."). *See also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

The Bond patent litigated in *Funk v. Kalo* clearly has nothing in common with the current claim under consideration: It is a garden variety *composition of matter* claim to a mixture of bacteria: "*An inoculant for leguminous plants* comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific." (emphasis added).

What Bond discovered was that by selecting particular strains of bacteria, synergistic and *unexpected* results were achieved. Thus, far from an old combination, Bond had achieved a synergistic and unexpected combination – much like the battery inventor Adams combined old elements but achieved unexpected – and hence patentable – results. *United States v. Adams*, 383 U.S. 39, 51-52 (1966).

Where, one then may ponder, does one reach the oft-cited quotation from *Funk v. Kalo* concerning "a hitherto unknown phenomenon of nature"? This comes from what appears to be the *belief* of the author that an invention even to a composition of matter cannot involve a patentable "invention" – or nonobviousness in the terminology of the current Patent Act – if the

invention takes advantage of the previously unknown characteristics which are "nature's secrets":

"[O]nce *nature's secret* of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such *unless we borrowed invention from the discovery of the natural principle itself*. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without *allowing a patent to issue on one of the ancient secrets of nature now disclosed.*" Funk v. Kalo, 333 U.S. at 132 (emphasis added).

That the quoted statement is merely dictum is underscored in the Frankfurter concurrence in Funk v. Kalo: "It only confuses the issue ... to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent. On the other hand, the suggestion that 'if there is to be [a nonobvious] invention from such a discovery, it must come from the application of the law of nature to a new and useful end' may readily validate Bond's claim. Nor can it be contended that there was no [nonobvious] invention because the composite has no new properties other than its ingredients in isolation. Bond's mixture does in fact have the new property of multi-service applicability. Multipurpose tools, multivalent vaccines, vitamin complex composites, are examples of complexes whose sole new property is the conjunction of the properties of their components. Surely the Court does not mean unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged." Funk v. Kalo, 333 U.S. at 134-35 (Frankfurter, J., concurring)(emphasis added).

**Petitioner's Section 112 Challenges:** Beyond a basic attack keyed to *Funk v. Kalo*, petitioner makes several independent challenges to the claim in dispute under enablement *and* definiteness under 35 USC § 112.

The Court conceivably could have its opinion turn on any or all of the issues under 35 USC § 112 which would create new challenges for practice.

**The United States as** *Amicus Curiae*: Of all the briefs filed by numerous *amici*, the most powerful in terms of impact, of course, is the brief of the United States of America as *amicus curiae*. The United States essentially says that for reasons not before the Court the patent is invalid as being too broad and hence anticipated, but comes down on the side of the patentee as to issues under 35 USC § 112; insofar as 35 USC § 101 is concerned, the issue was not raised by the parties below – says the United States – so that if it is considered it should be through a remand:

"The patent specification at issue here satisfies the enablement, written description, and definiteness requirements of 35 U.S.C. 112. The specification adequately enables and describes the claimed method by explaining how it works and how to perform it, and by including examples demonstrating that the patent applicants had performed the method. The claim is also sufficiently definite because its bounds are marked with precision, such that a person skilled in the art would understand whether any given method infringed the claim. Although petitioner contends (Pet. 24-25) that the specification does not adequately describe the claim's "correlating" step, the court of appeals construed that step to be "a simple conclusion that a cobalamin/folate deficiency exists vel non based on the assaying step." Pet. App. 18a.

"Petitioner's contention (Pet. 23) that holding claim 13 valid would mean that "parties could claim patent monopolies over basic scientific facts" confuses the Section 112 disclosure and drafting requirements with the Patent Act's separate limitations on the subject matter eligible for patent protection. Although laws of nature, natural phenomena, and abstract ideas are not patentable under 35 U.S.C. 101, petitioner did not contend in the lower courts that the patent claim is invalid under Section 101. Nor does the question presented in this Court fairly include that question. Instead, the question presented, construed in light of the arguments set forth in the body of the petition and in the courts below, asserts only that a consequence of affirming the jury's verdict on the Section 112 issues would be to grant a monopoly over a scientific relationship. Any such consequence, however, would flow from petitioner's failure to raise a Section 101 claim, not from any error in applying Section 112.

"If the Court nonetheless concludes that the question presented fairly encompasses a Section 101 challenge, a remand would be appropriate. The court of appeals' claim construction, the jury's findings, and the relief awarded all suggest that any use of a total homocysteine assay infringes claim 13, because doctors who review such assays can be presumed to perform mental correlations of the results with cobalamin or folate deficiencies or the absence thereof, even if they ordered the assays for a different reason. So construed, claim 13 appears impermissibly to encompass all "substantial practical application[s]" of the natural relationship that can be identified by reference to the limited record presently before the Court. *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972). Because petitioner did not raise a Section 101 challenge in the lower courts, however, respondents had no opportunity to create a full record on that issue. A remand for further evidentiary proceedings would therefore be appropriate if the Court reached the Section 101 issue.

"Claim 13 also appears to be invalid as anticipated by the prior art under 35 U.S.C. 102 The court of appeals' determination that any use of a total homocysteine assay infringes the patent appears to have the effect of impermissibly removing existing assay methods from the public domain. Like the Section 101 issue, however, that question is not fairly included in the question presented."

**Dean Sullivan's Affymetrix Brief:** A particularly interesting brief from Barbara Caulfield and Dean Kathleen Sullivan for Affymetrix, Inc. and Professor John H. Barton focuses upon 35 USC § 101. It presents an argument by a biotechnology player *against* patents. A sample:

"Fulfilling th[e] constitutional purpose requires a balance between rewarding existing research and ensuring that other research may go forward freely in the future. Allowing a patentee to remove a natural phenomenon from the public sphere would thwart this constitutional purpose by impeding rather than promoting the progress of biochemical research and medical treatments. Without access to testing and observing natural phenomena, medical researchers cannot build upon the discoveries of others.

"Allowing claims such as the one at issue here would block medical information based on natural, biochemical relationships from appropriate further scientific use. This impediment would be especially acute with respect to the information and phenomena that are rapidly being discovered

in the field of genome analysis. Disallowing claims such as claim 13, by contrast, will cause little harm to scientific progress because a wide range of other appropriate claims would remain available to researchers like Respondent. Thus the balance struck in Diehr and related cases on the scope of patentable subject matter should be preserved."

**I BM's Critique on Business Method Patent-Eligibility:** IBM takes a macroscopic view of the patent system and encourages the court *not* to enter the patent-eligibility fray under 35 USC § 101; yet, it also highlights the problem of a perceived too low standard of patentability.

Professor John R. Thomas of the Georgetown University Law Center participated as counsel on a brief led by IBM's David J. Kappos that is perhaps the most scholarly of all the presentations in this case to date.

IBM in its statement of interest warns about the need for a balance in the area of business method patents: "IBM is a globally recognized leader in the field of information technology research, development, design, manufacturing, and related services. During IBM's nearly 100-year history, its employees have included five Nobel laureates, five National Medal of Science recipients, and eight winners of the National Medal of Technology. The United States Patent and Trademark Office (USPTO) has granted IBM tens of thousands of United States patents, including more patents than any other corporate assignee for the past twelve years. IBM is the proprietor of more patents claiming computer-related inventions than any other entity in the world. IBM is also ranked in the top two for patents issued on business methods, as classified by the USPTO. IBM believes it can provide a balanced view on important issues implicated by this case - namely, the patentability standard under 35 U.S.C. § 101, and particularly as it relates to patenting of business methods."

IBM asks that the Court *refrain* from choosing this case as a vehicle to deal with business method patent eligibility: "Despite the significance of the issues surrounding subject matter eligibility under section 101, particularly for business methods, IBM believes that the facts of this case do not present a suitable opportunity for analyzing and articulating the proper scope of subject matter for patent eligibility." IBM adds that "[w]hile the question on which certiorari was granted is narrower than that posed to the Government, IBM submits this brief to address the subject of patent eligibility under section 101, particularly for business methods, in the event

the Court decides to undertake a broad review of subject matter patentability."

On the other hand, IBM criticizes the lenient standard of patentability under the Federal Circuit: It chides the grant of patents to frivolous inventions that should avoid patents to "a method of painting a surface using the posterior of an infant (U.S. Pat. No. 6,213,778) and a method for making jury selection determinations (U.S. Pat. No. 6,607,389) are not patentable subject matter because they do not produce technologically beneficial results." Later, IBM points to [i]ssued patents from such diverse areas as architecture, athletics, insurance, painting, psychology, and the law itself, [that] reveal just how far afield the patent system has gone in granting patents in virtually any area of human endeavor, such as teaching a golf putting stroke or a method for lifting a box."

On a more scholarly level, IBM says that "[s]ince this Court last interpreted section 101 of the patent statute, see Diamond v. Diehr, 450 U.S. 175, 191-93 (1981), certain decisions of the Federal Circuit Court of Appeals have broadened the scope of subject matter deemed eligible for patenting, particularly in the area of business methods. Under the standard currently followed by the Federal Circuit, an invention is eligible for patenting if "it merely achieves a useful, concrete, and tangible result." State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998). Under this lenient standard, the section 101 inquiry has taken an "end-justifies-the-means" approach, which has resulted in patents arising from a diverse range of human behavior traditionally outside the realm of patent protection, including economic analyses, artistic techniques, athletic skills, and abstract methods of doing business. As one Federal Circuit jurist remarked, under that court's case law, 'virtually anything is patentable.' Hughes Aircraft Co. v. United States, 148 F.3d 1385, 1385 (Fed. Cir. 1998) (Clevenger, J., dissenting from denial of rehearing) (citing State Street, 149 F.3d 1368)."

A Large Number of Briefs: According to Supreme Court website as checked on January 7, 2006, the following *additional* briefs were filed by *amici* – either for petitioner or neutral: Computer & Communications Industry Association; People's Medical Society; American Clinical Laboratory Association; American Heart Association; Patients Not Patents, Inc.; AARP; Public Patent Foundation; American Medical Association, et

al.; Intellectual Property Owners, Inc.; Bar of the City of New York; American Express Company; and Financial Services Industry

Supporting Respondent are *amici* briefs from the American Intellectual Property Law Association that was principally authored by Denise Kettleberger. Another brief was filed by the Boston Intellectual Property Law Association.

But, the "Doctor" is *not* Necessarily a Direct Infringer of the Claim: Whether the "doctor necessarily infringes" the claim is answered, no! The *claim* covers a two step process where the doctor only performs one step (b):

- "13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
  - "[(a)] [measuring] a body fluid for an elevated level of total homocysteine; and
  - "[(b)] [noticing] an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate."

Under the "all elements" rule as restated in *Warner-Jenkinson*, "[e]ach element contained in a patent claim is deemed material to determining the scope of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997). *See also Mobil Oil Corp. v. Filtrol Corp.*, 501 F.2d 282, 291-92 (9th Cir. 1974)(questioning "whether a method claim can be infringed when two separate entities perform different operations and neither has control of the other's activities."); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1567-58 (Fed. Cir. 1983); Mark A. Lemley *et al.*, *Divided Infringement Claims*, 33 Am. Intell. Prop. L. Ass'n Q. J. 189 (2005). (If step (a) is performed by the doctor's staff as his agent, a different answer may apply.)

# (6) Microsoft v. AT&T Patent Extraterritoriality

Microsoft Corp. v. AT & T Corp., No. 05-1056, proceedings below, T & T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed. Cir. 2005)(Lourie, J.)

<u>Issue</u>: Petitioner challenges the several Federal Circuit cases that have given an expansive interpretation of § 271(f), starting with *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir.), *cert. denied*, 126 S. Ct. 568

(2005). Under the Question Presented, Petitioner has a lengthy preamble followed by two specific questions it raises for review:

"Title 35 U.S.C. § 271(f)(1) provides that it is an act of direct patent infringement to 'suppl[y] ... from the United States ... components of a patented invention ... in such manner as to actively induce the combination of such components outside of the United States.'

"In this case, AT&T Corp. alleges that when Microsoft Corporation's Windows software is installed on a personal computer, the programmed computer infringes AT&T's patent for a 'Digital Speech Coder' system. AT&T sought damages not only for each Windows-based computer made or sold in the United States, but also, under Section 271(f)(1), for each computer made and sold abroad. Extending Section 271(f) - and consequently, the extraterritorial application of U.S. patent law - the Federal Circuit held that Microsoft infringed under Section 271(f)(1) when it exported master versions of its Windows software code to foreign computer manufacturers, who then copied the software code and installed the duplicate versions on foreign-manufactured computers that were sold only to foreign consumers. The questions presented are:

- "(1) Whether digital software code an intangible sequence of '1's' and '0's' may be considered a 'component[] of a patented invention' within the meaning of Section 271(f)(1); and, if so,
- "(2) Whether copies of such a 'component[]' made in a foreign country are 'supplie[d] ... from the United States.""

<u>Status</u>: The Respondent's reply to the *certiorari* petition is due March 23, 2006. (The *certiorari* petition was filed February 17, 2006.)

**Discussion**: Export of noninfringing components that are combined offshore to create a patented combination provides no infringement liability under the extraterritoriality principles of *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972)(export of unassembled components of patented shrimp deveining tool not an infringement of U.S. patent law). Under a statutory override, the export of individual components could be infringement under 35 USC § 271(f)(2)(infringement liability attaches to one who "supplies or causes to be supplied in or from the United States any component of a patented invention ...knowing that such component ... will

be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States[.]").

In *Microsoft*, the claimed invention is a patented combination where one element is the software, which accused infringer Microsoft provides to offshore manufacturers either by shipping a single master – a "Golden Disk" – or by simply transmitting a copy electronically to the overseas manufacturer.

The majority held that "software replicated abroad from a master version exported from the United States-with the intent that it be replicated-may be deemed 'supplied' [under 35 USC § 271(f)(2)". 414 F.3d at 1369. Even an internet transmission of software that is replicated abroad qualifies under the majority's interpretation of § 271(f): "[W]e cannot accept Microsoft's suggestion that software sent by electronic transmission must be treated differently for purposes of § 271(f) liability from software shipped on disks, see Tr. of Dec. 12, 2003 Hearing, at 8:8-17 (J.A. 351), as it would amount to an exaltation of form over substance. Liability under § 271(f) does not depend on the medium used for exportation: a disk is merely a container that facilitates physical handling of software, much like bottles for liquids or pressurized cylinders for gases. ... [W]hether software is sent abroad via electronic transmission or shipped abroad on a 'golden master' disk is a distinction without a difference for the purposes of § 271(f) liability. Liability under § 271(f) is not premised on the mode of exportation, but rather the fact of exportation." 414 F.3d at 1370-71.

The dissent forcefully argues that the majority is in direct conflict with the Supreme Court *Deepsouth* opinion: "The majority ... purports to construe § 271(f) to 'comport with Congress' [s] motivation for enacting § 271(f).' Apart from the impossibility of divining Congressional intent divorced from the language of the law, this court's reasoning misses the policy behind § 271(f). Congress enacted § 271(f) in response to the Supreme Court's holding in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972). *Deepsouth* held that making and shipping component parts of a patented combination invention did not constitute 'making' the patented invention in the United States. *Id.* at 527-29 ('We cannot endorse the view that the 'substantial manufacture of the constituent parts of a machine' constitutes direct infringement when we have so often held that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.'). Thus, because *Deepsouth* was not 'making' the

invention in the United States before exportation, there was no direct infringer in the United States to enable a charge of contributory infringement. *Id.* at 527. Deepsouth let U.S. manufacturers escape infringement by making and exporting less than the complete patented invention. Section 271(f) closed that loophole by attaching liability to U.S. manufacturers for making and exporting components of the patented invention." 414 F.3d at 1375 (Rader, J., dissenting).

<u>The Petition itself</u>: The Microsoft petition reflects the work product of Gibson Dunn's appellate team led by Theodore B. Olson, Counsel of Record, joined by Matthew D. McGill and Amir C. Tayrani.

The petition opens by noting that "[i]n the twenty-two years since it was enacted, this Court has never interpreted 35 U.S.C. § 271(f). For much of that time, the statute was viewed almost as a dead letter - a loop-holeclosing provision that worked. See Alan M. Fisch & Brent H. Allen, The Application of Domestic Patent Law to Exported Software: 35 U.S.C. 57 271(f), 25 U. Pa. J. Int'l Econ. L. 557, 567 & n.46 (2004) (noting that, on account of the 'sparse case law,' commentators have suggested that Section 271(f) 'serves little purpose at all'). In recent years, however, the Federal Circuit has articulated new and far reaching applications for Section 271(f), holding that the statute encompasses much more than simply the export of the unassembled, physical parts of a patented machine, as was the ease in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), the decision that prompted the legislative loophole-closing effort. In this case, the Federal Circuit held that Section 271(f) applies to the distribution of intangible software code to foreign computer manufacturers, concluding that digital software code constitutes a 'component' of a programmed-computer invention and that copies of that digital code created abroad by foreign computer manufacturers 'may be deemed 'supplied' from the United States.' And in its most recent application of Section 271(f), the Federal Circuit reached the conclusion that the statute could prohibit 'suppl[ying]' a 'component' of a patented process. See Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005)."

"This case brings into focus a recurring judicial debate concerning whether patent laws - and in particular Section 271(f) - should be interpreted according to their plain meaning and legislative history, or whether - as the decision below holds - they 'must ... be interpreted in a manner that is appropriate to the technology at issue,' so that the statutes might 'remain

effective.' Although this Court has consistently resolved that debate in favor of the former position, *see 3Brown v. Duehesne*, 60 U.S. (19 How.) 183, 197 (1857), the Federal Circuit has determined to pursue a course that would take into account 'advances in a field of technology ... that developed after the enactment of' the statute. In so doing, the court of appeals disregarded fundamental canons of statutory construction, as well as this Court's repeated expressions of disfavor toward the extraterritorial application of U.S. law in the absence of a clear expression of contrary congressional intent. *See*, *e.g.*, *F. Hoffmann-LaRoche Ltd. v. Empagran S.A.*, 542 U.S. 155, 165 (2004). Because the 'profound ramifications' for innovating businesses multiply with each new lower-court effort to ensure that Section 271(f) remains 'responsive to the challenges of a changing world,' 'this Court's interpretive guidance is now urgently needed."

The petition chides the majority below for considering "software" to be a "component" within the meaning of the statute: "The decision below is premised on a commonly held misunderstanding of the nature, and thus the patentability, of software. In everyday usage, 'software' is perceived as embodied in some kind of storage medium, such as a CD-ROM or a hard drive - as when one purchases a copy of Microsoft Word software on a CD-ROM. Similarly, 'software' is often understood as operating on a computer and giving that computer certain functionality - as when a computer is loaded with Microsoft Excel software and used to create and manipulate a spreadsheet. Although prevalent, these uses of the word 'software' are imprecise. By itself - that is, uncoupled from any storage medium or computer - software is nothing more than 'a set of instructions, known as code, that directs a computer to perform specified functions or operations.' Fantasy Sports Props., Inc. v. Sportslines.com, Inc., 287 F.3d 1108, 1118 (Fed. Cir. 2002); see also 17 U.S.C. § 101 (defining a 'computer program' as a 'set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result'); United States Patent & Trademark Office, Manual of Patent Examination Procedure ('MPEP') § 2106.IV.B.1(a) (8th ed. 2001) ('a computer program is merely a set of instructions capable of being executed by a computer'). Computer programmers develop software by first authoring 'source code' - humanreadable commands to the computer - in a computer language such as BASIC, FORTRAN, or C++. See Gates Rubber Co. v. Bando Chem. Indus., Ltd., 9 F.3d 823, 835 (10th Cir. 1993). That source code is then run through a compiler that translates the human-readable source code into computerreadable 'object code,' which is expressed in the binary digital language of

'0's' and '1's.' Each digit instructs the computer to open or close one of the millions of switches in its central processing unit. It is the 'opening and closing of the interconnected switches' that 'creates electrical paths ... that cause [the computer] to perform the desired function.' WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1348 n.3 (Fed. Cir. 1999). The object code is thus nothing more than a complex set of digital commands that instruct a computer to align its circuits in a particular manner to achieve a particular functionality. In this sense, software code is not unlike the pattern of perforations in a player piano music roll, with each unique pattern of perforations generating, when run on a player piano (i.e., hardware), a unique composition of music. Just as each perforation causes the piano to strike a particular string, each '1' or '0' of software code instructs a computer to close or open, respectively, a particular switch. See generally White-Smith Music Publ'g Co. v. Apollo Co., 209 U.S. 1, 9-10 (1908) (describing the mechanics of a player piano). Like the perforations in a music roll, software code is design information that reflects specific knowledge about how to make hardware perform certain operations. The distinction between software as integrated on a computer or other storage medium (such as a CD-ROM), and software as design information, is critical. When digital software code (like the pattern of perforations in a piano roll) is embodied on a physical medium (the actual piano roll) or alters the circuitry of a computer in a particularly useful way, that medium or computer, as physically and functionally altered by the software, may be a patentable invention. See In re Alappat, 33 F.3d 1526, 1545 (Fed. Cir. 1994) (en banc) (holding that a 'general purpose computer programmed to carry out the claimed invention' was patentable as 'a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software'); see also MPEP § 2106.IV.B.1(a); cf. Alappat, 33 F.3d at 1554 (Archer, C.J., concurring in part and dissenting in part) (recognizing that, under Alappat, a music roll with perforations embodying a new song could be patentable). In contrast, software code alone (the particular sequence of '1s' and '0's') - like the arrangement of holes to be punched into the music roll of a player piano - is neither a 'process' nor a 'machine, manufacture, or composition of matter.' 35 U.S.C. § 101. Thus, although software code may be copyrightable, see, e.g., Apple Computer, Inc. v. Franklin Computer Corp., 714 F.2d 1240, 1248 (3d Cir. 1983), it is not itself patentable.

"Contrary to the Federal Circuit's conviction that, '[w]ithout question, software code alone qualifies as an invention eligible for patenting,' (quoting *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1339 (Fed. Cir.), *cert. denied*, 126 S. Ct. 568 (2005)), the Patent and Trademark Office has explained that 'a claim for a computer program, without the computer-readable medium needed to realize the computer program's functionality,' is unpatentable because computer programs are neither 'physical things' nor 'acts being performed.' MPEP § 2106.IV.B.1(a). Accordingly, the duplication of software code can itself never constitute an act of patent infringement. *See* 35 U.S.C. § 271(a) (limiting infringement actions to the manufacture, use, sale, or importation of a 'patented invention'). At stake in this case is Microsoft's fight to export digital software code - a sequence of '1's' and '0's' - to foreign companies that duplicate the code and install it on foreign-manufactured computers for sale in foreign markets."

The Petition seeks to demonstrate that the present case is but one of a series of cases that misconstrue § 271(f). In addition to focusing upon the view that *Eolas* was wrongly decided, petitioner also draws attention to a *subsequent* case where *certiorari* will also undoubtedly be sought, *Union Carbide Chems*. & *Plastic Tech. Corp. v. Shell Oil Co.*, \_F.3d \_, 2006 WL 47462, at \*1 (Fed. Cir. Jan. 10, 2006) (Lourie, J., dissenting from denial of reh'g en banc). Discussing *Union Carbide*, the Petition notes that "[t]he digital software code actually 'installed' on the foreign-manufactured computers is thus a second-generation copy of the digital software code transmitted from the United States - a foreign-made copy of a foreign-made copy of the original. *See Union Carbide Chems*. & *Plastics Tech. Corp.*, 425 F.3d at 1379 (citing the decision below as concerning 'exportation of a 'master' computer readable disc that was further copied abroad, with the copies installed as software on assembled computers')."

The Petition accuses the Federal Circuit of judicial expansion of the law: Quoting Judge Lourie's dissent, "[t]his case presents a recurring question of vital importance to the U.S. software industry. The Federal Circuit's 'recent[] exten[sion] of the meaning' of Section 271(f)(1) to include foreign-made copies of software code... vastly expands the extraterritorial reach of U.S. patents involving software. As the Federal Circuit has enlarged the law, U.S. patents on programmed-computer inventions grant monopolies enforceable against American competitors not only as to computers manufactured or sold in the United States, but also as to computers made and sold abroad. This self-described extension of Section 271(f) eviscerated

the well-established 'right' of American software companies 'to compete with an American patent holder in foreign markets,' Deepsouth Packing Co., 406 U.S. at 531, thereby exposing those businesses to potentially crippling liability - here, tripling Microsoft's infringement liability." In a following footnote, the Petition focuses upon the fact that Judge Lourie – dissenting in the denial of en banc rehearing in Union Carbide – is also the author of Eolas: "Judge Lourie's description of the Federal Circuit's interpretation of Section 271(f) in *Eolas* and *AT&T* as a 'recent[] exten[sion]' is particularly telling inasmuch as he authored the majority opinion in AT&T. The Petition emphasizes that "[s]ending software code alone to foreign manufacturers is manifestly different in kind from the conduct that Congress addressed in the wake of *Deepsouth*. Software code is design information, and if design information could constitute a 'component [] of a patented invention,' then the export of blueprints, formulas, and methodologies – in other words, knowledge -- would itself constitute an act of infringement, thereby giving U.S. patents global force and effect. The Federal Circuit's interpretation of the phrase 'component[] of a patented invention' thus runs headlong into this Court's long-standing rule that the patent laws do not apply extraterritorially, see Dowagiac Mfg. Co. v. Minn. Moline Plow Co., 235 U.S. 641, 650 (1915), and the more general canon of construction that U.S. laws must not be given extraterritorial effect in the absence of a clear expression of congressional intent to reach foreign conduct, see, e.g., Sale v. Haitian Ctrs. Council, Inc., 509 U.S. 155, 176 (1993)."

Further, "[e]ven if software code could constitute a 'component[] of a patented invention' within the meaning of Section 271(f), the Federal Circuit's additional quantum leap to the conclusion that copies of U.S.designed software made entirely *outside* the United States are, despite their foreign provenance, 'supplie[d] ... from the United States,' amplifies the need for this Court's review. Like its interpretation of 'component,' the Federal Circuit's textually indefensible interpretation of 'supplie[d]' broadly expands the extraterritorial reach of the U.S. patent laws. Indeed, if the Federal Circuit is correct that - at least where software is concerned - 'the [foreign] act of copying is subsumed in the [domestic] act of 'supplying' 'then the Federal Circuit has indeed categorically excluded software companies from the 'right of American companies to compete with an American patent holder in foreign markets.' Deepsouth Packing Co., 406 U.S. at 531. The Federal Circuit's excursion into foreign markets at once trenches upon Congress's authority to regulate foreign commerce and greatly reduces (if not entirely eliminates) the incentive for inventors to obtain

patents in jurisdictions other than the United States. It thus threatens to disrupt foreign nations' patent law schemes and creates the possibility of retaliatory action and substantial international discord."

The extraterritorial reach of the decision below is focused upon: "It is axiomatic that American patent laws generally are 'not intended to [] operate beyond the limits of the United States.' Brown, 60 U.S. (19 How.) at 195; see also 35 U.S.C. § 154(a)(1) ('Every patent shall ... grant to the patentee ... the right to exclude others from making ... or selling the invention throughout the United States') (emphasis added). Accordingly, this Court has long recognized that U.S. patent laws afford no protection against efforts to practice a patented invention outside the territorial jurisdiction of the United States. See Dowagiac Mfg. Co., 235 U.S. at 650 ('The right conferred by a patent under our law is confined to the United States and its Territories and infringement of this right cannot be predicated [on] acts wholly done in a foreign country.') (citation omitted); see also Deepsouth Packing Co., 406 U.S. at 531 (acknowledging 'the right of American companies to compete with an American patent holder in foreign markets'); Rotec Indus., Inc. v. Mitsubishi Corp., 215 F.3d 1246, 1251 (Fed. Cir. 2000) ('extraterritorial activities ... are irrelevant'). Section 271(f), enacted specifically in response to this Court's decision in *Deepsouth*, places an eminently sensible, but intentionally quite narrow, limitation on that right."

Returning to *Union Carbide*, "Section 271(f) plainly was not intended to prohibit the export of intangible items. See Union Carbide Chems. & Plastics Tech. Corp., \_F.3d at \_, 2006 WL 47462, at \*1 (Lourie, J., dissenting from denial of reh'g en banc) ('The whole tenor of [Section 271(f)] relates to *physical* inventions .... ') (emphasis added). Absent congressional intent to the contrary, words in a statute must be given their ordinary meaning, see Williams v. Taylor, 529 U.S. 420, 431 (2000), and one does not ordinarily speak of a car's design specifications as being a 'component' of the car. See Webster's Third New International Dictionary of the English Language 466 (1976) (defining 'component' as 'a constituent part' or 'ingredient'). But even if the term 'component' - taken alone - could conceivably be construed to include the essential intangible predicates to the invention, such as design specifications, the statutory context makes clear that the term is limited only to those 'components of a patented invention' capable of being 'combin[ed],' 35 U.S.C. § 271(f)(1), and intangible information cannot be 'combined' with other physical parts to form a 'patented invention,' i.e., a 'process, machine, manufacture, or composition

of matter,' *id.* § 101. Rather, 'combination' most commonly refers to the assembly of tangible parts into a whole. *See* Webster's Third New International Dictionary of The English Language 452 (defining 'combine' as 'to join in physical or chemical union'); *see also <u>Rotec Indus.</u>*, 215 F.3d at 1252 n.2 (Section 271(f) 'precludes competitors from avoiding liability simply by supplying components of a patented product from the United States and assembling them abroad')."

Petitioner focuses upon recent Supreme Court case law that cautions against extraterritorial expansion of American law: "By eliminating the ability of American software companies - and other technology-based firms - to compete with American patent holders in foreign markets, the decision below exponentially expands the extraterritorial reach of U.S. patent law. Yet the presumption against the extraterritorial application of U.S. law is deeply rooted in this Court's jurisprudence. Indeed, in *Empagran*, 542 U.S. 155, this Court recently emphasized that - in order to prevent U.S. encroachments on foreign sovereignty - courts must adopt *any* reasonable construction of a statute that *avoids* extraterritorial application. *Id.* at 174. Because Congress did not clearly express its intention for Section 271 (f) to encompass intangible materials - let alone foreign-manufactured copies of intangible materials - the Federal Circuit's conclusion squarely conflicts with this Court's precedent restricting the extraterritorial reach of U.S. law."

Turning to comity, the Petition states that "[i]t is a 'longstanding principle of American law that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States.' *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 248 (1991). This presumption against extraterritoriality is grounded in comity considerations and 'serves to protect against unintended clashes between our laws and those of other nations which could result in international discord.' *Id.; see also Foley Bros. v. Filardo*, 336 U.S. 281, 286 (1949) (holding that a statute imposing an eight-hour work day did not apply to Americans employed overseas because 'labor conditions ... are the primary concern of [the] foreign country' in which the workers are employed).

"The presumption against extraterritoriality also reflects the fact that the legislative and executive branches are much better equipped than the judiciary to evaluate the complex foreign policy considerations raised by the extraterritorial application of U.S. law. Indeed, decisions affecting international relations are 'of a kind for which the Judiciary has neither

aptitude, facilities nor responsibility.' Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 111 (1948).

"Because of these comity considerations and separation-of-powers concerns, courts must not construe a U.S. law as encompassing foreign conduct 'unless ... the affirmative intention of the Congress' to apply a law extraterritorially is 'clearly expressed' in the statutory language. *Arabian Am. Oil Co.*, 499 U.S. at 248; *see also Benz v. Compania Naviera Hidalgo*, S. A., 353 U.S. 138, 147 (1957) (holding that the Labor Management Relations Act did not apply to a labor dispute involving a foreign ship operated by foreign seamen because Congress had not 'clearly expressed' its 'affirmative intention' to reach such conduct).

"Even where Congress has unequivocally expressed its intention to give a U.S. law extraterritorial effect, the parameters of that authorization must be strictly construed in light of the general presumption against extraterritoriality. In Empagran, 542 U.S. 155, for example, this Court concluded that the Sherman Act - which generally has been held to apply to foreign conduct - did not provide a cause of action for plaintiffs harmed by foreign price-fixing activity that caused both domestic and independent foreign effects because the plaintiffs were harmed exclusively by the conspiracy's foreign effects. *Id.* at 173. The Court expressed concern that the availability of such a suit would 'create[] a serious risk of interference with a foreign nation's ability independently to regulate its own commercial affairs.' Id. at 165. The Court therefore held that, even if the more natural reading of the statute encompassed the foreign activity, comity considerations compelled a contrary conclusion because the statutory language did not 'show that [the Court] must accept th[e] reading' that provided for an extraterritorial effect. Id. at 174. The Court instructed that, as long as 'the statute's language reasonably permits an interpretation consistent with' the general presumption that Congress seeks to avoid interference with other nations' sovereignty, a court 'should adopt it.' Id.

"The presumption against the extraterritorial application of U.S. law is especially strong in the patent context because the application of U.S. patent law to foreign commercial activity intrudes upon other nations' intellectual property schemes and thereby creates a significant risk of international discord. This Court has thus long recognized that U.S. patent laws generally are 'not intended to[] operate beyond the limits of the United States.' *Brown*,

60 U.S. (19 How.) at 195; see also Dowagiac Mfg. Co., 235 U.S. at 650.

"Indeed, the proposition that U.S. patent law generally does not possess extraterritorial effect has been clear since at least the mid-nineteenth century, when this Court held in *Brown* that U.S. patent law did not extend to a French-built vessel that sailed into an American port. 60 U.S. (19 How.) at 198-99. The Court explained that applying U.S. patent law to foreign-manufactured goods would 'embarrass the treatymaking power in its negotiations with foreign nations, and ... interfere with the legislation of Congress when exercising its constitutional power to regulate commerce.' *Id.* at 197.

"The territorial limits on U.S. patent law not only reflect the comity and separation-of-powers concerns that animate the general presumption against extraterritoriality, but are also an expression of 'this Nation's historical antipathy to monopoly and of repeated congressional efforts to preserve and foster competition." *Deepsouth*, 406 U.S. at 530 (footnote omitted). Patent law strikes a delicate balance between the objectives of promoting competition and rewarding innovation. Thus, although the issuance of a patent precludes competitors from making, using, or selling the patented invention *in the United States*, the patent does not undermine the 'fight of American companies to compete with an American patent holder in *foreign* markets.' *Id.* at 531 (emphasis added). 'To the degree that the inventor needs protection in markets other than those of this country,' the inventor must 'seek it abroad through patents secured in countries where his goods are being used.'"

# (7) Empresa Cubana "Charming Betsy" Issue:

Empresa Cubana Del Tabaco v. General Cigar Co., Inc., Supreme Court No. 05-417, opinion below, Empresa Cubana Del Tabaco v. Culbro Corp., 399 F.3d 462 (2nd Cir. 2005).

**Issue**: The first *certiorari* question in *Empresa Cubana* asks – "Whether the Executive's foreign affairs powers under Article II and the Trading with the Enemy Act to conduct the United States' embargo of Cuba oblige the courts to defer to the Executive's reasoned determination that its embargo regulations do *not* bar judicial relief granted to a Cuban enterprise, particularly when the Executive advises that its construction of the regulations avoids the violation of treaty obligations (the requirement to

protect 'well-known' trademarks under Article 6bis, Paris Convention for the Protection of Industrial Property), implicates the reciprocal protection of U.S.-owned trademarks in Cuba, and is consistent with the embargo's purposes."

<u>Status</u>: On January 9, 2006, the Court issued an invitation asking for the *certiorari* views of the Solicitor General whether to grant review ("CVSG"). The vote on *certiorari* will take place at a point in time that would place the case on the October 2006 term for argument, *if* certiorari is granted.

<u>Discussion</u>: Empresa Cubana raises a question that implicates the Charming Betsy canon that a statute should be interpreted consistent with American treaty obligations. The Charming Betsy canon is implicated in the pending appeal in eBay v. MercExchange, where the United States has Paris Convention and TRIPS treaty obligations that in some instances require injunctive relief – contrary the position of petitioner.

The question implicates the *Charming Betsy* canon that statutes should be interpreted consistent with treaty obligations. See Cert. Pet. at 17:

"The Executive's submission is powerfully supported by the doctrine that 'an act of Congress ought never to be construed to violate the law of nations' - here, ratified treaties - 'if any other possible construction remains.' *Murray v. The Charming Betsy*, 6 U.S. (2 Cranch) 64, 118 (1804); *see also Sale*, 509 U.S. at 178 n.35. *Charming Betsy* applies with no less force to regulations than to statutes, pursuant to which they are issued. *Cf. South Dakota v. Bourland*, 508 U.S. 679, 697 n.16 (1993) (that 'regulations do not purport to abrogate treaty rights [is] not a startling proposition'). The Executive's plausible construction of the CACR shows that it is 'possible,' *Charming Betsy*, 6 U.S. at 118, to avoid conflict with the Paris Convention and TRIPs both as a textual and as a policy matter. Thus, the Executive's construction must be accepted under *Charming Betsy*."

The amicus curiae brief of the National Foreign Trade Council, at § IV, In the Absence of a Clear Statement of Congressional Intent, Courts Must Not Construe a Statute to Abrogate Treaties, discusses several cases as being "only a few of the many examples of Chief Justice Marshall's simple, but powerful, 200 year old maxim of statutory construction: 'An act of Congress ought never to be construed to violate the law of nations [i.e., a treaty] if any

other possible construction remains.' *Murray v. The Schooner Charming Betsy*, 6 U.S. 64, 118 (1804)."

#### (8) SmithKline Inherent Anticipation Case

SmithKline Beecham Corp. v. Apotex Corp., No. 05-489, opinion below, 403 F.3d 1331 (Fed. Cir. 2005)(Rader, J.), aff'g on different grounds, 247 F.Supp.2d 1011 (N.D.Ill. 2003)(Posner, J.).

<u>Issue</u>: "Whether the Federal Circuit erred in holding, in conflict with this Court's decision in *Tilghman v. Proctor*, 102 U.S. 707 (1881), and its progeny, that the 'unwitting' and 'unappreciated' prior creation of a product renders a subsequent patent of that product invalid as 'inherently anticipated', and thus not novel under Section 102 of the Patent Act."

<u>Status</u>: On January 9, 2006, the Court issued an invitation asking for the *certiorari* views of the Solicitor General whether to grant review ("CVSG"). The vote on *certiorari* will take place at a point in time that would place the case on the October 2006 term for argument, *if* certiorari is granted.

#### (9) Phillips Claims Issues – Nystrom v. Trex

Nystrom v. TREX Co., Inc., No. 05-950, opinion below, 424 F.3d 1136 (Fed. Cir. 2005)(Linn, J.). See Phillips Claim Construction and De Novo Deference, supra.

#### Questions Presented:

- "1. Whether the Federal Circuit is correct in holding that there are no underlying factual inquiries involved in a district court's patent claim construction and, therefore, all aspects of the district court's claim construction are subject to *de novo* review on appeal.
- "2. Whether the Federal Circuit's current method of claim construction in patent cases, as set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)[(en banc)], is in conflict with this Court's precedent prohibiting the reading of limitations from the patent's specification into the claims.
- "3. Whether the Federal Circuit's application of *Phillips* in this case is in conflict with this Court's precedent prohibiting the reading of limitations from the patent's specification into the claims."

**<u>Status</u>:** A *certiorari* vote is expected in the current term. The case has not been scheduled for conference. (The Response to the petition was due March 2, 2006).

**<u>Discussion</u>**: Post-*Phillips* claim construction dilemmas as illustrated particularly by this case. The invention involves a board for exterior construction where *shape* and not the *composition* of the board was critical to patentability. The claim reads:

"1. A *board* for use in constructing a flooring surface for exterior use, said *board* having a top surface, a bottom surface and opposite side edges, said top surface being *manufactured to have* a slightly rounded or curved configuration from a longitudinal center line thereof downwardly toward each side edge, thereby defining a *convex top surface* which sheds water and at the same time is comfortable to walk on, and said bottom surface having a concave configuration for nesting engagement with the top surface of another board so that a plurality of the boards may be stacked one on top of the other with the stability of conventional boards having flat top and bottom surfaces." *Nystrom*, emphasis as quoted in the court's opinion.

The accused infringer successfully argued that despite the use of the broad term – board – and despite the absence of any definitional statement in the specification to limit the scope of the invention to a *wooden* board, nevertheless the court based upon the narrow scope of exemplification gave the invention such a narrowed interpretation. Ron Nystrom is the archetypical 'small inventor' working out of his garage, who carried out his experiments with wood and not the more expensive and sophisticated synthetic board materials that are the state of the art. *Nystrom*, 424 F.3d at 1140 ("Nystrom is the inventor and sole owner of the [] patent. He is a working carpenter and the owner of a two-truck, two-employee lumberyard. He has been in the business of building exterior decks for twenty-five years. [Accused infringer] TREX is a manufacturer of exterior decking planks made from composites of wood fibers and recycled plastic.").

Despite having broad claim wording to cover *any* board, the court limited the scope of his invention where Ron Nystrom only used wood – and disclosed such wood in his embodiments in the specification. Because the specification disclosed wood but did not additionally disclose synthetic boards, the court limited the scope of a "board" to a "wooden board". It did so in the name of *Phillips*:

"[A]s explained in *Phillips*, Nystrom is not entitled to a claim construction divorced from the context of the written description and prosecution history. The written description and prosecution history consistently use the term 'board' to refer to wood decking materials cut from a log. Nystrom argues repeatedly that there is no disavowal of scope in the written description or prosecution history. Nystrom's argument is misplaced. Phillips, 415 F.3d at 1321 ('The problem is that if the district court starts with the broad dictionary definition in every case and fails to fully appreciate how the specification implicitly limits that definition, the error will systematically cause the construction of the claim to be unduly expansive.'). What *Phillips* now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public -i.e., those of ordinary skill in the art - that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source. *Id.*; see also Snow v. Lake Shore & Mich. S. Ry. Co., 121 U.S. 617, 629-30 (1887) ('It is not admissible to adopt the argument made on behalf of the appellants, that this language is to be taken as a mere recommendation by the patentee of the manner in which he prefers to arrange these parts of his machine. There is nothing in the context to indicate that the patentee contemplated any alternative for the arrangement of the piston and piston-rod.')."

A related issue concerns invalidity rulings under 35 USC § 112, where there is a lack of representative exemplary disclosure for a genus. See *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344 (Fed. Cir. 2005)(Bryson, J.)('The trouble with allowing [the] claim ... to cover all ways of performing DWT-based compression processes that lead to a seamless DWT is that there is no support for such a broad claim in the specification. The specification provides only a single way of creating a seamless DWT, which is by maintaining updated sums of DWT coefficients. There is no evidence that the specification contemplates a more generic way of creating a seamless array of DWT coefficients.').

<u>Outcome</u>: The petition reads much like a brief to the Federal Circuit. Despite the obvious merits of the first two questions as warranting ultimate Supreme Court resolution, it is a very long shot for *certiorari* to be granted in this case.

# (10) Phillips Claims Issues – Izumi v. Philips

Izumi Products Co. v. Koninklijke Philips Electronics N.V., Supreme Court No. 05-961, opinion below, 140 Fed.Appx. 236 (Fed. Cir. 2005)(Lourie, J.). See Phillips Claim Construction and De Novo Deference, supra.

**Question Presented**: "The American patent system has long required that patents include two distinct elements: First, a description of the invention in such terms as will 'enable' skilled persons to make and use the invention; and Second, one or more 'claims' that delimit the patent's scope for purposes of determining whether the patent has been infringed. In this infringement case, the Federal Circuit employed an interpretive methodology that unpredictably allows the enabling disclosure to narrow the claims' plain meaning. The question presented is:

"Whether patent claims that are amenable to interpretation based on their plain meaning may be narrowed by an enabling disclosure that neither explicitly disavows the claims' scope nor explicitly defines the claims' terms."

<u>Status</u>: A response was scheduled to be due March 6, 2006 (per a review of the Supreme Court electronic docket on March 3, 2006). The case should be distributed for a decision on *certiorari* this term; argument, if granted, would be in the October 2006 term

**Discussion**: The non-precedential opinion includes a dissent: "[T]he restriction of the scope of the claimed [feature] improperly reads a limitation from the specification into the claims. I can discern no proper basis to do so and would give the ... limitation the full scope of its ordinary and customary meaning." *Izumi*, 140 Fed.Appx. at 245-46 (Linn, J., dissenting).

The dissent adds that "[c]laim terms are to be given their ordinary and customary meaning to one of skill in the relevant art. *Johnson Worldwide Assocs.*, *Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999). ... Our precedent is clear that 'the fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the

objectives.' Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908 (Fed.Cir.2004)...." Id. at 246.

Furthermore, "this description..., when considered in context, is not a disclaimer of subject matter, but simply an explanation of why inner cutters having not only recesses but also these particular angles are preferred embodiments in achieving one of the objectives of the invention. 'Such a description, of course, does not limit the scope of the claims.' *Honeywell Inc. v. Victor Co. of Japan*, 298 F.3d 1317, 1326 (Fed.Cir.2002) (holding that claim need not be construed in a manner that would lead to the solution of both prior art problems discussed in the written description)." *Id.* at 246-47.

**Outcome**: No prediction is offered.

# [Coming Soon] Shell v. Union Carbide Patent Extraterritoriality:

Shell Oil Co. v. Union Carbide Chemicals & Plastics Technology Corp., cert. petition expected, proceedings below, Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 434 F.3d 1357 (Fed. Cir. 2006)(order denying reh'g en banc)

Relationship to Microsoft (Case 6): To the extent that certiorari is granted in Microsoft Corp. v. AT & T Corp., No. 05-1056, proceedings below, AT & T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed. Cir. 2005)(Lourie, J.), it is likely that a certiorari decision in the Shell Oil case would be held in abeyance until the conclusion of proceedings in Microsoft. Thereafter, the Court in all likelihood would give this case a GVR treatment, i.e., certiorari would be granted, the decision below would be vacated and the case remanded to the Federal Circuit for further consideration in light of Microsoft.

Going Beyond Microsoft: Unlike other cases dealing with 35 USC § 271(f) where a component of a patented combination is exported for offshore assembly of the patented combination, here, there is no patented combination involved at all: Rather, the claim in question is to a process and the "component" is a material used in that process. There clearly is no liability under classic patent infringement principles under 35 USC § 271(a) because the "component" itself is unpatented; neither is there inducement liability because the accused infringing act – carrying out the patented

process – takes place outside the United States. Yet, the panel in *Union Carbide* nevertheless has held that carrying out the process abroad is the creation of the patented combination under 35 USC § 271(f). In the *en banc* rehearing request, four of the twelve members of the court dissented; Judge Lourie sets forth a detailed dissent that is joined by Chief Judge Michel and Judge Linn; Judge Dyk dissents without opinion.

Judge Lourie notes that "[t]he panel opinion held that '\s 271(f) governs method/process inventions." *Union Carbide Chemicals & Plastics Tech.* Corp. v. Shell Oil Co., 425 F.3d 1366, 1380. However, I believe that conclusion is contrary to the statutory scheme and to recent case law." Union Carbide, 434 F.3d at 1358 (Lourie, J., dissenting from denial of en banc reh'g). He explains that "[t]he statute itself speaks of supplying 'components of a patented invention, where such components are uncombined ... in such manner as to actively induce the combination of such components outside of the United States.' 35 U.S.C. § 271(f). The whole tenor of that provision relates to physical inventions, i.e., apparatus or compositions, not methods. We recently extended the meaning of 'component' to include what traditionally would be physical components, but which, in an electronic world, supplied electronically, are the equivalent of physical components. See Eolas Techs. v. Microsoft., 399 F.3d 1325, 1338 (Fed.Cir.2005); AT & T Corp. v. Microsoft Corp., 414 F.3d 1366, 1368 (Fed.Cir.2005). But the inventions in those cases were apparatus or systems, not methods or process. And in RIM, we distinguished method claims, holding that, while a system claim could be infringed even though one of its components was outside of the United States, that was not true for the method claim. NTP. Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1322 (Fed.Cir.2005) (declining to find infringement under § 271(f) with regard to a method claim)." Id.

The rationale for disagreement with the panel is stated thusly: "A component of a process is a step in the process; it is not the physical material to be used in the process. What the panel opinion here holds is that supplying a component to be used in one of the process steps can create infringement. That is, in my view, an incorrect an extension of the statutory language." *Id.* 

# [Coming Soon] LizardTech "Possession"/"Written Description"

Lizardtech, Inc. v. Earth Resource Mapping, Inc., 433 F.3d 1373 (Fed. Cir. 2006)(en banc)(order denying reh'g en banc)(per curiam).

**Status**: Certiorari petition due April 5, 2006.

<u>Discussion</u>: In <u>LizardTech</u>, the court by a split vote again refrains from an <u>en banc</u> consideration of its controversial "possession" line of case law under 35 USC § 112, ¶ 1...In conflict with the statutory wording and its interpretation prior to the Federal Circuit, the concurring opinion supports the <u>dictum</u> in <u>LizardTech</u> of the "possession" rule from what are now several panel opinions. As stated in <u>LizardTech</u>, 35 USC § 112, ¶ 1, includes a requirement that the specification "must describe the invention sufficiently to convey to a person of skill in the art that the patentee had **possession** of the claimed invention at the time of the application[.]" 424 F.3d at 1345.

For the writer's views on the possession requirement, see Wegner, *The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years*, 37 Akron L. Rev. 243 (2004); *see also* Wegner, *When a Written Description is Not a "Written Description": When Enzo Says it's Not*, 12 Fed. Cir. Bar J. 271-283 (2002).

<sup>\*</sup> This paper represents the personal views of the writer and does not necessarily reflect the views of any organization or client. The writer is a partner with Foley & Lardner LLP. This paper was last updated March 9, 2006.