

Tomorrow, April 16, 2007, is *certiorari* decision day in Top Ten No. 3 *Quanta*, a case that focuses upon *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992)) (Newman, J.). The *Mallinckrodt* Federal Circuit line of cases undermines the Supreme Court's historic doctrine of patent "exhaustion".

Quanta's chances for grant of review have been bolstered by the *amicus* effort of Supreme Court specialist Andrew Pincus – on behalf of Dell, Hewlett-Packard and Gateway. Pincus focuses upon the Federal Circuit's repudiation of Supreme Court precedent:

"Several times in recent years this Court has granted review in cases presenting important questions of patent law in order address claims that the Federal Circuit had adopted legal principles that are inconsistent with the relevant decisions of this Court. *E.g.*, *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (argued Nov. 28, 2006); *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007); *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

"This case presents another example calling out for review. Misconstruing this Court's decision in *United States v. Univis Lens Co.*, 316 U.S. 241, 250 (1942), and undermining reasoned, well-settled patent policy, the Federal Circuit's ruling here - the culmination of a series of decisions beginning with *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992) - permits patentees to invoke the patent infringement remedy to collect separate royalty payments at each stage of the manufacturing process and supply chain, the precise result *rejected* by this Court in *Univis Lens*. Review by this Court is plainly and urgently warranted." [Pincus *amicus* brief, pp. 3-4; original emphasis]

See for a more detailed discussion of the case the *Top Ten* summary.

Hal Wegner

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Top Ten Patent Cases – A Post *KSR* List*

KSR: Once *KSR* is decided, the new Top Ten lineup is reshuffled:

- 1 *Microsoft* – § 271(f) Extraterritoriality; “Business Methods”
- 2 *Amgen* – *Cybor de novo* Claim Construction
- 3 *Quanta v. LG* – Patent “Exhaustion”
- 4 *Leclerc-Wallace* – Anti-Foreigner Discrimination
- 4 *Joblove* – Tamoxifen Patent Settlement – Antitrust
- 6 *Nuijten* – “Signal” Patent-Eligibility; *State Street Bank*
- 7 *Integra* – Post-*Merck* “Safe Harbor”
- 8 *Pharm. Res. v. D.C.* – Drug Pricing Federal Preemption
- 9 *BMC v. Paymentech* – “Joint Infringement”
- 10 *Teva v. Novartis* – Justiciable controversy

A preview of the Top Ten cases appears at page 2, followed by a brief outline of the issues presented in the cases that begins at page 3.

* This paper was last revised on March 27, 2007, and represents the personal views of the writer, Harold C. Wegner, former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School. Partner, Foley & Lardner LLP. This paper does not necessarily represent the views of any colleague, organization or client thereof.

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Preview

No. 1 *Microsoft* – Last Merits Patent Decision This Term: A decision is likely by May and certainly by the end of June, before the Court term ends.

Nos. 2-5, Four Cases on the *Certiorari* Radar Screen for Next Term: Four further cases have a legitimate shot at grant of *certiorari* for the coming October 2007 term that will run through June 2008; perhaps one or two of these cases will have *certiorari* granted: No. 2 *Amgen* (*de novo* claim construction review); No. 3 *Quanta* (patent “exhaustion”); No. 4 *Leclerc-Wallace* (anti-foreigner bar discrimination) and No. 5 *Joblove* (“reverse payment” patent settlement). (No. 4 *Leclerc-Wallace* deals with a *state* bar discrimination, but should petitioners prevail, this would impact PTO anti-foreigner discrimination.)

Nos. 6-10, Cases percolating up the appellate chain: No. 6 *Nuijten* may “benefit” from the fallout of No. 1 *Microsoft* in terms of *dictum* relating to patent-eligibility under § 101; no matter which was the Federal Circuit decides this case, *Nuijten* could wind up at the Supreme Court.

No. 7 *Integra* has been pending for nearly two (2) full years following the 2005 Supreme Court *Merck v. Integra* reversal of the Federal Circuit.

No. 8 *Pharm. Res. v. D.C.* (to be argued in April) challenges the District Court’s invalidation of a D.C. law regulating prescription drug pricing.

No. 9 *Paymentech* deals with a thorny issue of “joint” infringement.

No. 10 *Teva v. Novartis* involves dismissal of an Orange Book pharmaceutical dispute for want of a justiciable controversy – now challenged on the basis of *MedImmune*. It has dropped to the bottom of the list as a predictable reversal, now that the Federal Circuit has given *MedImmune* “footnote 11” a broad interpretation in *Sandisk*.

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(1) Microsoft: § 271(f) Extraterritoriality; “Business Methods”
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.)

Status: Oral argument took place February 21, 2007; a decision is expected before the end of the Term.

Issue (in general terms): Does the export of a single copy of unpatented software to be replicated offshore for offshore creation of a patented computer combination create liability under 35 USC § 271(f)?

Issues (as formally before the Court): “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.’”

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The following summary of *Microsoft* was issued on February 22, 2007:

There really is no substitute to actually *hearing* the oral argument to gain an impression of where the Court may be going, although much insight can be garnered from the words of the transcript alone. The writer was unable to attend the argument yesterday; yet, Mary Calkins and George Best (two of several former Federal Circuit Law Clerks who regularly follow appellate patent matters) each provided a first hand assessment. Ms. Calkins has permitted me to share her analysis of the argument, which is included within this further summary that provides a more nuanced approach that paints some of the gray areas that are not so otherwise discernable from the written record alone.

On the Merits of § 271(f): Ms. Calkins “initial feeling is that the Court will likely overturn the Federal Circuit, but frankly [she is] not sure as [to Justices] Ginsburg, Souter and possibly even Alito[, as they] seemed to be looking for reasons to uphold the Federal Circuit’s statutory interpretation; [Justice] Scalia seemed to think the whole issue should be moot, and [Justice] Kennedy did not say much. [Justice] Breyer predictably was concerned with international law being disturbed and [Justice] Stevens dislikes patents so [Breyer and Stevens] were quite easy to read.”

Based upon the opinions from the Court over the past year or so, and reading the opinions in the several § 271(f) cases from the court below and, particularly, the briefs in this appeal, it is, indeed, to be expected that the Court will overturn the Federal Circuit’s construction of § 271(f).

Patent-Eligibility under § 101; Software; Business Methods:

Ms. Calkins noted that “[a] lot of the questions [were] asked [that] had to do with whether software is, or should be, patentable at all, and the justices did not seem to be in agreement on that either, so there may be some interesting concurrences or dissents on that issue even if the court predictably overturns the [Federal Circuit] on the extraterritoriality/damages issue.”

Professor Dennis Crouch in his same day analysis based upon the transcript of the argument provides key quotations from several of the justices *and statements from all counsel including the government as amicus curiae* that

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suggests that there should be a narrower construction of patent-eligibility than under current Federal Circuit jurisprudence. Professor Crouch has an excellent, concise set of quotations from the transcript on this point that will save the casual reader from wading through the fifty-plus pages of transcript. *See* Dennis Crouch, *Patently O, Microsoft v. AT&T Oral Arguments*, February 21, 2007, [http://www.patentlyo.com/patent/2007/02/microsoft_v_att_2.html]

A Breyer/Stevens Anti-Federal Circuit § 101 Opinion: It is very safe to say that both Justice Stevens and Justice Breyer will vote to hold that § 271(f) does not extend to Microsoft's activities, and that either or both of them will write an opinion that also says that § 101 patent-eligibility as interpreted by the Federal Circuit is broader than Supreme Court precedent. The only real question is whether the Stevens or Breyer opinion will be a *majority* opinion for the Court.

Subject to Ms. Calkins reservations concerning the § 271(f) issue, although she also predicts a likely reversal on this issue, we should cautiously await the decision to see whether, indeed, the Court does reverse on § 271(f).

If the Court *does* vote to reverse on § 271(f), then the Stevens or Breyer opinion will be for the majority, and include in that opinion at least *dictum* that scales back the scope of patent-eligibility under § 101. (If Stevens and Breyer are in the minority on § 271(f), one or both will undoubtedly author a separate opinion expressing their views on § 101.)

Two-Fold Significance of the Absence of the Chief Justice: The recusal of the Chief Justice has two major implications for this case:

First, AT&T needs only four votes to win this case. For Microsoft to win, it will still need five votes. (A 4-4 tie vote results in a nonprecedential affirmance of the decision below.)

Second, if in the majority, Justice Stevens stands in the place of the Chief Justice insofar as nomination of the writer of the majority opinion. Perhaps a younger Stevens would have nominated himself for this task, but perhaps Justice Breyer will be nominated to write the majority opinion, and that

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opinion will include statements that the scope of patent-eligibility under 35 USC § 101 is narrower than existing Federal Circuit precedent.

(It is difficult to imagine that a majority opinion that would narrow the scope of § 101 would be issued without at least a concurring or dissenting opinion focusing upon this issue.)

Software, Business Methods, Rough Sledding Ahead! Proponents of an open door to business method and/or software patent-eligibility under 35 USC § 101 should not sleep well: It won't take renting a DVD of "Halloween 6" or some other horror movie to accomplish this feat: Instead, just reread the edited transcript provided by Professor Crouch on the quotes from the Court and counsel on § 101 patent-eligibility.

No. 6 *Nuijten*, on the § 101 Highway to the Court: The upcoming *Nuijten* decision of the Federal Circuit may be part of a revolving door to the Supreme Court for the further evolution of the § 101 patent-eligibility standards; presumably, the Federal Circuit will hold their decisions in these cases to benefit from the guidance that the Court will provide in *Microsoft* -- to either follow or distinguish what the Court will say about patent-eligibility issues. (No. 6 *Nuijten* focuses upon patent eligibility of a signal, *per se*, and has already been argued, Gajarsa, Linn, Moore, JJ.)

(2) : *Cybor de novo* Appellate Claim Construction

Amgen, Inc. v. Hoechst Marion Roussel, Inc., No. 06-1291, *opinion below*, 457 F.3d 1293 (Fed. Cir. 2006), *reh'g en banc denied*, 469 F.3d 1039 (2006).

Questions Presented: "In virtually every patent infringement case, federal district judges are called on to determine the scope of one or more claims in a patent. Such "claim construction" requires the judge to assess not only the state of the art and customary meaning of claim terms at the time of the invention, but also the contemporaneous meaning to a skilled practitioner of both the patent's technical description of the invention and the patent applicant's statements to the Patent and Trademark Office during the prosecution process. Many patent cases also include disputes over the 'doctrine of equivalents,' a significant doctrine that prevents a copyist from

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avoiding liability ‘by making only insubstantial changes to a patented invention.’ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

“This case raises two questions concerning the administration of these important doctrines and the allocation of judicial authority between trial and appellate courts:

“1. Are all aspects of a district court’s claim construction subject to *de novo* review, as the Federal Circuit has held despite vociferous criticism from numerous judges and commentators, or instead should the Federal Circuit have reviewed the factual determinations underlying the district court’s claim construction deferentially?

“2. By restricting the ways in which a presumption of ‘prosecution history estoppel’ may be rebutted, and engaging in *de novo* review of a district court’s determinations that the presumption *has* been rebutted, has the Federal Circuit effectively resurrected the categorical bar to a claim of infringement under the doctrine of equivalents that was expressly rejected in *Festo* and *Warner-Jenkinson*?”

Status: The deadline for Respondent to file an opposition is April 25, 2007. A vote whether to grant *certiorari* should take place before the end of the Term. *If certiorari* is granted briefing would take place over the summer and an oral argument would be scheduled for the Fall 2007 term that commences in October. (The possibility remains, of course, that the Court could issue a CVSG order responsive to the Petition phase that would build in a considerable delay in this timing.)

Discussion: The *Amgen* petition challenging *Cybor de novo* appellate review has a hard hitting substantive attack that hits bullseyes in its portrayal of an inter-circuit conflict that isolates the Federal Circuit from the regional courts of appeal (pp. 21-22, ¶ 4); it has key policy discussions (citing *Daubert*) (pp. 13-14):

“Incorrect results... waste[s] tremendous resources: “Plenary *de novo* review of claim construction does not work. It produces incorrect results and

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causes litigants and district courts to waste tremendous resources. The practice, which has been savaged by a sizable minority of the Federal Circuit, rests on the false premise that claim construction entails no factual inquiry. Construction of patent claims depends on technological mastery and is therefore, like the inquiry into the reliability of scientific testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), something for which trial courts are uniquely suited and owed special deference.” (Amgen Petition, pp. 13-14)

A “simplistic syllogism... fl[y]ing in the face of Rule 52(a)”: The Federal Circuit’s simplistic syllogism – if an issue is for the court, it must be subject to complete *de novo* review on appeal – flies in the face of Rule 52(a) and is belied by well-established practice in patent and other areas of the law in which the factual determinations undergirding a court’s legal pronouncement are reviewed for clear error.” (Amgen Petition, p. 14)

Indiscriminate[] ... power grab by the Federal Circuit: “The *de novo* standard of review, as applied indiscriminately to facts and technical mastery underlying claim construction, is a power grab by the Federal Circuit at the expense of the district courts and the judicial process. The standard, adhered to in three en banc decisions despite vociferous opposition from a substantial minority of the Federal Circuit and criticism from the bench, bar, and beyond, is overdue for further review. (Amgen petition, p. 15, footnotes omitted)

The Gajarsa Concurrence – But “Cybor’s core is rotten, too”: Judge Gajarsa’s concurrence in denial of rehearing is wide of the mark. Judge Gajarsa took issue only with the periphery of *Cybor*, not its core, saying he would reconsider *Cybor* only to the extent that a district court has had to resolve *conflicting expert testimony*. But *Cybor*’s core is rotten, too: *all* claim constructions deserve at least some deference. Patents can be understood only with reference to technology, and the district judge who has immersed himself in that technology and its terminology – including by listening (as Judge Young did) to *non-conflicting* experts – is in the best position to construe the patent. (Amgen petition, p. 19, footnotes omitted)

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Circuit Splits on Document Construction: “Claim constructions should be reviewed in the same way as other conclusions entrusted to a judge but based on factual determinations. For example, validity under the nonobviousness standard of 35 U.S.C. § 103, though ultimately a question of law, rests on “several basic factual inquiries” akin to the inquiries underlying claim construction. See *Graham*, 383 U.S. at 17; pages 17-18, *supra*. Those inquiries, under Rule 52(a), are reviewed only for clear error. *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986). Similarly, under the Uniform Commercial Code, when a contract contains “usage of trade” terminology, “the existence and scope of such a usage are to be proved as facts,” U.C.C. § 1-205, which are then reviewed for clear error. *E.g.*, *Voest-Alpine Trading USA Corp. v. Bank of China*, 288 F.3d 262, 265 (5th Cir. 2002). The law abounds with other examples of deferential appellate review of the facts undergirding a legal conclusion. See, *e.g.*, *Ornelas v. United States*, 517 U.S. 690, 699 (1996) (facts underlying judge’s determination of probable cause are reviewed for clear error); *United States v. Bajakajian*, 524 U.S. 321, 337 n.10 (1998) same for factual findings made in inquiring into excessiveness of a fine). Claim constructions should be treated the same way. Nor should the standard of review depend, as Judge Gajarsa’s concurrence suggested, on whether the district court’s claim construction makes use of live testimony. There is no reason to believe that when this Court acknowledged the “evidentiary underpinnings” of claim construction, *Markman II*, 517 U.S. at 390, it had only extrinsic evidence in mind. The patent and, especially, its prosecution history – though documentary in nature – are still *evidence* from which a tribunal must make case-specific findings, not just announce principles of law. And it is settled that federal judges’ factual findings are reviewed for clear error even when based only on documentary evidence.” (Amgen petition, pp. 21-22, ¶ 4)

An Anti-Federal Circuit Tenor: Yet, despite the merits of the attack, the reader first has his breath taken away by the aggressiveness and some would say unwarranted tenor of the petition. It portrays an “imperial” Federal Circuit “practice ... lambasted for years by bench, bar, and academy because... it not only produces inaccurate results, but also misallocates judicial resources, spawns needless disputes, prolongs litigation, and destroys certainty.” (p. 2). *Cybor* is “applied indiscriminately..., a power grab by the Federal Circuit at the expense of the district courts and the judicial process.” (p. 15)

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comments: hwegner@foley.com

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(3) *Quanta v. LG, Patent Exhaustion*

Quanta Computer, Inc. v. LG Electronics, Inc., No. 06-937, *opinion below*, *LG Electronics, Inc. v. Bizcom Electronics, Inc.*, 453 F.3d 1364 (Fed. Cir. 2006)(Mayer, J.)

Issue: Whether the Federal Circuit erred by holding, in conflict with decisions of this Court and other courts of appeals, that respondent's patent rights were not exhausted by its license agreement with Intel Corporation, and Intel's subsequent sale of product under the license to petitioners.

Status: Respondent's brief in opposition is due March 9, 2007. Unless there is a CVSG order, *certiorari* will be determined during the current Term; grant of *certiorari* would mean a likely Fall argument early in the October 2007 Term.

Battle of Supreme Court Heavyweights: Following a trend of greater sophistication by the patent community with the increasing use of Supreme Court appellate specialists to represent them before the highest Court, Petitioner's lead counsel Maureen E. Mahooney duels Supreme Court boutique expert (and now frequent Federal Circuit participant as well) Richard G. Taranto.

Conflict with Supreme Court Precedent: At the heart of the controversy is the Federal Circuit line of case law starting with *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), that permits a patentee to have his cake and eat it too: He can license his patents but conditioned in a manner that the purchaser from the licensee becomes an infringer, said by Petitioner to directly conflict with the Supreme Court line of precedent dating back to *Motion Picture Patents Co. v. Universal Film Manufacturing Co.*, 243 U.S. 502 (1917).

Discussion: Petitioner's *Statement of the Case* lays out the fundamentals: "[LGE] purchased a portfolio of patents [that it] now contends ... are infringed by every computer in the world, whenever microprocessors and chipsets are combined with generic components such as busses and memory. A year after its purchase, LGE resolved its standoff with [Intel] by negotiating a *** license payment from Intel that gave Intel an unrestricted right to 'make, use, [and] sell' products incorporating LGE's patents. LGE

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insisted, however, that Intel send a ‘notice’ to its own customers purporting to inform them that Intel's license did not protect *them* from infringement suits if they actually used microprocessors or chipsets purchased from Intel in a computer. The district court correctly found ... that the only reasonable use of [the licensed] products was to incorporate them into computers in the manner that LGE now contends is infringing.

Under the patent exhaustion doctrine that this Court has applied for more than 90 years ... [since] *Motion Picture Patents Co. v. Universal Film Manufacturing Co.*, 243 U.S. 502 (1917)[,] an authorized first sale of a patented article exhausts the patent owner's rights in that article, and nullifies any ‘conditions’ that the patent owner has tried to attach to its use or resale. Beginning with its decision in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), however, the Federal Circuit has steadily eroded the exhaustion doctrine. In this decision the Federal Circuit held that exhaustion is entirely optional, and easily nullified by a ‘notice’ announcing that the patent owner would prefer that it not apply. That is an unprecedented and extremely dangerous expansion of the patent monopoly, in direct conflict with numerous decisions of this Court.

“This case is important on several levels. First, on these specific facts LGE is now holding the entire computer industry hostage for billions of dollars in duplicative royalties, on patents that under this Court's precedents have clearly been exhausted. Second, on a broader level the Federal Circuit's new jurisprudence of ‘notice’ restrictions threatens to usher in a new era of servitudes and restraints on alienation running with chattels, by which patent owners attempt to suppress competition and control the use of patented goods after an authorized first sale. If LGE's tactics are not rejected now, they are likely to spread through the economy like the common cold - producing decades of litigation over ‘notice’ restrictions stamped on sold goods such as ‘single use only,’ ‘for use only with Microsoft software,’ ‘cannot be resold for less than \$1000,’ and anything else that patent owners can dream up.”

Respondent's Opposition: “Petitioners strain to make a broad doctrinal issue out of a narrow case-specific ruling. The district court, like petitioners themselves, accepted the governing legal principle that a patentee *may* condition its manufacturer-licensee's sales and thereby preserve its patent

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rights against purchasers from the licensee-manufacturer. It concluded, however, that there was no sufficiently conditional sale in this case. The Federal Circuit, following the same legal principle, disagreed with the trial court's case-specific assessment of the terms of dealing in this case, and returned the case to the district court for trial (on five patents, including one not at issue in the Petition). That interlocutory ruling presents no issue warranting review.

“The Federal Circuit's ruling presents no issue as to the governing legal principle – which has been settled in plain terms since *Mitchell v. Hawley*, 83 U.S. 544 (1873), as reaffirmed in *General Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175 (1938), and never undercut by any other authority. Petitioners, in the courts below and even in the Petition, have accepted the legal principle governing this case: that a patentee *may* restrict the patent-practicing authority to be conveyed through its manufacturer-licensee's sales to downstream customers. Despite its effort to obscure the issue by discussing situations indisputably not presented in this case (such as patentees' sales of their own products), the Petition positively stresses the distinction of the situation actually presented here, for which the governing legal principle is established and accepted. ...

Petitioner's Reply Brief: “Federal Circuit precedent allowing patent owners to sell goods subject to use or resale ‘conditions,’ starting in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), conflicts with this Court's cases and is the subject of widespread scholarly condemnation. The Federal Circuit has essentially revived the old rule of *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912), that a purchaser's right to use a patented good is a matter of implied license rather than patent exhaustion (‘nothing more nor less than an unrestricted license presumed from an unconditional sale,’ *id.* at 24) and therefore can be limited or defeated if the patent owner specifies ‘conditions’ or restrictions on the purchaser's ‘license’ to use or resell the goods it has purchased. That has not been the law since this Court expressly overruled *A.B. Dick* in *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917).

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“Respondent[] [argues] that even if a sale by the patentee itself exhausts the patent and nullifies any ‘conditions,’ a sale by *a licensee* need not have that effect, if the patentee has otherwise specified in the license. That proposed distinction is inconsistent with this Court's cases, which have always recognized that ‘in the essential nature of things, when the patentee, *or the person having his rights*, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use.’ *Adams v. Burke*, 84 U.S. 453, 456 (1873) (emphasis added [by Petitioner]). *Adams* involved a sale by a licensee/assignee rather than the patentee. So did *United States v. Univis Lens Co.*, 316 U.S. 241, 244 (1942). Respondent's proposed distinction is also absurd. Licensing someone else to exercise the patentee's rights cannot expand those rights. The patentee cannot do indirectly what this Court's cases prohibit it from doing directly. Otherwise every patentee would erect a shell entity to ‘license’ its patents, and then let that shell make the sales.”

(4) *Leclerc-Wallace* Anti-Foreigner “Louisiana Rule”

Leclerc v. Webb, Sup. Ct. No. 06-11, *opinion below*, 419 F.3d 405 (5th Cir. 2005); *Wallace v. Calogero*, Sup. Ct. No. 05-1645, *opinion below*, 419 F.3d 405 (5th Cir. 2005).

This set of cases originally was matched by a third case, *Lacavera v. Dudas*, Sup. Ct. No. 06-338, *opinion below*, 441 F.3d 1380 (Fed. Cir. 2006)(Mayer, J.), where the Court *denied certiorari* after the PTO had granted Petitioner full patent attorney status, rendering most of her complaints against the PTO moot.

The three cases raise discrimination challenges against state government – in *Leclerc* and *Wallace* – and the Federal Government – in *Lacavera* – where otherwise qualified candidates for the bar have been denied full or partial admittance on the basis of visa restrictions. In *Leclerc* and *Wallace* petitioners who are local law school graduates have been denied permission to take the Louisiana bar because they are neither American citizens nor green card holders. In *Lacavera*, a former full fledged member of the patent bar who is now a respected member of the Google, Inc., law department and continues to be fully qualified in terms of legal, technical and ethical standards has been denied continued full registration status because of her

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“crime” of being a Canadian citizen without a green card. Ironically, as a member of a state bar she is fully licensed to practice at *other* agencies of the Federal government but her lack of a green card is used as an excuse by the Federal Government to deny continued full registration to practice before the United States Patent and Trademark Office.

Status: On October 2, 2006, the government was given an order styled as an invitation to the Solicitor General to provide views whether to grant *certiorari* – a CVSG order.

Question 1 in *Leclerc*: “Whether a burden imposed solely on nonimmigrant aliens lawfully residing in the United States, such as the Louisiana rule precluding such persons from Bar admission, is subject to strict scrutiny under the Equal Protection Clause, a question on which this Court granted *certiorari* but failed to reach in *Toll v. Moreno*, 458 U.S. 1 (1982), and which remains the subject of conflicting appellate decisions.”

Question 2 in *Leclerc*: “Whether the Louisiana rule excluding lawfully admitted nonimmigrant aliens from Bar admission is preempted by federal immigration law and policy.”

Question 2 in *Wallace*: “Whether Federal immigration law preempts state licensing regimes that categorically ban H-1B visa-holders from obtaining a state license, as the Supreme Court of Vermont held in *Dingemans v. Board of Bar Examiners*, 568 A.2d 354 (Vt. 1989), or whether there is no preemption, as the Fifth Circuit held below.”

Questions Presented in *Lacavera*: Although the *Lacavera* petition was denied undoubtedly in major part due to the mootness of the principal complaint of petitioner, the issue will recur and is therefore worth studying: “The U.S. Patent and Trademark Office (‘USPTO’) excludes nonimmigrant aliens from registration before the patent bar. Nonimmigrant aliens are aliens lawfully living and working in the United States pursuant to visas that are more restricted in duration and employment than the visas of immigrant aliens. The exclusion from the patent bar does not apply to immigrant aliens, U.S. citizens, or non-U.S. citizens who reside outside of the United States and who are registered to practice before a foreign patent office that offers reciprocal admission to persons registered to practice before the USPTO.”

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The Court of Appeals for the Federal Circuit ('Federal Circuit') upheld the USPTO rule against a challenge that the rule exceeds the statutory authority of the USPTO and violates the equal protection aspect of the due process clause of the Fifth Amendment to the U.S. Constitution.

“The questions presented are as follows:

“1. Does the USPTO, in the exercise of its statutory authority to register patent practitioners who have the ‘necessary qualifications’ to practice before it, have the authority to refuse to register nonimmigrant aliens as patent practitioners solely on the basis of their immigration status, where the nonimmigrant aliens are otherwise qualified for registration and authorized by United States Citizenship and Immigration Services (‘USCIS’) to practice as patent practitioners in the United States?

“2. Did the Federal Circuit, in upholding a USPTO rule denying registration to nonimmigrant aliens, inappropriately apply only a ‘rational review’ standard where it should have applied at least ‘heightened scrutiny,’ if not ‘strict scrutiny,’ to a federal agency rule that discriminates against nonimmigrant aliens without serving any special national interest?

“3. Do bar admission rules, such as the state rule that is before this Court in *Leclerc v. Webb* and *Wallace v. Calogero*, and the federal rule that is the basis of this case, that deny aliens lawfully within the United States access to employment opportunities based on the duration and employment restrictions of their current visas, violate the aliens' rights to ‘equal protection’ in the absence of any evidence that the visa restrictions relate to valid state or federal interests in ensuring competency of practitioners?”

In denying Ms. Lacavera’s appeal, the Federal Circuit noted that it “[f]irst... determines whether the statute speaks to the issue of the challenge, and if it is silent or ambiguous, we defer to the agency's reasonable interpretation.” *Lacavera*, 441 F.3d at 1383 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984)). But, “the statute is silent as to whether the PTO may consider visa restrictions in determining whether or not to grant recognition.” *Id.* Indeed, the history of the statute is to provide *technically qualified* patent attorneys as the “necessary qualifications”; at the time the predecessor to the current statute was created

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there clearly was no contemplation of foreign patent attorneys or problems associated with their registration.

In a unique interpretation of the statute, the Federal Circuit says that “[i]t was reasonable for the PTO to interpret legal authority to render service as being a necessary qualification. Accordingly, it was reasonable for the PTO to enact regulations that limit an alien's ability to practice before it to those activities in which the alien may lawfully engage. Therefore, the PTO did not exceed its statutory authority in promulgating the regulations in question.” (But, Lacavera could also presumably return home to Canada and then legally provide services as a patent attorney.)

Additionally, Lacavera raised “Equal Protection” arguments parallel to those raised in the *Wallace* and *Leclerc* petitions now before the Court.

The Lacavera says that the PTO has exceeded its statutory authority:

“The USPTO rule should be stricken because it exceeds the statutory authority of the USPTO and violates nonimmigrant aliens' right to equal protection. The USPTO has no Congressional authority to interpret or enforce immigration law. Yet it refuses to register nonimmigrant aliens that are authorized by USCIS to practice as patent practitioners in the United States. The USPTO purports to enforce visa restrictions by creating case-by-case limits on the recognition of nonimmigrant aliens that practice before it. The Federal Circuit decision to uphold the USPTO rule was a marked departure from prior precedents holding that an agency cannot expand its Congressionally-limited authority into an area over which it has no jurisdiction. *See e.g., Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990) (holding that the Department of Labor's statutory authority to promulgate safety standards cannot be used to bootstrap it into an area in which it has no jurisdiction); *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 153 F.3d 155, 161 (Fed. Cir. 1998), *reh'g and reh'g en banc denied*, 161 F.3d 764 (1998), *aff'd*, 529 U.S. 120 (2000) (invalidating FDA regulations of tobacco products because FDA lacks jurisdiction to regulate such products). The decision below invites any agency, regardless of its Congressional mandate, to expand its authority to include creating and policing restrictions on aliens.” Lacavera petition, pp. 6-7.

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An Equal Protection argument is also strenuously argued:

“The USPTO rule denying registration to nonimmigrant aliens also violates the equal protection aspect of the due process clause of the Fifth Amendment. The Federal Circuit mistakenly applied only the ‘rational review’ standard that is applicable to acts of Congress under *Mathews v. Diaz*, 426 U.S. 67, 78 (1976). However, this Court made clear in *Hampton* that in the case of a federal agency rule like the USPTO rule, the decision to deprive aliens of employment opportunities must be justified by reasons that are properly the concern of the agency. *Hampton*, 426 U.S. at 116. Since the USPTO has no special national interest in its discriminatory rule, at least ‘heightened scrutiny,’ if not ‘strict scrutiny,’ should have been applied to the USPTO rule denying registration to nonimmigrant aliens.” Lacavera Petition, p. 7; citing *Cf. id.* at 100-105, *cf. Ramos v. U.S. Civil Service Comm'n*, 376 F. Supp. 361, 366 (D.P.R. 1974), *aff'd in relevant part*, 426 U.S. 916 (1976); other citations omitted.

Petitioner points out that all that the PTO has provided is “equal discrimination” which is not “equal protection”:

“The Federal Circuit decision set a dangerous precedent by misapplying the law of equal protection to hold that the petitioner was not denied equal protection because the USPTO treats all nonimmigrant aliens the same by refusing to register any of them. Equal discrimination is *not* equal protection. This Court established long ago that for purposes of equal protection analysis, ‘similarly situated’ persons must be identified by criteria that threaten a legitimate interest of the agency. *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 448 (1985). Here, the USPTO treats qualified nonimmigrant aliens differently than all other qualified persons seeking registration before the patent bar by denying them registration. There is no evidence that an applicant's immigration status threatens any legitimate interest of the USPTO in ensuring competency of patent practitioners. The decision below opens the door to any federal agency arbitrarily discriminating against nonimmigrant aliens without establishing even a rational basis for doing so.” Lacavera Petition, pp. 7-8; original emphasis; citations omitted.

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At the time of the litigation before the tribunals below, Ms. Lacavera was in the process of seeking a green card. The PTO's *Official Gazette* has now published a notification that it intends to grant Ms. Lacavera registration status as a patent attorney. Even with a green card and even with full patent attorney registration as a green card holder, she would still be subject to the discrimination that has faced previous patent attorneys in a like situation: If the green card holder returns home, then she or he will be disbarred as once again not having the appropriate green card status which the PTO has arbitrarily imposed as a requirement for *continued* registration. Particularly now that a green card is *not* permanent but must be renewed, the visa sword over patent attorney registration is particularly serious.

Jacobus Rasser and Dr. Bernhard Geissler provide two of the more notorious denials of continued patent attorney registration based solely upon lack of citizenship or green card possession: Rasser had been a member of the Ohio bar and a registered patent attorney and later Vice-President and the top patent attorney for the worldwide Cincinnati-based Proctor & Gamble; yet, he was stripped of his patent attorney registration simply because he left the United States to return to Europe. *In re Rasser*, 1985 WL 71975 (PTO Com'r 1985). (Later, Rasser did obtain his patent attorney registration.) Dr. Geissler, a renowned patent scholar at the Max Planck Institute in Munich before coming to America and for many years a leading patent attorney for Phillips Petroleum was stripped of his patent attorney status he became a partner in a leading Munich patent attorney firm. *In re Geissler*, 1974 WL 19945 (PTO Com'r 1974).

There is nothing at all subtle about the PTO's discrimination against aliens to bar them from registration before the PTO. Indeed, ever since 1984, while other jurisdictions have *liberalized* the admittance of foreigners to bars, the PTO has sought to further *exclude* foreigners whenever possible. Thus, going back twenty years ago to the time the PTO started the trend of *restriction* of foreigners as patent attorneys or agents, it recognized that it *could* admit non-citizens; but, it stated in 1984 that “[t]here is no known legal requirement or other public policy which ... makes desirable the registration or continued registration of non-citizens residing in a foreign country”. *Practice Before the Patent and Trademark Office* (notice of proposed rulemaking), 49 FR 33790, 33793 (1984).

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(5) *Joblove* (Tamoxifen) Patent Settlement – Antitrust

Joblove v. Barr Labs., Supreme Court No. 06-830, *proceedings below*, *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2nd Cir. 2006).

Issue: "Under what circumstances is an agreement by a brand pharmaceutical manufacturer (and patent holder) to share a portion of its future profits with a generic market entrant (and alleged patent infringer), in exchange for the generic's agreement not to market its product, a violation of the antitrust laws?"

Status: The Respondent's Brief was filed on February 15, 2007, along with a brief *amici curiae* of 41 Professors of Economics, Business and Law and a brief *amicus curiae* of American Antitrust Institute.

Discussion: This has a stronger factual underpinning for grant of *certiorari* than the *Schering-Plough* case from the previous term, but its diffuse "Question Presented" and unfocused argumentation make grant problematic. Instead of pinpointing a specific inter-circuit conflict or asking a *specific* question, Petitioner more generally asks for a treatise "[u]nder what circumstances..." an antitrust violation may exist.

Nevertheless, *if* the *Schering-Plough* case was only one vote shy of the necessary four for grant of *certiorari*, it remains conceivable that an additional vote might be picked up in which case that the Court *may* grant review.

(6) *Nuijten* "Signal" Patent-Eligibility; *State Street Bank*

In re Nuijten, Fed. Cir. No. 06-1371.

Issue: *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), is partial basis for Appellant and supporting *amicus curiae* Intellectual Property Owners in their test case to have a claim to a signal, *per se*, considered to be directed to patent-eligible subject matter under 35 USC § 101.

A Test Case to Measure the Viability of *State Street Bank*: To the extent that the Federal Circuit issues a clear pronouncement *either way*, this may represent a vehicle for a Supreme Court test as to the limits of § 101 patent-

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eligibility and also permit an opportunity for a merits decision that deals with the *Metabolite* case. See *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 126 S.Ct. 2921, 2927-28 (2006)(Breyer, J., dissenting from dismissal, joined by Stevens, Souter, JJ.).

Status: A decision is awaited; oral argument was held February 5, 2007 (Gajarsa, Linn, Moore, JJ.)

Discussion: The Federal Circuit is asked to hold that the scope of patent-eligible subject matter under 35 USC § 101 includes a “signal”, suggesting an expansion of the scope of protection that is supported by the *State Street Bank* “business method” patent-eligibility case.

The “signal” claim in controversy reads as follows: “14. A signal with embedded supplemental data, the signal being encoded in accordance with a given encoding process and selected samples of the signal representing the supplemental data, and at least one of the samples preceding the selected samples is different from the sample corresponding to the given encoding process.”

Looking only to cases decided on the merits, it is logical to find that the “signal” is patent-eligible under 35 USC § 101.

To the extent that the Federal Circuit *does* reverse the PTO and were the government to seek review at the Court by *certiorari*, the case would represent a vehicle to explore the *dictum* from Justice Breyer in the *Metabolite* that questions the validity of *State Street Bank*:

“[Patentees] point to this Court's statements that a ‘process is not unpatentable simply because it contains a law of nature,’ *Flook*, 437 U.S., at 590; see also *Gottschalk*, 409 U.S., at 67, and that ‘an *application* of a law of nature ... to a known ... process may well be deserving of patent protection.’ *Diehr*, 450 U.S., at 187. ...

“[Respondents argue that] claim 13 is a patentable ‘application of a law of nature’ because, considered as a whole, it (1) ‘entails a physical transformation of matter,’ namely, the alteration of a blood sample during whatever test is used, Brief for Respondents 33 (citing *Cochrane v. Deener*,

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94 U.S. 780, 788 (1877); *Gottschalk, supra*, at 70, 93 S.Ct. 253), and because it (2) ‘produces a ‘useful, concrete, and tangible result,’ ‘namely, detection of a vitamin deficiency, [Patentee’s brief,] 36 (citing *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (C.A.Fed.1998)).

“... [T]o use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter. Neither *Cochrane* nor *Gottschalk* suggests that that fact renders the phenomenon patentable. See *Cochrane, supra*, at 785 (upholding process for improving quality of flour by removing impurities with blasts of air); *Gottschalk, supra*, at 71-73 (rejecting process for converting numerals to binary form through mathematical formula).

“Neither does the Federal Circuit's decision in *State Street Bank* help [patentees]. That case does say that a process is patentable if it produces a ‘useful, concrete, and tangible result.’ 149 F.3d, at 1373. But this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary. The Court, for example, has invalidated a claim to the use of electromagnetic current for transmitting messages over long distances even though it produces a result that seems ‘useful, concrete, and tangible.’ *Morse, supra*, at 116. Similarly the Court has invalidated a patent setting forth a system for triggering alarm limits in connection with catalytic conversion despite a similar utility, concreteness, and tangibility. *Flook, supra*. And the Court has invalidated a patent setting forth a process that transforms, for computer-programming purposes, decimal figures into binary figures – even though the result would seem useful, concrete, and at least arguably (within the computer's wiring system) tangible. *Gottschalk, supra*.

“Even were I to assume (purely for argument's sake) that claim 13 meets certain general definitions of process patentability, however, it still fails the one at issue here: the requirement that it not amount to a simple natural correlation, *i.e.*, a ‘natural phenomenon.’ See *Flook, supra*, at 588, n. 9 (even assuming patent for improved catalytic converter system meets broad statutory definition of patentable ‘process,’ it is invalid under natural phenomenon doctrine); *Diehr*, 450 U.S., at 184-185, 101 S.Ct. 1048

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(explaining that, even if patent meets all other requirements, it must meet the natural phenomena requirement as well).

“At most, respondents have simply described the natural law at issue in the abstract patent language of a ‘process.’ But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge. Cf. *id.*, at 192, 101 S.Ct. 1048 (warning against ‘allow[ing] a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection’). One might, of course, reduce the ‘process’ to a series of steps, e.g., Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce *any* process to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable ‘natural phenomenon,’ and I can find nothing in claim 13 that adds anything more of significance.” (emphasis added)

The PTO Relies upon Infringement Case Law: The PTO focuses not on Section 101 patent-eligibility cases, but rather infers an absence of patent-eligibility by looking to *dictum* in cases involving infringement, including *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003). The PTO argues that “[s]ince [*Bayer*] relied on section 101 case law for its conclusion that ‘manufacture’ refers to ‘physical goods’ or ‘material things,’ *Bayer’s* holding should apply in this section 101 case.”

The PTO Invokes the Breyer Metabolite Dictum: The PTO meets the challenge of patent-eligibility head on, denying that a “signal” is within any of the four categories of patent-eligible subject matter, even a “manufacture” under 35 USC § 101. The PTO invokes the Supreme Court procedural dissent of Justice Breyer: “Congress is in the best position to perform the complex balances necessary to promote innovation without stifling it. *See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2922 (2006) (Breyer, J., dissent from dismissal as improvidently granted) (‘[T]he reason for the [abstract idea] exclusion is that sometimes too much patent protection can impede rather than “promote the Progress of Science and useful Arts.’); *id.* (‘Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that

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underprotection can threaten.’). ... [A]n electrical signal does not fall into any of the four statutory categories, essentially because it is neither ‘concrete’ nor ‘tangible’ enough to qualify as patentable subject matter. For similar reasons, the claimed electrical signals can be excluded from patentability as being too abstract. *Labcorp*, 126 S. Ct. at 2928 (Breyer, J) (dissent from dismissal as improvidently granted) (describing the result produced by the computer programming process in *Gottschalk v. Benson* - which rejected the claims as abstract - to be ‘arguably’ tangible when the software is executed ‘within the computer's wiring system’).”

The PTO Challenges the Science behind the IPO Amicus Brief: The PTO challenges the scientific basis for arguments by *amicus curiae* Intellectual Property Owners, Inc. It questions the science behind IPO’s argument that a signal is a “manufacture”. As explained by the PTO in its brief, “Amicus IPO argues that ‘the creation of an electrical signal meets the *Chakrabarty* Court's definition of manufacture: producing a signal from electricity (*i.e.*, electrons) by giving the electricity new forms, qualities and properties, through the data encoding process, where the production occurs by a machine.’ This argument fails on several levels. First, Nuijten's claims are not limited to signals that involve electrons or any other type of matter; they include optical signals and radio signals, neither of which require electrons for propagation, and none of which thus require matter. ... Even if the signals were limited to electrical signals (and somehow excluded optical, radio, and other pure-energy signals), IPO's reliance on the fact that electrons ‘have mass’ (and thus are ‘matter’) is misplaced. An electrical signal is not transmitted, as IPO's brief implies, by a cluster of electrons traveling from point A to point B. Instead, an electrical signal propagates, at nearly the speed of light, *through* the electrons in a conductor:

“[I]t's important to distinguish between the speed of the electrons and that of the electrical signal in the wire. As soon as electrons at one end of the wire begin moving, their electric fields affect adjacent electrons, which also begin moving. This effect propagates down the wire at what is in fact nearly the speed of light, so the current begins everywhere almost simultaneously.’

“Thus, contrary to IPO's suggestion, an electrical signal, like optical signals and radio signals, is simply energy, *i.e.*, an electric field, and does not

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qualify as patentable subject matter for the same reasons that other energy signals do not.” (Appellee’s brief, citations and footnotes omitted).

Big Pharma versus the IPO and the EE Industry: While there is no *amicus* participation from the pharmaceutical industry in *this* case, subsequent to the briefing in *Nuijten* one of the major American pharmaceutical houses has taken the opportunity to challenge patent-eligibility in No. 2 *Microsoft*. See the discussion of No. 2 *Microsoft*, at the section *Eli Lilly Brief Against Computer Code Patent-Eligibility*, *supra*.

(7) *Integra: Post-Merck “Safe Harbor”; “Research Tools”*

Integra Lifesciences I, Ltd. v. Merck KGaA v. Integra Lifesciences I, Ltd., Fed. Cir. 02-1052, *on remand from Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

On June 13, 2005, *now eighteen (18) months ago*, the Supreme Court reversed and remanded the Federal Circuit. After yet another oral argument on June 5, 2006, a panel of the Federal Circuit (Newman, Rader, Prost, JJ.) continues to hold the case, without decision or remand to the trial court in a litigation that has now run ten years.

There are numerous loose ends relating to “research tools” and “experimental use” and other issues, as discussed in Harold C. Wegner, *Post-Merck Experimental Use and the “Safe Harbor”*, 15 Fed. Cir. Bar. J. 1 (2005).

Outcome: Whether the court will issue a further substantive clarification of the law or simply remand the case to the trial court is unclear.

(8) *Pharm. Research v. D.C. – Drug Pricing Federal Preemption*

Pharmaceutical Research and Mfrs. of America v. District of Columbia, Fed. Cir. App. No. 2006-1593, *opinion below*, 406 F.Supp.2d 56 (D.D.C. 2005).

In *Pharmaceutical Research and Mfrs. of America v. District of Columbia*, Fed. Cir. App. No. 2006-1593, *opinion below*, 406 F.Supp.2d 56 (D.D.C. 2005), the local government challenges the trial court’s nullification of its law relating to pricing of drugs protected by patents.

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Status: Oral argument is scheduled at the Federal Circuit on April 4, 2007.

Issues as Phrased by the Parties: Per appellant D.C. government the issues are –

"1. Whether the district court erred as a matter of law in concluding that, from the record presented below, plaintiffs-appellees had established Article III standing to challenge the pre-enforcement validity of the District of Columbia's Prescription Drug Excessive Pricing Act of 2005?"

"2. Whether the district court erred as a matter of law in concluding that, on its face, the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 is preempted by federal law governing patented prescription drugs?"

PhRMA and BIO phrase three issues –

"1. Whether the district court correctly held that PhRMA and BIO have standing on behalf of their members -- the world's leading pharmaceutical and biotechnology companies -- to challenge a District of Columbia law that regulates the prices at which their members sell patented prescription drugs?"

"2. Whether the district court correctly held that the Prescription Drug Excessive Pricing Act of 2005 is preempted because it targets patented prescription drugs -- and *only* those drugs that are under patent -- for price regulation that restricts the system of rewards Congress created to encourage the development of new medicines?"

"3. Whether the Act violates the Foreign Commerce Clause by benchmarking prescription drug prices in the District of Columbia against prices in foreign countries, thereby burdening manufacturers' business decisions in those foreign markets and impinging on the federal government's exclusive authority to conduct foreign relations?"

Appellate Jurisdiction: There is also present the jurisdictional question – *which neither party raises at this stage* – as to whether the Federal Circuit has appellate jurisdiction over a non-patent case on the basis that the defense at trial was federal preemption on the basis of federal patent law. Since the transfer of this appeal from the D.C. Circuit, the Federal Circuit has

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expressly held that a patent preemption argument is *not* basis for appellate jurisdiction at the Federal Circuit. See *Thompson v. Microsoft Corp.*, 471 F.3d 1288 (Fed. Cir. 2006)(Linn, J.).

If *Thompson* is followed, should the case be transferred to the D.C. Circuit? (The D.C. circuit had originally received the appeal but transferred the case to the Federal Circuit.)

(9) *BMC v. Paymentech* – “Joint Infringement”

BMC Resources, Inc. v. Paymentech, L.P., Fed. Cir. App. No. 2006-1503

Issue: Is there “joint infringement” liability where a claim covers a plurality of steps and no single party performs all of the steps of the invention where no single party controls or directs the actions of all who cumulative perform the invention?

Status: Oral argument is scheduled for April 5, 2007.

Claim 6: “A method of paying bills using a telecommunications network line connectable to at least one remote payment card network via a payee's agent's system, wherein a caller begins session using a telecommunications network line to initiate a spontaneous payment transaction to a payee, the method comprising the steps of:

[a] **prompting the caller** to enter a payment number selected from one or more choices of credit or debit forms of payment;

[b] **prompting the caller** to enter a payment amount for the payment transaction;

[c] **accessing a remote payment network** associated with the entered payment number, the accessed remote payment network determining, during the session, whether sufficient available credit or funds exist in an account associated with the payment number to complete the payment transaction, and

upon a determination that sufficient available credit or funds exist in the associated account,

[c] **charging the entered payment amount** against the account associated with the entered payment number,

[e] **adding the entered payment amount** to an account associated with the

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entered account number, and [e] **storing the account number**, payment number and payment amount in a transaction file of the system.” [paragraph lettering and underlining added]

Some of the steps in the process are performed by a financial institution, so that no single party performs all steps of the patented invention.

Attempt to Extend the Scope of Patent Protection: While “joint infringement” is established where one party performs all but one step of a patented process and the other step is performed at his direction, the prevailing view is that a claim should be drafted in a manner that all steps can be performed by a single actor. Failure to draft such a claim leaves the patentee powerless. For an extensive review of this subject, see Harold C. Wegner, *E-Business Patent Infringement: Quest for a Direct Infringement Claim Model*, presented to the SOFTIC 2001 Symposium, http://www.softic.or.jp/symposium/open_materials/10th/en/wegner-en.pdf. A more recent treatment is provided by Mark A. Lemley *et al.*, *Divided Infringement Claims*, 33 AIPLA Q. J. 189 (2005).

(10) *Teva v. Novartis* – Justiciable controversy

Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., Fed. Cir. No. 2006-1181

Issue: “Whether there is an ‘actual controversy’ sufficient to support subject matter jurisdiction over Teva's claim for a declaration that certain patents were invalid... where: (i) appellee listed the patents in the Orange Book with respect to its Famvir[®] product, thus representing that an infringement action under those patents ‘could reasonably be asserted’ against any generic formulation of that drug; (ii) Teva committed a statutory act of infringing ...by submitting an Abbreviated New Drug Application ... to market a generic formulation of Famvir[®] before the expiration of the patents; (iii) Novartis sued Teva to prevent Teva from launching its generic formulation of Famvir[®] alleging that Teva's ANDA infringed another patent listed in the Orange Book with respect to Famvir[®]; (iv) appellee has consistently and aggressively enforced its pharmaceutical patents against Teva and other generic drug companies; and (v) appellee has refused to give any assurance that it would not sue Teva for infringement of the patents.”

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Status: The case was argued in 2006 (Mayer, Gajarsa, Friedman, JJ.), before the Supreme Court's decision in *MedImmune*. On January 9, 2007, Teva asked the court to consider the effect of *MedImmune* on this case.

SanDisk Precedential Interpretation of "Footnote 11": The outcome of *Teva* is foreshadowed by *SanDisk Corp. v. STMicroelectronics, Inc.*, ___ F.3d ___ (Fed. Cir. 2007)(Linn, J.), where the court confirmed the broad sweep of *MedImmune* "footnote 11", *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007):

"[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk*, p. 13; emphasis added.

Narrow Holding in *SanDisk*: The holding is narrowly drawn, specifically noting that the new law is in conflict with *Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153 (Fed. Cir. 1996):

"We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the application of the principles of declaratory judgment jurisdiction to the facts and circumstances of each case. We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights." *SanDisk*, pp. 13-14, citing *MedImmune*, footnote 11.

***SanDisk* Boundaries to a Trial Court's Discretion:** "Although the district court is given the discretion, in declaratory judgment actions, to dismiss the

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case, there are boundaries to that discretion. See *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995). ‘When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal.’ *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993). Furthermore, the exercise of discretion must be supported by a sound basis for refusing to adjudicate an actual controversy. See *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005); *Capo, Inc. v. Dioptics Med. Prod., Inc.*, 387 F.3d 1352, 1357 (Fed. Cir. 2004).” *SanDisk*, p. 19.

SanDisk Concurrence in the Result: The concurring member of the court “agree[s] with the [majority] that a fair reading of footnote 11 of the Supreme Court’s opinion in *MedImmune* compels [its] result, and I therefore concur in the judgment reversing the district court’s dismissal order in this case.” *SanDisk*, Bryson, J., concurring.

But, the concurrence also notes that the limited opinion of the majority cannot, in practice, be limited: “[T]he rule adopted by the court in this case will effect a sweeping change in our law regarding declaratory judgment jurisdiction.”