

Wegner's Top Ten Supreme Court Patent Cases

Top Ten Patent Cases *

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- 3 *Amgen: Cybor de novo* Claim Construction
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Top Ten Cases Disposed of This Term (pp. 22 *et seq.*)

- Apotex*: Justiciable Controversy, *cert. denied* (former No. 6)
- Ferring*: Inequitable Conduct, *cert. denied* (former No. 9)

What's New:

Coming Soon: No. 2 *MedImmune* may be decided shortly.
No. 8 *Integra* and No. 9 *Voda* are both way overripe for decision.

Top Ten List – Changes in the last week:

- No. 3 *Amgen* jumps *Microsoft* on the list because of the contentious Federal Circuit denial of *en banc* rehearing that increases the likelihood that either *Amgen* or an *Amgen*-like case will eventually lead to an overruling of *Cybor*, a far more important event perhaps than anything on the Top Ten list other than No. 1 *KSR*.
- No. 6 *Leclerc-Wallace-Lacavera* involves a December 1, 2006, deadline for a government response in *Lacavera*.
- New to the list is No. 10 *Paymentech* on “joint” (partial) infringement.

* This paper was last revised on November 30, 2006, 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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(1) *KSR v. Teleflex: Obviousness Standard*

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 Cir. 2005)(Schall, J.)(non-precedential), *appeal from trial court opinion*, 298 F.Supp.2d 581 (E.D. Mich. 2003).

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Status: A decision is expected in mid- to late Winter 2007. The oral argument took place on November 28, 2006.

Issue (in general terms): Should the Court interpret *Graham* as permitting a finding that an invention is “obvious” under its three part test or should the Court affirm the Federal Circuit’s expansion of *Graham* to *additionally* require that the patent challenger establish that there is a “teaching, suggestion, or motivation’ that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.”

The three part *Graham* test: “Under [35 USC] § 103[(a)], the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810-11 (1986)(*per curiam*)(quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

Issue (as formally before the Court): Whether the Federal Circuit has erred in holding that a claimed invention cannot be held “obvious”, and thus unpatentable under 35 U.S.C. § 103(a), in the absence of some proven “teaching, suggestion, or motivation’ that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.”

The Once Predicted 9-0 Reinstatement of the Trial Court’s judgment:

When *certiorari* was granted earlier this year, there were many who saw this case as a slam dunk victory, an outright reversal of the Federal Circuit reversal of summary judgment. Just in the month before oral argument, Petitioner’s counsel was quoted in the *ABA Journal* that “I think [the court] will vote 9-0 to reinstate the district court judgment. That’s what the solicitor general has urged... as well as the patent office. So I don’t think I’m going too far out on a limb here.” Steve Seidenberg, *Stating the Obvious*, ABA

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Journal, pp. 14-15 at 15 (October 2006). Confidence on the part of both sides in advance of the argument was manifested perhaps best by the fact that instead of hunkering down in secret “moot court” sessions, public appearances were made including what appears to be unprecedented in the patent world – a web television broadcast advertised to the public comprising an appearance by lead counsel for both sides one week before the oral argument: It is hardly any wonder that Respondent’s counsel was fully prepared for Petitioner’s arguments, having heard them the previous week “live” from Petitioner’s counsel at a press conference-like venue.

The Expected Outcome Scenarios: While it is expected that the Supreme Court will reverse and remand the *KSR* case, it will do so setting only a somewhat modified obviousness standard.

There are several scenarios for outcomes in this case:

“Teaching-Suggestion-Motivation” as a “Nonexclusive” Test: It seems clear that the Court may well maintain the Federal Circuit’s teaching-suggestion-motivation test, but as a “nonexclusive” factor for determining obviousness. Under this scenario, it would be relegated to one of the factors that a court may use in determining obviousness, much like the “secondary considerations” outlined in *Graham v. John Deere & Co.*, 383 U.S. 1, 17-18 (1966). Even though a “secondary consideration” strongly favoring the patentee may be present – as in *Graham* – this does not necessarily mean that the patentee will prevail: Indeed, in *Graham* the patentee lost.

“Codification” of the Kahn “Implicit Motivation” Standard: It is possible that in addition to making teaching-suggestion-motivation a *nonexclusive* test, the Court may also follow the Federal Circuit’s test that an *implicit* motivation must be established for a finding of obviousness. Depending upon how the test is formulated by the Supreme Court, this could very well completely water down the teaching-suggestion-motivation test to nothingness – or provide a meaningful basis to avoid hindsight reconstructions of inventions.

The *Kahn* case states that “[a] suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art, as ‘the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references....

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The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.”

Kahn, 441 F.3d at 988-89 (quoting *In re Kotzab*, 217 F.3d 1365, 1370 (Fed.Cir.2000) (emphasis added; internal citations omitted by the court)).

The Federal Circuit has *not* backed away from a requirement for teaching-suggestion-motivation, as manifested in *Optivus Technology*, the final case to be handed down before the oral argument in *KSR*: “Whether an invention would have been obvious is a legal conclusion based on underlying factual findings such as the scope and content of the prior art, *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), and the existence of a motivation to combine prior art references, *In re Kahn*, 441 F.3d 977, 985 (Fed.Cir.2006).” *Optivus Technology, Inc. v. Ion Beam Applications S.A.*, ___ F.3d ___, ___ (Fed. Cir. 2006)(Linn, J.).

The cited *Kahn* case may be emerging as a leading Federal Circuit case if the emerging trend from several other cases is followed. The author of the opinion below in *KSR* has also joined the *Kahn* group. See *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1372-73 (Fed. Cir. 2006)(Schall, J., concurring)(“ I concur in the judgment of reversal. See *Alza Corp. v. Mylan Labs., Inc.*, [464 F.3d 1286 (Fed.Cir. [] 2006)[(Gajarsa, J.)]; *In re Kahn*, 441 F.3d 977, 987-88 (Fed.Cir.2006); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1322 (Fed.Cir.2005).” Two members of the court cite *Kahn* in a more sweeping opinion that is tantamount to their “amicus” brief to the Court in *KSR*. See *DyStar*, 464 F.3d at 1537 (Michel, C.J., joined by Rader, J.).

“Gobbledygook” – Ridicule of the Kahn Test: The thinking *against* the *Kahn* case being included as part of a revised standard is capsulized by comments from members of the Court who did not see a meaningful addition to *Graham* by incorporation of an “implicit motivation” standard. When Respondent’s counsel said that the *Kahn* test “adds an analytical framework. It’s an elaboration”, the Chief Justice interrupted: “It adds a layer of Federal Circuit jargon that lawyers can then bandy back and forth, but ... particularly if it’s nonexclusive [as one possible factor in determining obviousness], you can say you can meet or teaching, suggestion, or motivation test or you can show that it’s nonobvious, it seems to me that [*the*

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implicit motivation test] is worse than meaningless because it complicates the inquiry rather than focusing on the statute.” Chiming in, Justice Scalia “agree[d] with the Chief Justice. It is misleading to say that the whole world is embraced within these three nouns, teaching, suggestion, or motivation, and then you define teaching, suggestion, or motivation to mean anything that renders [the invention] nonobvious. This is gobbledygook. It is... irrational.”

Tests unlikely to be Adopted: Three further, different tests for obviousness were raised at the oral argument, the first by the United States, the second by Respondent and the third a musing of Justice Breyer. None of the three is expected to be at the center of any majority opinion, while an opinion by Justice Breyer may very utilize his theory:

(i) The United States’ “sufficiently innovative” Innovation Test: The United States in its *amicus* brief substitute for a teaching-motivation-test of an invention being “sufficiently innovative” was challenged by Justice Ginsburg: “I understand [the government’s *amicus*] brief to say that [the obviousness test] has to be supplemented by what you have... labeled ‘sufficiently innovative.’ And then I begin to think, well, what’s ‘sufficiently innovative?’ How is a trier of fact supposed to know if something [is ‘sufficiently innovative.’] In other words I think what you’re suggesting as a supplement is rather vague.”

(ii) Respondent’s “Apparent” Test: Respondent argued that the teaching-suggestion-motivation test was largely analytical, to avoid the hindsight establishment of obviousness. In hindsight, virtually any combination invention is *capable* of being made, yet the test proposed by Respondent is whether the combination would have been *apparent* to the worker in the art. This test, however, was posed more to explain what is meant by “obvious” in the statute, using a synonym to take prejudice out of the argument based upon prior conceptions of the meaning of the term.

(iii) Justice Breyer’s “Patents on a Wall” Test: Justice Breyer showed an interest in the test proposed by the late Judge Rich in *Winslow* and showed that he was implicitly toying with the idea of using that test as part of the obviousness inquiry. Under the *Winslow* test:

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“[T]he proper way to apply the 103 obviousness test to a case like this is to first picture the inventor as working in his shop with the prior art references – which he is presumed to know – hanging on the walls around him. One then notes that what applicant Winslow built here he admits is basically a ... bag holder having air-blast bag opening to which he has added two bag retaining pins. If there were any bag holding problem in the [primary prior art reference] Gerbe machine when plastic bags were used, their flaps being gripped only by spring pressure between the top and bottom plates, Winslow would have said to himself, 'Now what can I do to hold them more securely?' Looking around the walls, he would see [the secondary prior art reference] Hellman's envelopes with holes in their flaps hung on a rod. He would then say to himself, 'Ha. I can punch holes in my bags and put a little rod [pin] through the holes. That will hold them. After filling the bags, I'll pull them off the pins as does Hellman. Scoring the flap should make tearing easier.’” *In re Winslow*, 365 F.2d 1017, 1021 (CCPA 1966)(Rich, J.).

The *Winslow* test is seemingly simple and easy to apply; yet, even the author of that test admits that it is flawed as a basis for general analysis of obviousness. See *In re Antle*, 444 F.2d 1168, 1171 (CCPA 1971)(Rich, J.).

Caution concerning an Upset of an Established Practice: In questioning the Deputy Solicitor General, Justice Souter expressed a concern, reprised by others, that caution should be exercised in making any major change in the standard of obviousness that has been the basis of practice for a generation. The Court is also aware that there is now a more than twenty year practice under the teaching-suggestion-motivation test that is applied both in the context of validity determinations as well as by the Patent and Trademark Office (PTO) in their grant of patents on a daily basis. Respondent's counsel asked the rhetorical question whether there could be any presumption of patent validity for the some 160,000 patents that have annually been granted under the teaching-suggestion-motivation should it be overruled. The Court, indeed, appeared to be impressed by this line of argumentation.

Justice Souter assumed for sake of argument that the teaching-suggestion-motivation test may be wrong, but with its longstanding acceptance in the patent community, perhaps this factor should dictate its maintenance: “I'm raising the question that comes up in the old motto....[I]f the error is common enough and long enough, the error becomes the law.

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And, in effect, is that what we are confronted with here?" The Deputy Attorney General said that nevertheless the Federal Circuit should be reversed because "it would be [a] dangerous proposition for this Court to endorse that line of argumentation...." Justice Souter persisted: "No. But if we see it your way, are there going to be 100,000 [patent litigation] cases filed tomorrow morning?"

Questioning the Deputy Solicitor General, Justice Scalia pointed out that beyond the application of the test of obviousness by the Federal Circuit, "[i]t isn't just the Federal Circuit that has been applying this test. It's also the Patent Office and it's been following the Federal Circuit's test for 20 years or so. ... Assuming that we sweep [the suggestion-teaching-motivation] test aside and say that it's been incorrect, what happens to the presumption of validity of... patents which the courts have been traditionally applying? Does it make any sense to presume that patents are valid which have been issued under an erroneous test for the last twenty years?"

In an interesting response, the Deputy Solicitor General bluntly answered: "Your Honor, I think that it would make sense because the statute requires it, and as a practical matter it doesn't make any difference, because the only category of cases in which the result would change under our test is the category in which as a matter of law, in light of the factual issues that are required under *Graham*, as a matter of law the Court concludes that the difference between the claimed invention and the prior art is so trivial that it cannot be given the protection of a patent."

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(2) *MedImmune*: Patent Licensee Validity Challenge

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

Issue (in general terms): Whether a patent licensee may bring a declaratory judgment action for patent invalidity where the licensee *continues* to pay royalties and otherwise operate under the license – thus permitting the licensee to continue under the license if the licensee loses the validity challenge?

Issue (as formally before the Court): "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?"

Status: The case is awaiting decision (after oral argument on October 4, 2006). A decision is expected at any day the Court is sitting, possibly before the end of 2006.

The Oral Argument: The conventional wisdom has been that the *MedImmune* case is a fight over whether a patent licensee should continue to have a right to challenge patent validity as held in the 1969 *Lear v. Adkins*, and particularly whether this right should exist where – as in *MedImmune* – the licensee *continues* to pay royalties under the license so that if it were to lose the validity challenge it could continue to operate under the license.

Yet, the oral argument revealed that the Court appears to be more interested in the *broader* question concerning the Federal Circuit's denial of a justiciable controversy where a party is not in threat of an *immediate* lawsuit, perhaps more so than the precise question in *MedImmune* dealing with the right of a licensee to sue for invalidity while paying his license fees.

At least some members of the Court appeared skeptical of the Federal Circuit's denial of a justiciable controversy unless the declaratory judgment plaintiff is under threat of an *immediate* suit for infringement.

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Relationship to the Apotex Case: There is a close relationship between the *MedImmune* case and the issue presented in *Apotex, Inc. v. Pfizer, Inc.*, No. 05-1006, *petition denied* (October 10, 2006), *proceedings below*, 159 Fed.Appx. 1013 (Fed. Cir. 2005)(Linn, Dyk, Prost, JJ.)(Rule 36 per curiam affirmance), *trial court proceedings*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005)(Chin, J.)(dismissing action for want of a justiciable controversy). In *Apotex*, the issue in general terms is whether a generic pharmaceutical manufacturer may bring a declaratory judgment action against a pioneer drug patent holder where the pioneer drug patent holder has refrained from threatening an *immediate* infringement suit (where the pioneer drug patent holder surely *will* bring a patent infringement lawsuit once the generic enters the market)?

(More formally as stated in the *certiorari* petition, the Question Presented is – “[W]hether ... a suit [brought by generic drug manufacturers seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer] states a justiciable controversy when... the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.”).

Respondent Pfizer obviously considered that it would lose this case if it went forward and therefore successfully took actions to moot the controversy with Apotex, as manifested by the Court's denial of *certiorari* on October 10, 2006.

(3) Amgen: Cybor de novo Claim Construction

Amgen Inc. v. Hoechst Marion Roussel, Inc., expected petition, *opinion below*, 457 F.3d 1293 (Fed. Cir. 2006), *reh'g en banc denied*, ___ F.3d ___ (November 22, 2006).

Issue: Whether the Federal Circuit is correct to apply a *de novo* standard of a trial judges factually-based document construction (here, a patent claim) contrary to FRCP 52(a) contrary to the deferential standard of the regional circuits, particularly in the interpretation of heavily fact-based claim terminology in a complex biotechnology case?

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Status: A *certiorari* petition is due February 20, 2007. (Rehearing *en banc* was denied by the Court of Appeal on November 22, 2006.)

Discussion: Perhaps the single most controversial case at the Federal Circuit is its ruling in *Cybor Corp. v. FAS Tech., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (*en banc*), that reaffirmed a determination that any claim construction ruling – even one heavily based upon expert testimony and other fact-driven issues – is a matter reserved for *de novo* review.

Further discussion: A separate paper discusses the issues, Harold C. Wegner, *Cybor: Alive but Mortally Wounded by Amgen* [November 22, 2006].

(4) *Microsoft*: § 271(f) Extraterritorial Infringement

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: *Certiorari* was granted October 27, 2006. Oral argument (not yet scheduled) should take place in late Winter; a decision will be rendered before the end of June 2007.

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

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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.’”

Likely Outcome – Near Term: Grant of *certiorari* is likely.

Detailed Discussion of the Issues: The issues are considered in detail in Harold C. Wegner, *A Foreign Square Peg in a Domestic Round Hole: The Eolas-AT&T-Carbide Trilogy*, Hot Topics in Patent Law, George Mason University School of Law, July 18, 2006, Arlington, Virginia [available at www.foley.com], Publications – Articles (posted July 25, 2006)].

The Two Different Questions Posed in the Petition: The *Microsoft* petition raises two separate questions: (1) Whether *code* may be deemed to be a “component” of a patented invention; and (2) assuming that “code” can be such a component, whether the *offshore* creation of multiple copies of such code provides components “supplie[d]” from the United States under 35 USC § 271(f)(1) where the only nexus to the United States is the supply a single master of the code that is never, itself, made a component of a combination.

Question 1 – Invoking Arguments Implicating Patent-Eligibility and *State Street Bank*: The first question conjures up visions of patent-eligibility disputes under 35 USC § 101 that have taken place over the years, including *Parker v. Flook*, 437 U.S. 584, 590 (1978), and *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), and – most recently – in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 126 S.Ct. 2921, 2928 ([*State Street Bank*] does say that a process is patentable if it produces a ‘useful, concrete, and tangible result.’ 149 F.3d, at 1373. [T]his Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary.”). While *Microsoft* focuses

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upon an interpretation of § 271(f)(1) and not § 101, it is inevitable that if *certiorari* is granted that the debate will again consider patent-eligibility issues under § 101.

Question 2 – Invoking Extraterritoriality: The second question deals with ongoing controversies over extraterritoriality as stubborn xenophobes fail to gain foreign patent protection yet seek to fit a square peg into a round hole: They try to force what should be a foreign patent infringement claim into a domestic patent framework contrary to *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972).

The United States as *Amicus* Supports Grant of Review: The United States as *amicus curiae* comes out strongly in favor of grant of *certiorari* in its *amicus curiae* brief filed responsive to the Order of the Court inviting the Solicitor General to express the views of the United States. While the United States supports grant of *certiorari* on *both* questions it splits its answer on its view of the merits: It considers code to be within the scope of what may be a component of a patented combination, but strongly argues that supplying a master for *offshore* creation of individual units is not an act of infringement.

The United States argues that the Federal Circuit's "holding [that the creation of copies of software overseas, based on a master version provided from the United States, constitutes the supply of those software copies from the United States]... is contrary to the text and history of Section 271(f), [as it] improperly extends United States patent law to foreign markets and puts United States software companies at a competitive disadvantage vis-a-vis their foreign competitors in foreign markets. Respondent's remedy lies in obtaining and enforcing foreign patents, not in attempting to extend United States patent law to overseas activities." Brief of United States on petition for grant, p. 7.

The government points out that "[i]t is undisputed that the golden master disk sent from the United States 'is never installed on a computer that is then sold.' Nor does respondent contend that petitioner supplies any other components from the United States. Because the master copies supplied from the United States are not installed on any of the computers at issue, petitioner has not supplied a component of those computers from the United States. As the Federal Circuit has explained in other contexts, "§ 271(f) is

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clear on its face. It applies only when components of a patent[ed] invention are *physically present* in the United States and then either sold or exported.” *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1117 (emphasis added [by the government]), *cert. denied*, 543 U.S. 1003 (2004).” Brief of the United States on petition for grant, pp. 12-13; citations omitted.

In asking for grant of *certiorari*, the United States government stressed the anti-American result of the Federal Circuit’s decision has on the domestic software industry:

“Under the court of appeals’ decision, companies that design software in the United States cannot distribute their software abroad without running the risk that they will be compelled to pay royalties under United States patent law with respect to all of their foreign sales. Their foreign competitors, by contrast, run no such risk of global liability under United States law, because they are exempt from application of Section 271(f) with respect to their foreign conduct.

“As a result, United States software companies will find themselves at a substantial competitive disadvantage in foreign markets, and may even be foreclosed from competing in those markets altogether. That disadvantage will harm the software sector of the American economy and could ultimately compel some software companies to relocate their research and development operations abroad.. Moreover, the logic of the court of appeals’ decision could be extended to other high-technology industries.” Brief of the United States on petition for grant, pp. 16-17; citations omitted.

(5) Tamoxifen Patent Settlement – Antitrust

In re Tamoxifen Citrate Antitrust Litigation, 429 F.3d 370 (2nd Cir. 2005), *amended opinion released*, ___ F. 3d ___, 2006 WL 2401244 (2006).

Issue (1): Whether a *Schering-Plough* type of “reverse payment” drug litigation settlement creates a patent antitrust violation?

Issue (2): Whether a patent antitrust violation may exist where parties to a patent infringement litigation settle *after* a trial court holding of unenforceability due to patent fraud which leads to vacatur of the trial court ruling on order of the Federal Circuit?

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Status: (On August 21, 2006, the Second Circuit in a 2-1 vote (comprising two opinions in a 100 page manuscript decision) again denied the patent antitrust claim. The Second Circuit website states that the opinion was *released* on August 21, 2006, while the opinion states that it is *amended* on August 10, 2006.) A petition to the Supreme Court is expected.

Discussion: This case has many parallels to the *Schering-Plough* case where *certiorari* was denied during the past term. By a 2-1 vote, a panel of the Second Circuit said there was no antitrust violation. While the *Schering-Plough* case was pending, a suggestion for rehearing *en banc* was filed. It was assumed that the Second Circuit was awaiting the outcome of the *certiorari* vote in *Schering-Plough*, and if *certiorari* were denied, the Second Circuit would similarly deny rehearing *en banc*.

(6) Leclerc-Wallace-Lacavera 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); *Lacavera v. Dudas*, Sup. Ct. No. 06-338, *opinion below*, 441 F.3d 1380 (Fed. Cir. 2006)(Mayer, J.).

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 “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 in each of the three cases to brief the case. In the two state court actions, the order was styled as an invitation to the Solicitor General to provide views whether to

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grant *certiorari* – a CVSG order. In the federal case the government was ordered to respond to the petition – which it had previously waived. While there is no time deadline for briefing the state court petitions, a deadline of November 1, 2006, was imposed on the government in the *Lacavera* case.

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*: “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. 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:

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“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?”

The *Lacavera* petition provides a *federal* anti-foreigner discrimination as to PTO practice that piggybacks off the pending petitions against *state law* discrimination under the Louisiana rule in *Wallace* and *Leclerc*.

Catherine C. Lacavera is a respected attorney at law and once was a registered patent attorney who is fully employed by Google Inc., first as a patent counsel and now as a patent litigation counsel. Because she lacked a green card when the case was heard, she was denied registration as a patent attorney. *Lacavera*, 441 F.3d at 1382 (“Lacavera, a Canadian citizen and nonimmigrant alien, began working in the United States as an attorney in September 2001 pursuant to a one year TN visa, which permitted her only to prepare and prosecute patent applications at the New York office of the White & Case law firm. In January 2002, Lacavera began the application process for recognition before the PTO, and she successfully passed the April 17, 2002, patent examination. Because of legal restrictions imposed by her visa, she was granted limited recognition. Although Lacavera's visa had a one year duration, she received timely extensions from the INS, and the

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PTO extended her limited recognition period accordingly. At the time this appeal was filed, Lacavera held an H-1B visa and, with the appropriate INS authorization, had changed employers. Her present visa has a three year duration and lists preparation and prosecution of patent applications for Google, Inc. as her sole employable activity. Her current limited recognition status is consistent with her work and time restrictions.”)

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 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 petition makes a cogent argument 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

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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.

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

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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.

At the time of the litigation before the tribunals below, Ms. Lacavera was in the process of seeking a green card. 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). 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

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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).

(7) *Nuijten* “Signal” Patent-Eligibility; *State Street Bank*

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

Issue: Seeking to stretch *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), Appellant and supporting *amicus curiae* Intellectual Property Owners have crafted a test case to have a signal, *per se*, considered by itself to be 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-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, Suter, JJ.).

Status: As of October 1, 2006, no oral argument date had been set by the Federal Circuit.

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

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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*, 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

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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 (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)

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(8) *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 more than sixteen months ago*, the Supreme Court reversed and remanded the Federal Circuit. After a further period for briefing and 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. *Integra* represents a Bleak House scenario at its worst, a patent litigation that was commenced more than ten full years ago and still has no end in sight.

(9) *Voda* Transnational Patent Enforcement

Voda v. Cordis Corp., Fed. Cir. No. 05-1238

Issue: Where a trial judge has exercised supplemental jurisdiction to hear foreign counterpart patent infringement claims as part of a previously domestic patent infringement lawsuit, should the Federal Circuit impose a *per se* rule against exercise of such jurisdiction?

Discussion: Appellant and its establishment *amici* seek a “bright line” rule to bar *any* consideration of foreign patent infringement where one American company sues another American company in a district court for *domestic* patent infringement and the defendant-accused infringer shifts operations offshore – *even where essentially the same patent rights and accused products are involved*.

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All members of the panel brought challenging questions to both sides. Judge Prost focused upon the "bright line" rule proposed by appellant and appeared shocked that her court was being told that it was unable to interpret foreign law – which (she pointed out) courts do all the time. She came back to this point more than once in her questioning of appellant's counsel. Judge Newman posed a hypothetical question: Where an American patentee wants to enforce actions everywhere, what choice does he have other than a transborder enforcement action? Appellant's counsel gave a solution: Win the American case to get a litigation war chest, and then use the winnings to sue everywhere else. Puzzled looks were the only followup to this answer.

Status: The appeal was argued January 12, 2006, before a panel of Newman, Gajarsa, Prost, JJ., and is awaiting decision.

Proceedings on the Domestic Infringement Issues at the Trial Court:

The United States, long considered to be the bastion of strong intellectual property rights, has now *denied* injunctive relief against adjudged willful infringer Johnson & Johnson's Cordis unit – in essence granting a compulsory license – in *Voda v. Cordis Corp.*, 2006 WL 2570614 (W.D.Okla. 2006)(Leonard, J.), even though the Court at the same time found that Cordis' infringement was willful and that the case was exceptional.

Collectively, enhanced damages and attorney fees led to an award in excess of \$ 10,000,000.00. As the accused infringement is a multinational affair with German infringement being a major component, perhaps Dr. Voda will now go to Düsseldorf to the premiere German *Landgericht* for patent causes and get injunctive relief across the ocean, at least for Germany.

(10) *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?

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Status: So far, oral argument has not been set for this case.

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 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).

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FORMER TOP TEN CASES NOW DECIDED

Apotex: Justiciable Controversy (former No. 6)

Apotex, Inc. v. Pfizer, Inc., No. 05-1006, *petition denied* (October 10, 2006), *proceedings below*, 159 Fed.Appx. 1013 (Fed. Cir. 2005)(Linn, Dyk, Prost, JJ.)(Rule 36 per curiam affirmance), *trial court proceedings*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005)(Chin, J.)(dismissing action for want of a justiciable controversy)

Future Relevance: The issue in *Apotex* is very much alive. *Certiorari* may well have been granted in this case, but for Respondent's decision to *moot* the issue that was the direct cause for the denial of *certiorari*.

Issue (in general terms): May a generic pharmaceutical manufacturer bring a declaratory judgment action against a pioneer drug patent holder where the pioneer drug patent holder has refrained from threatening an *immediate* infringement suit (where the pioneer drug patent holder surely *will* bring a patent infringement lawsuit once the generic enters the market)?

Issue (as formally before the Court): “[W]hether ... a suit [brought by generic drug manufacturers seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer] states a justiciable controversy when... the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.”

The Unanswered Order to the Solicitor General: A CVSG order dated May 15, 2006, asking the Solicitor General for his views whether to grant *certiorari* demonstrates the importance of this case. No brief was ever filed as the Court *denied* the *certiorari* petition on the strength of Pfizer's suggestion of mootness.

From the Pfizer Suggestion of Mootness: Pfizer conceded its case on the merits and gave up any right to enforce its patent against Petitioner. Pfizer's brief explains its position:

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“Two intervening developments have eliminated any arguable present or future controversy between the parties about the patent that is the subject of this declaratory judgment action.

“First, on August 10, 2006, Pfizer sent to counsel for Apotex an unconditional covenant not to sue Apotex with respect to that patent, United States Patent No. 5,248,699 (the ‘699 patent’). ... This covenant ensures that Apotex will never face any risk of a lawsuit by Pfizer under the subject patent.

“Second, on August 14, 2006, Teva ... publicly announced that it had begun marketing its generic version of Zolofit[®]. ... Under the statutory regime applicable to this case..., Teva's marketing started the 180-day exclusivity period that Apotex sought to trigger with a hypothetical court judgment in its favor. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Therefore, any future court judgment regarding the '699 patent would no longer have any effect on the exclusivity period.”

Ferring Inequitable Conduct (former No. 9)

Ferring B.V. v. Barr Laboratories, Inc., Sup. Ct. No. 06-672, *cert. denied*, October 30, 2006, *opinion below*, 437 F.3d 1181 (Fed. Cir. 2006)(Dyk, J.); *see also* , 437 F.3d at 1195 (Newman, J., dissenting).

Issues: As stated under the *Questions Presented*: “Pursuant to this Court's holding in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945), a federal court may invoke its inherent equitable powers to render unenforceable an otherwise valid patent where the patentee has engaged in ‘inequitable conduct’ during prosecution of the patent application before the United States Patent & Trademark Office (‘PTO’). This Court characterized such ‘inequitable conduct’ as a form of unclean hands. Lower courts have formulated a test for evaluating whether a patentee engaged in ‘inequitable conduct’ during patent prosecution, allowing this doctrine to be invoked generally whenever (1) the patentee misrepresented or did not provide the PTO with ‘material’ information and (2) the patentee did so with an ‘intent’ to deceive. The questions presented in this case are:

“1. Whether the ... Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold of what constitutes

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'material' information that a patentee must disclose to the PTO so as to include information that has no bearing on patentability.

"2. Whether the ... Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold for establishing intent to deceive the PTO so as to include a judicial determination that the applicant 'knew or should have known' the information not provided to the PTO was 'highly material.'"

Why Certiorari was Denied: While the briefing by both Petitioner and *amicus curiae* PhRMA clearly demonstrate that the Federal Circuit has stretched the doctrine of inequitable conduct in ways that demand relief, a briefing by committee is apparent that provides no clear pathway to *certiorari*. Assuming that at some point in time the Court is presented with a different approach, this very important issue may very well be taken up by the Court.

Discussion: A spirited dissent manifests the intra-circuit conflict over inequitable conduct. *Ferring*, 437 F.3d at 1195 (Newman, J., dissenting). The dissent portrays a widespread and important problem that the court should address: "As this litigation-driven issue evolved, the law came to demand a perfection that few could attain in the complexities of patent practice. The result was not simply the elimination of fraudulently obtained patents, when such situations existed. The consequences were disproportionately pernicious, for they went far beyond punishing improper practice. The defense was grossly misused, and with inequitable conduct charged in almost every case in litigation, judges came to believe that every inventor and every patent attorney wallowed in sharp practice." *Id.*

The dissent cites with approval Michael D. Kaminski, *Effective Management of U.S. Patent Litigation*, 18 *Intell. Prop. & Tech. L.J.* 13, 24 (2006) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed.Cir.1988) (*en banc* in relevant part)).

The dissent points to the extreme nature of the *Ferring* case: "Today my colleagues on this panel ... restore a casually subjective standard, [but] also impose a positive inference of wrongdoing, replacing the need for evidence

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with a 'should have known' standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent intent, presumes inequitable conduct, and wipes out a valuable property right, all on summary judgment, on the theory that the inventor 'should have known' that something might be deemed material. The panel majority, steeped in adverse inferences, holds that good faith is irrelevant and presumes bad faith. Thus the court resurrects the plague of the past, ignoring the ... requirements of clear and convincing evidence of a misrepresentation or omission material to patentability, made intentionally and for the purpose of deception." *Ferring*, 437 F.3d at 1196-97 (emphasis added).

The accused conduct involved the presentation of expert testimony under oath concerning the meaning of terminology and its significance: The inequitable conduct found by the majority was the failure of the patentee to have identified past professional ties of the affiants to the patentee. *Ferring*, 437 F.3d at 1197.

The Vermont Yankee Approach: The Federal Circuit can be quite properly criticized for its *ad hoc* approach to inequitable conduct, overstepping what the agency regulations provide in violation of *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519 (1978). As pointed out by an *amicus*:

"[T]he PTO has over the years defined the 'Duty to disclose information material to patentability.' 37 C.F.R. § 1.56 (2006). By its disavowal of the PTO's regulation, the Federal Circuit has acted in a manner that is inconsistent with this Court's landmark administrative law decisions that set the boundaries between federal agency and federal court authority." PhRMA brief, p. 12. Amicus quotes from *Vermont Yankee*: "Absent Constitutional constraints or extremely compelling circumstances, the 'administrative agencies 'should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties.'" PhRMA, pp. 12-13, quoting *Vermont Yankee*, 435 U.S. at 543-44 (citations omitted). Amicus adds that "[t]he principles of *Vermont Yankee* apply *a fortiori* here because Congress made it clear that the PTO regulations 'shall govern the conduct of proceedings in the Office.' 35 U.S.C. § 2(b)(2)(A)." *Id.* at p. 13.

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Petitioner's View of *Vermont Yankee*: Buried near the end of its brief, Petitioner at p. 27 cites *Vermont Yankee* for the proposition that “[i]t is fundamental that issues concerning administrative process are particularly within the competence and expertise of federal agencies, and that the courts should permit agencies to be masters of their own procedures.”