

## Wegner's Top Ten Patent Cases\*

- 1 *Quanta v. LG* – Patent “Exhaustion” [awaiting CVSG brief]
- 2 *Integra* – Post-Merck “Safe Harbor” [awaiting decision]
- 3 *Nuijten* – Patent-Eligibility; *State Street Bank* [awaiting decision]  
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- 4 *Pharm. Res. v. D.C.* – Federal Preemption [awaiting decision]
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- 7 *Classen v. Biogen* – “Metabolite déjà vu” [August argument]
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*Bilski* – Patent-Eligibility under § 101 [briefing stage]  
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*Amgen v. ITC* – “Safe Harbor” [August argument]  
*z4 v. Microsoft* – Claim Construction [August argument]  
*Sinorgchem v. ITC* – Chinese Acc. Infringer [August argument]  
*Ferguson* – Patent-Eligibility under § 101 [early stages]

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### **(1) *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:** On April 16, 2007, the Court issued a CVSG, an Order asking the government for the views of the United States whether to grant *certiorari*. It is unlikely that the government will issue its brief in time for a vote before the Court goes on its summer recess.

### **(2) *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).

**Status:** A decision in this case is long overdue, as discussed below.

A *related* case dealing with the "safe harbor" of 35 USC § 271(e)(1) will be argued in the near term. *See* (-) *Amgen v. ITC – "Safe Harbor"*, *infra*.

**The Patent Bleak House (con'd):** June 5th and June 13th marked two anniversaries for *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), the landmark Supreme Court decision judicially expanding the "safe harbor" free from patent infringement liability for pre-regulatory approval experimentation and testing of drug candidates. The issues are considered in detail in Wegner, *Post-Merck Experimental Use and the "Safe Harbor"*, 15 Fed. Cir. Bar. J. 1 (2005).

### **June 14th, Starting a Third Year at the Federal Circuit since Reversal:**

The Federal Circuit still has this case languishing on its docket, now more than two full years since the June 13, 2005, Supreme Court decision; the Federal Circuit is now into yet a *third* year without a decision.

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**June 5th Argument Anniversary:** The oral argument on remand took place more than one year ago on June 5, 2006, Newman, Rader, Prost, JJ.

**A Fifth and Senior Judge Awaiting the Case in San Diego:** The *fifth* trial judge assigned to this case, the Hon. Rudi M. Brewster, 75, who took senior status in 1998, awaits the remand. In 1999, prior to the appellate journey, with no regular judge available based upon heavy dockets, the parties needed a trial judge in the San Diego federal court outside the active judiciary. They welcomed Senior Judge James Martin Fitzgerald who had retired from active service as District Judge in Alaska a decade earlier. Senior Judge Fitzgerald is now 86 years of age and apparently no longer sitting on the bench. (He was apparently selected because the Alaskan was willing to sit in San Diego. He was not selected for patent law expertise as there is no record on FIP-CS on Westlaw of his trial of any patent case, other than a land patent.)

**Judicial Reform (con'd):** Opponents of judicial reform that would provide a pool of patent-experienced District Court judges to handle *all* patent cases have yet to come up with a satisfactory answer for the all too numerous *Bleak House* examples of which *Merck v. Integra* is just one. Germany, the U.K. and Japan each does a far better job of making sure that *all* patent disputes are before patent-experienced experts in the judiciary; that the United States, with its leadership position in patent-based technology development does not is inexcusable.

**(3) *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.).

**(4) 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).

The local government challenges the trial court's nullification of its law relating to pricing of drugs protected by patents.

**Status:** Awaiting decision, argued April 4, 2007 (Bryson, Plager, Gajarsa,, JJ.)

**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?

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"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 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.)

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### **(5) *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:*** Awaiting decision, argued April 5, 2007 (Rader, Gajarsa, Prost, JJ.).

***Likely Outcome:*** Questioning, particularly by the presiding judge, suggests affirmance of the trial court denial of infringement.

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**Discussion:** 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](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).

**(6) Seagate – En Banc Revisit to Echostar; Underwater Devices**  
*In re Seagate Technology, LLC*, Misc. No. 830

**Issues:** Per order dated January 27, 2007, in *In re Seagate Technology, LLC*, \_\_ Fed Appx. \_\_, 2007 WL 196403 (Fed. Cir. 2007)(en banc)(per curiam), the Court has asked for *en banc* arguments on three issues:

1. “Should a party's assertion of the advice of counsel defense to willful infringement extend waiver of the attorney-client privilege to communications with that party's trial counsel? See *In re EchoStar Commc'n Corp.*, 448 F.3d 1294 (Fed.Cir.2006).”
2. “What is the effect of any such waiver on work-product immunity?”
3. “Given the impact of the statutory duty of care standard announced in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed.Cir.1983), on the issue of waiver of attorney-client privilege, should this court reconsider the decision in *Underwater Devices* and the duty of care standard itself?”

**Status:** *En banc* oral argument took place, June 7, 2007, at 2:00 PM, before a ten member panel presided over by Newman, J. (The Chief Judge and Circuit Judge Moore were recused).

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**(7) *Classen v. Biogen* – “Metabolite déjà vu” Medical Diagnosis**  
*Classen Immunotherapies, Inc. v. Biogen IDEC*, Fed. Cir. 2006-1634, *opinion below*, unreported (D. Md. 2006)(Quarles, J.), *earlier opinion*, 381 F.Supp.2d 452 (2005).

**Issue:** The Federal Circuit is faced with *Metabolite déjà vu*, an invention very close to the type of claim in *LabCorp v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (dissent from dismissal for improvident grant of certiorari). Unlike *Metabolite* where the issue was not phrased under 35 USC § 101, here, the claims in question were held invalid under that section.

Patentee-appellant's states the issue in a bland phrase the questions whether “the Classen patents 5,723,283; 6,420,139 and 6,638,739 invalid under 35 U.S.C. § 101?” The second issue raised by Merck is “[w]hether the district court properly granted summary judgment of invalidity under 35 U.S.C. § 101 on grounds of nonpatentable subject matter, given that the patents' claims cover *thinking about* whether a particular immunization schedule for infectious disease, even a prior art schedule, may reduce (relative to other schedules) the risk of later chronic disease, and *immunizing* with that schedule, either before (as to one patent) or after (as to two patents) *thinking about* that risk.” (original emphasis).

**Status:** Argument is scheduled for August 8, 2007.

**Discussion:** Even though the claims ‘include the active step of immunizing patients in accordance with a schedule determined to be low risk...’, *Classen* at p. 12, the claims were nevertheless held invalid under 35 USC § 101: “[I]nsignificant post-solution activity will not transform an unpatentable principle into a patentable process.’ ... [T]he ... patents are an indirect attempt to patent the idea that there is a relationship between vaccine schedules and chronic immune mediated disorders[;] the Court finds they are an attempt to patent an unpatentable natural phenomenon.’ *Id.* at p. 12 (quoting *Diamond v. Diehr*, 450 U.S. 175, 192 (1981)).

**The Outcome ... What AIPLA, BIO and IPO have Said:** Success on appeal should turn on the merits of a case, but where the legal team on one side has tremendous firepower unmatched by an appellee, the outcome is far

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less predictable. Successful mega-pharma accused infringer below has superbly briefed the case on appeal.

While there has been much discussion about the dangers of *Metabolite* in the various bar and industry groups over the past year, it is in the *amici* briefing where the rubber meets the road. Here, there has been no help from AIPLA, BIO and IPO or any other *amici*, they have been nonexistent in this case. The question must be raised as to precisely how the *amici* committees of the several biotech, university and patent bar groups allocate their resources and focus their interests.

***Understanding the Controversy:*** As explained by appellee Merck: “Classen ...has sued Merck ... for alleged direct and indirect infringement of Classen's patents relating to administering vaccines. Classen's patents stem from his (disputed) ‘discovery’ that early immunization against infectious disease protects against later development of chronic disease, although the claims of his patents are far broader and purport to cover the use of any immunization schedule, early or late, if the practitioner merely believes that the schedule used is better than some other. Yet all Merck has done that allegedly infringes is what it did well before Classen's ‘discovery’ - selling its vaccine against hepatitis B with the same recommended schedule for early immunization.

“What is critical both for Classen's assertions of infringement and to distinguish his alleged invention over the evident Merck prior art is a mental conclusion reached by a health practitioner about a secondary benefit when immunizing a patient. According to Classen, a health practitioner who immunizes against hepatitis B using the same long-standing schedule now becomes an infringer by mentally considering Classen's ‘discovery’ and concluding, in agreement with Classen, that this long-used schedule has a benefit of reducing a patient's risk for later development of chronic disease such as diabetes. To infringe the claims as Classen construes them, the practitioner need not undertake any new physical steps to assess that benefit or to administer the vaccine, or even make any changes to the existing immunization schedule. It is the thought process in determining the existence of an immunization schedule's benefit for risk of a chronic disease that is the claimed Classen invention. \* \* \*



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“Under Classen's claim construction, a health practitioner who administers Merck's hepatitis B vaccine in precisely the same way as before becomes an infringer if he or she mentally concludes, based on information produced or collected by anyone (regardless of statistical or scientific validity), that doing so may reduce the patient's chances of developing a chronic disease such as diabetes. In short, to become an infringer, it is not necessary to change any physical act but only to reach a mental conclusion in accord with Classen that there is a secondary benefit from long-standing practice in reducing the risk of a chronic disease. Aside from the evident invalidity issues of nonpatentable subject matter and of inherent anticipation, this raises the issue that infringement is possible only by those who believe in Classen's theory when immunizing, while those who perform the same physical acts uninformed of Classen's theory or who do not believe it do not infringe.

“Classen has not shown that any possible infringer, let alone Merck, has reached a mental conclusion that Classen is correct. All Merck has done is continue to sell its hepatitis B vaccine with a recommended early schedule for immunization, just as before Classen's ‘discovery.’ In fact, the only evidence of record that might be construed as reflecting Merck's mental conclusions rejects Classen's view. Thus, the district court was correct in concluding that Merck has not infringed.

“The district court was also correct in concluding that Classen has patented a mental process of reaching a conclusion that his theory of risks and benefits associated with schedules for immunizations is correct. Such subject matter is not patentable. Alternatively, because Classen's patent claims would cover the practitioner's use of an existing immunization schedule simply because the practitioner now recognizes a previously unrecognized benefit ‘discovered’ by Classen, the claims are invalid for inherent anticipation.”

***Dodging a Bullet – Avoiding the Metabolite Issue:*** It is entirely conceivable that the *Metabolite* issue could be ducked by the panel if one is selected that is less uninterested in establishing new law but instead more interested in a correct decision without creating further controversy. Thus, there are plural issues in *Classen* that could be basis to render the *Metabolite* issue moot.

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### **(8) *Pfizer v. Apotex* – Mootness Petition**

*Pfizer Inc. v. Apotex, Inc.* No. 06-1582, *opinion below*, 480 F.3d 1348 (Fed.Cir.2007).

*Issue:* Whether the Supreme Court should grant *certiorari* for the purpose of vacating the panel opinion below as moot.

*Status:* This case should be set for a Conference this Fall, with an announcement of its decision as part of an early October 2007 Orders List.

*Discussion:* On June 11, 2007, the Supreme Court denied emergency relief to Pfizer that had been requested as the first of two Questions Presented. Now, the only matter left open is the Pfizer request that the opinion below be “cancelled”, i.e., vacated as moot.

#### **Questions Presented [as stated in the Petition]:**

1. Whether the Federal Circuit's failure to reconsider its judgment under the *KSR* standard merits summarily granting the petition, vacating the judgment, and remanding for further consideration in view of *KSR*?
2. Whether, if the petition is not granted prior to [the date of patent-keyed Norvasc<sup>®</sup> exclusivity on] September 25, 2007[,], the Court should instead grant the petition and order the Court of Appeals' judgment vacated under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), and *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994).

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### **(9) Paice v. Toyota – Post-eBay Injunctive Relief**

*Paice LLC v. Toyota Motor Corp.*, No. 2006-1610, *opinion below*, 2006 WL 2385139 (E.D.Tex. 2006)(Folsum, J.).

**“Issue 5” (as phrased by Paice):** Whether the district court committed reversible error by imposing a compulsory, prospective license of \$25/car for the remaining life of the [ ] patent, where (a) neither statutory law nor judicial precedent provided the court the ability to impose prospective monetary relief, (b) the legal issue of damages under the compulsory license was not presented to a jury as required by the Seventh Amendment, and (c) the trial court's imposition of a compulsory license effectively curtails any exclusive rights Paice hoped to grant in the future.

**Status:** The appeal was argued on May 7, 2007 (Lourie, Rader, Prost, JJ.).

### **(10) Comiskey – Patent-Eligibility under § 101**

*In re Comiskey*, Fed. Cir. App. No. 2006-1286

**Status:** The case is awaiting a decision. It case was argued before a panel of Michel, C.J., Dyk, Prost, JJ., where the § 101 issue was raised *sua sponte* by the court during oral argument, with post-argument supplemental briefing following a post-argument Order.

The case is explained in more detail in the attached paper, *Comiskey: Chief Judge as a PTO “Primary Examiner*.

### **(Other) Bilski – Patent-Eligibility under § 101**

*In re Bilski*, Fed. Cir. App. No. 2007-1130

**Status:** The case is in the briefing stages. It will become important if one of the Top Ten cases such as *Nuijten* or *Comiskey* does not resolve patent-eligibility issues found in *Bilski*.

**Discussion:** The gist of the case is found in the AIPLA *Amicus Curiae* brief:

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“The patent application at issue involves a method for managing or ‘hedging’ the consumption risk costs associated with a commodity sold at a fixed price. The method may be performed with the assistance of a computer but is not limited to the use of a computer. Claim 1 is exemplary. It reads:

**“A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:**

**“ (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;**

**“ (b) identifying market participants for said commodity having a counter-risk position to said consumers; and**

**“ (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.**

\* \* \*

### “SUMMARY OF ARGUMENT

“The proper test for determining what constitutes statutory subject matter under 35 U.S.C. § 11 is set forth in *Diamond v. Diehr*[, 450 U.S. 175 (1981)].

“Specifically, whether a process claim incorporating an abstract idea is statutory subject matter depends on whether the claimed process, when viewed as a whole, recites a practical application with a useful result. *Diehr*, 450 U.S. at 187 (‘an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection’) (emphasis in original); *id.* at 188 n.11 (noting that the difference between an unpatentable abstract idea, scientific truth, or phenomenon of nature and a patentable invention is the application of that idea, truth or phenomenon ‘to a new and useful end’) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

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“Further, while a transformation of physical subject matter from one state to another may be relevant in determining whether a claim that includes an abstract idea recites statutory subject matter, such a transformation is not required under § 101. AIPLA urges this Court to reject any requirement that claims incorporating abstract ideas include a strictly physical transformation in order to fall within the scope of § 101.

“Congress employed expansive terms (i.e., ‘process, machine, manufacture, or composition of matter’) to describe the scope of patentable subject matter. With the broad categorical language of § 101, Congress was fulfilling its Constitutional mandate to foster innovation and public disclosure over a wide variety of useful arts. However, Congress balanced this broad standard for patentable subject matter with stricter requirements set forth in other provisions of the patent statute, including novelty, non-obviousness, written description, definiteness, and enablement, which determine whether the § 101 patentable subject matter is entitled to patent protection.

“In connection with its review of the *Bilski et al.* claims, this Court should consider whether each claim, taken as a whole, describes a practical application of a process with a useful result. If so, then the claims cover statutory subject matter and are eligible for patent protection, provided that they also meet the conditions of patentability set forth in §§ 102, 103, and 112. Applying the *Diehr* test, the *Bilski et al.* claims fall within the bounds of statutory subject matter because they achieve a practical and useful result: allowing commodity suppliers and consumers to engage in commodities transactions while minimizing the risks associated with fluctuations in demand for such commodities and providing investment opportunities for market participants.”

The appellee has now filed its brief in this case:

“This case presents this Court with an opportunity to clarify the scope of patentable subject matter for process claims. In the section 101 case law cited and discussed by *Bilski* and amicus AIPLA, e.g., *Diamond v. Diehr*, 450 U.S. 175 (1981); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998); *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); *In re Alappat*, 33

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F.3d 1526, 1543 (Fed. Cir. 1994) (en banc); and *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992), the Supreme Court and this Court grappled with the question of patent eligibility for a then relatively new technology - computer-based programming inventions that employ a mathematical formula or algorithm. Ultimately, this Court has adhered to the long-standing judicially-created principle for analyzing the eligibility of process claims - such technological processes are eligible so long as they transform subject matter to a different state or thing. Specifically, this Court applied the transformation principle to computer technology by holding that transformation of computer data signals to produce a useful, concrete, and tangible result satisfies section 101.

“Bilski's claimed method, however, is wholly unlike the inventions in the above-cited cases. The Board affirmed the examiner's section 101 rejection of claim 1, because (1) the case law has consistently held that a section 101 ‘process’ transforms matter or energy to a different state or thing, and (2) the claim recites a disembodied concept, running afoul of the abstract idea exception. The question to be resolved in this appeal is how the law in these computer-implemented ‘mathematical algorithm’ cases should be applied to a claim that simply calls for a party to enter into two sets of transactions. Since this Court's decisions in *State Street* and *AT&T*, many applicants appear to have assumed (as does Bilski) that the sole test for patent eligibility is whether the invention produces a useful, concrete, and tangible result. The PTO has thus been inundated with an unprecedented number of patent applications relating to subject matter that arguably does not fall within the traditional rubric of ‘inventions’ in the ‘useful arts.’ The inventions include legal methods, methods of teaching, methods of holding conversations, and even a method for swinging on a playground swing. Oftentimes these claims, typically claimed as processes, do not require any machine or apparatus for implementing the method, nor do the claims require any transformation of subject matter, tangible or intangible, from one state into another. And while many business method patents were historically directed toward computer systems and data processing, a growing number of applications attempt to cover business concepts themselves, without any requirement for processing one set of data into another.”

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### **(–) *Plavix – Pfizer v. Apotex Conflict with Papesch***

*Sanofi-Synthelabo v. Apotex, Inc.*, Federal Circuit appeal anticipated from decision below, \_\_ F.Supp. 2d \_\_, 2007 WL 1746134 (S.D.N.Y. 2007), *earlier proceedings sustaining preliminary injunction*, 470 F.3d 1368 (Fed. Cir. 2006)(Lourie, Bryson, Clevenger, JJ.).

**Status:** An appeal is expected late summer 2007.

**Discussion:** By late summer 2007 an appeal will be taken from the trial court confirmation of validity of the Plavix<sup>®</sup> patent. At the trial, the challenger had specifically relied upon *Pfizer v. Apotex*, but was rebuffed by the trial judge. Unless he retires in the meantime, it is expected that when the argument takes place most likely in Winter 2008, the presiding judge will be the author of the *en banc* reaffirmation of *Papesch* seventeen years ago. Unless there is a resolution of the *Pfizer v. Apotex* deviation from *Papesch* before that time in an intervening case, it may be expected that the panel in the *Plavix* case will be confronted with the utterly inconsistent principles of the two cases. (This case is part of a paper, *Chemical Obviousness in a State of Flux* [June 22, 2007].)

### **(–) *Amgen v. ITC – “Safe Harbor”***

*Amgen, Inc. v. Int’l Trade Comm’n*, App. No. 2007-1014

**Issue:** Per intervenor, “[d]id the ITC correctly determine that Amgen failed to raise any genuine issue of material fact as to whether Roche's importations and uses of [Continuous Erythropoiesis Receptor Activator, the new pharmaceutical product that is the subject of this investigation,] were exempt from infringement liability under 35 U.S.C. §271(e)(1) and, therefore, that there was no violation of §337?”

**Status:** Oral argument is scheduled for August 7, 2007.

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**Discussion:** This case is subsidiary to the leading Supreme Court case on the scope of the “safe harbor” under 35 USC § 271(e)(1), *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); see Wegner, *Post-Merck Experimental Use and the “Safe Harbor”*, 15 Fed. Cir. Bar. J. 1 (2005). But, the Supreme Court decision remains in limbo now more than two (2) full years after the Supreme Court decision, awaiting a further Federal Circuit decision in the case styled here as No. 2 *Integra*, *supra*.

### **(–) z4 v. Microsoft – Claim Construction**

*z4 Technologies, Inc. v. Microsoft Corp.*, Fed. Cir. App. No. 2006-1638

**Issue:** An issue of claim construction is of particular interest, discussed below.

**Status:** argument August 9, 2007, presents an interesting issue of claim construction and infringement.

**Discussion:** The claim construction issue is difficult to ascertain from the briefing. The claim language requires (per the patentee) “comparing stored and submitted ‘information related to ... the software ... and the computer ... to determine *if the user* is an authorized or an unauthorized user.’ The district court's construction of ‘user’ is correct, and the construction proposed by Microsoft does not lead to non-infringement.”

Per the patentee, “[t]he district court's construction of ‘user’ in the ‘authorized’/‘unauthorized’ user limitation was correct based on the claim language and the specification. Applying the district court's construction or Microsoft's proposed ‘person’ construction, when a user attempts to activate Microsoft software, Microsoft ‘determines whether the user is an authorized or unauthorized user’ in a manner expressly covered by [the] claims - using ‘information related to ... the software ... and the computer.’ There was no claim construction error, and substantial evidence supports the jury's infringement verdict on these limitations.”



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### **(-) *Sinorgchem v. ITC* – Chinese Alleged Infringement**

*Sinorgchem Co. v. Intern. Trade Comm'n*, No. 2006-1633, argument August 7, 2007.

**Issue:** The case has several issues that, alone, would not make the case exceptional. What is exceptional is the upgraded level of representation for a Chinese accused infringer, represented, here, by Carter G. Phillips.

**Status:** Oral argument is scheduled August 7, 2007.

### ***Ferguson* – Patent-Eligibility under § 101**

*In re Ferguson*, Appeal No. 2007-1232

The opinion of the Board below is not available; neither is any brief available on Westlaw. The only information so far is from the Appellee's brief in *Bilski, supra*, that includes a reference to "*In re Ferguson*, Appeal No. 2007-1232, in which the Board rejected method claims of marketing a product under 35 U.S.C. § 101."

Presumably, the *Ferguson* appeal is still early in the briefing stage.