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New Cases:

No. (3) *Kubin* represents perhaps the most important biotechnology appeal in recent years. A reliable source has said that a Notice of Appeal has recently been filed in this case; the opinion below is discussed in some detail in Wegner, *Post-KSR Patent Procurement*.

No. (10) *Egyptian Goddess* – Depending upon the interest generated by the *amici* briefs in this case, this test concerning design patents

To Watch In January ...

January 7th: No. (2) *McFarling* – *Certiorari* Decision Possible
January 8th: No. (8) *Sang Su Lee II* – Federal Circuit Argument
January 16th: No. (1) *Quanta v. LG* – Supreme Court Argument

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(1) *Quanta*– 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 LG]'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: *Quanta* is set for argument January 16, 2008, with a decision expected in the time frame March-May 2008 (but not later than the end of June 2008)

The Factual Setting of *Quanta*: Respondent LG purchased a Wang patent portfolio of key patents necessary to use integrated circuits which it licensed to Intel – but where it expressly, contractually denied Intel's chip purchasers from effectively using Intel chips without its *own* license from LG. The Federal Circuit in essence held that its case law effectively putting contract law on a status above patent exhaustion blocks reliance on that doctrine.

“Established Law” –Created in 1992; G. Franklin Rothwell: New lawyers – or at least those new to patent law – may measure established precedent by the yardstick of the past decade; in that sense, Federal Circuit law *is* such established precedent, in the same manner that the previous “motivation” mandate (overruled in *KSR*) was “established” precedent.

In fact, *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992)(Newman, J.), was regarded as a sea change in the law, trumping patent exhaustion. Much of the credit for this pro-patentee development goes to G. Franklin Rothwell, the intellectual heart and cofounder fifty years ago of the firm once styled as Sughrue Rothwell. (In the early 1980's he jumped to what is today Rothwell, Figg, Ernst & Manbeck P.C.)

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The Law of Patent Exhaustion: The principle of patent exhaustion was established more than 150 years ago in *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539 (1853), as refined in *Adams v. Burke*, 84 U.S. (17 Wall.) 453 (1873): Once a patentee sells a patented product, the patentee cannot use his patent right to sue a subsequent purchaser of that patented product under the patent law; the “first sale” of the patented product “exhausts” the patent right. The Court last visited patent exhaustion in *Univis Lens Co.*, 316 U.S. 241 (1942). Patent exhaustion has been bedrock patent law until the effective abrogation of *Univis* by a panel of the Federal Circuit fifteen years ago in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992)(Newman, J.).

Patent exhaustion principles are perhaps easiest understood from *Adams v. Burke*, which confirmed the principle of patent exhaustion in the context of mid-nineteenth century New England mortuary commerce. Whereas today a global business in a particular patented item may range many thousands of miles from Boston to Beijing to Barcelona, in a simpler era of mid-nineteenth century America, the business of premium coffins of Cambridge (Massachusetts) of territorial patent holder Lockhart & Seelye focused on Boston – and for good measure what is today essentially an area inside Route 128 Beltway – then simply contractually defined in its assignment as “a circle whose radius is ten miles, having the city of Boston as a centre.”

The mortician Burke purchased Lockhart & Seelye patented coffins which he then used in his business situated in Natick in the area of Lake Cochituate – seventeen miles outside the Boston center. Sued for patent infringement by Adams – now owner of the patent right other than the territorial right sold to Lockhart & Seelye – sued for patent infringement. In defense, Burke argued that he had used “no coffin [in Natick] containing the invention..., except such coffins containing said invention as have been manufactured by said Lockhart & Seelye, within a circle, whose radius is ten miles, having the city of Boston as its centre, and sold within said circle by said Lockhart & Seelye, without condition or restriction.”

The Court in *Adams v. Burke* found that the patent right was exhausted upon the first sale of the patented coffins. Thus, the mortician Burke who purchased the patented coffin in Boston had a free and clear right to use and resell that coffin independent of the patent right. As stated by the Court

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nearly a century later “it is fundamental that sale of a patented article by the patentee or under his authority carries with it an ‘implied license to use.’” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964)(citing *Adams v. Burke*, 84 U.S. (17 Wall.) at 456; *United States v. Univis Lens Co.*, 316 U.S. 241, 249 (1942)).

More than 150 years after *Bloomer v. McQuewan*, a panel of the Federal Circuit in *Mallinckrodt v. Medipart* in essence abrogated that case to the extent that it gave free rein to patentees to create contractual restrictions to vitiate exhaustion. Five years later, a second panel summarized the demise of *Adams v. Burke* in *B. Braun Medical, Inc. v. Abbott Laboratories*, 124 F. 3d 1419 (Fed. Cir. 1997)(Clevenger, J.):

“In [*Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed.Cir.1992)], we canvassed precedent concerning the legality of restrictions placed upon the post-sale use of patented goods. As a general matter, we explained that an unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of the device thereafter. 976 F.2d at 706. The theory behind this rule is that in such a transaction, the patentee has bargained for, and received, an amount equal to the full value of the goods. See *Adams v. Burke*, 84 U.S. (17 Wall.) 453, 456-57 (1873); *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 663 (1895). *This exhaustion doctrine, however, does not apply to an expressly conditional sale or license.* In such a transaction, it is more reasonable to infer that the parties negotiated a price that reflects only the value of the ‘use’ rights conferred by the patentee. As a result, express conditions accompanying the sale or license of a patented product are generally upheld. See *Mallinckrodt*, 976 F.2d at 708; cf. *General Talking Pictures Corp. v. Western Elec. Co.*, 305 U.S. 124, 127 (1938) (‘That a restrictive license is legal seems clear.’). ...[V]iolation of valid conditions entitles the patentee to a remedy for either patent infringement or breach of contract. See *Mallinckrodt*, 976 F.2d at 707 n. 6.”

B. Braun, 124 F. 3d at 1426 (emphasis added) (The panel did allow that “express conditions, however, are contractual in nature and are subject to antitrust, patent, contract, and any other applicable law, as well as equitable considerations such as patent misuse.” *Id.*)

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In the decade since *B. Braun* not even one Federal Circuit case has ever considered or cited *Bloomer* nor *Adams v. Burke* in connection with patent exhaustion.

The United States as *Amicus Curiae* Supporting Petitioner: The United States has filed briefs supporting petitioner both at the petition and merits briefing stages:

(a) United States brief at the petition stage: The United States as *amicus curiae* in response to a call for the views of the Solicitor General (CVSG), advised in favor of grant of *certiorari*. The government explained the historic role of *Adams v. Burke* exhaustion:

“Since *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539 (1853), this Court repeatedly has made clear that the exclusive rights to use or to sell are exhausted, as to a given article embodying the invention, upon the first valid sale of the article in commerce, whether by the patentee itself or by an authorized licensee. *Id.* at 549-550; see, e.g., *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 497 (1964) (plurality opinion); *Univis Lens*, 316 U.S. at 251-252; *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 508-518 (1917); *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666 (1895); *Hobbie v. Jennison*, 149 U.S. 355, 361-363 (1893); *Adams v. Burke*, 84 U.S. (17 Wall.) 453, 456 (1873). Thus, under this Court's cases, a patentee who sells a machine embodying the invention (either directly or through an authorized licensee) cannot bring a patent infringement suit against the purchasers for using the machine for its only reasonable use or for reselling the machine to others. See, e.g., *Univis Lens*, 316 U.S. at 250-252; *Motion Picture Patents*, 243 U.S. at 515-518; *Keeler*, 157 U.S. at 666; *McQuewan*, 55 U.S. (14 How.) at 549-550; *Adams*, 84 U.S. (17 Wall.) at 456. Instead, the enforceability of downstream limitations after an authorized sale would arise “as a question of contract, and not as one under the inherent meaning and effect of the patent laws.” *Keeler*, 157 U.S. at 666; accord, e.g., *Motion Picture Patents*, 243 U.S. at 509, 513; *McQuewan*, 55 U.S. (14 How.) at 549-550.”
Quanta, Government's CVSG *amicus curiae* brief, pp. 6-7.

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In advising the Court that it should grant *certiorari* in *Quanta*, the Solicitor General stated that “[t]he doctrine of patent exhaustion, also known as the first-sale doctrine, implicates fundamental questions concerning the scope of the exclusive rights conferred under the patent laws. Since this Court last squarely addressed the doctrine in *United States v. Univis Lens Co.*, 316 U.S. 241 (1942), the doctrine has evolved in the Federal Circuit in a manner that appears to conflict with this Court's patent-exhaustion cases, thereby creating uncertainty as to when a patentee may enforce, through federal-court actions for patent infringement (as opposed to state-law contract actions), downstream limitations on purchasers following an authorized sale. Whatever rights a patentee may have to enforce such limitations as a matter of contract, the question whether a patentee may invoke federal patent law to enforce such limitations against authorized purchasers is one of considerable practical importance, and this case presents an adequate vehicle for addressing that question.” *Id.* at p. 6.

(b) The United States at the Merits Stage: In its merits stage brief in support of petitioner, there is essentially a four part argument, summarized by the government as follows:

“I. Since at least 1853, this Court has held that a patentee's (or authorized licensee's) sale of an article embodying the patentee's invention frees that particular article from any further patent-law restrictions on its use or resale. Restrictions on downstream use or resale may arise as a matter of state contract law, but not patent law; in acquiring valid title to the article, the purchaser also acquires the right to use and to sell it without fear of patent-infringement claims by the patentee. That understanding of the scope of the patent rights afforded patentees under the patent law is known as the patent-exhaustion or first-sale doctrine, and is derived from the text and history of the patent statute, the purposes of patent law, and the adverse practical consequences of an alternative rule.

“II. In recent years, the first-sale doctrine has evolved in the Federal Circuit in a manner that is at odds with this Court's precedents. Under the Federal Circuit's approach, the doctrine is merely a default rule that is overridden whenever a patentee chooses to impose explicit unilateral or bilateral restrictions on the rights of purchasers to use or to sell the patented article. Such restrictions (with certain limitations derived from antitrust or other

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law) are enforceable against all downstream users in a patent-infringement suit. That approach is irreconcilable with this Court's cases, which make clear that the patent-exhaustion doctrine applies despite explicit restrictions imposed by the patentee. *E.g.*, *United States v. Unis Lens Co.*, 316 U.S. 241 (1942).

“The Federal Circuit's approach to the first-sale doctrine rests on the mistaken premises that (1) for patent-exhaustion purposes, a “conditional” sale includes an authorized sale where title passes but the patentee has purported to impose restrictions on use or resale by downstream purchasers, and (2) the patentee can enforce such restrictions through a patent-infringement suit without regard to the patent-exhaustion doctrine. Those premises are inconsistent with this Court's cases.

“III. This Court should not follow the Federal Circuit's lead and transform a long-standing substantive limitation on patent rights into a default rule applicable only when the patentee fails to impose explicit restrictions on the rights acquired by purchasers in authorized sales. The patent-exhaustion doctrine is grounded in sound doctrinal and policy reasons. The inconvenience and inefficiency of the Federal Circuit's approach could extend the entire length of a product's distribution chain, and could enable patentees to demand and obtain royalties beyond those that the statute was intended to provide. That approach also gives inadequate scope to the antitrust laws. With regard to post-sale limitations on the right to use or to sell, a patentee-seller should be placed in no better position with respect to the antitrust laws than any other seller.

“IV. The judgment below rests on an erroneous understanding of the patent-exhaustion doctrine. Because the court of appeals did not determine whether Intel's authorized sales to petitioners resulted in exhaustion of the relevant patents under the appropriate standard, vacatur and remand are appropriate.

(2) McFarling – Patent Exhaustion

McFarling v. Monsanto Co., No. 07-241, *opinion below*,
Monsanto Co. v. McFarling, 488 F.3d 973 (Fed. Cir. 2007)(Bryson, J.).

Issue (second Question Presented): “Do the doctrines of patent exhaustion and patent misuse permit the purchaser of a patented good to use that good and dispose of its products as it sees fit, absent a valid contract?”

Status: A Conference is scheduled for January 4, 2008, which may result in either grant or denial of *certiorari* but – quite possibly – a decision to *defer* the case until after a decision in *Quanta*, *supra* case no. (1).

GVR if no Decision January 7th and Quanta is Reversed: If the case is deferred and if *Quanta* prevails in its appeal, then it is quite likely that there will be a “GVR”. A GVR would most likely be in the form of a single sentence order that (a) grants *certiorari*, (b) vacates the decision below and (c) remands to the Federal Circuit for consideration in light of *Quanta*.

Petitioner McFarling Piggybacks Off the Quanta Case: Mississippi soybean farmer Homan McFarling was found to be an infringer where he created second generation seeds by growing soybeans from patented seeds obtained from the patentee. He argues that the subsequent harvesting and use of second generation seeds cannot be patent infringement because the patent right has been exhausted. As stated in the Petition, “[i]t defies both common sense and the patent-exhaustion doctrine to hold, as the Federal Circuit did here, that a farmer who buys seeds from Monsanto in order to plant them, and actually does plant them, infringes Monsanto's patent because the plants naturally produce new copies of the seeds as they grow. This Court's precedents have long held that one who purchases a good from the patent owner or from a licensee is free to make the ordinary and expected use of that good, at least unless restricted by a valid contract. This Court has applied that principle even where, as here, the defendant buys precursor materials and makes the patented invention from those materials. [The instant case] completes the Federal Circuit's decades-long effort to circumscribe this Court's exhaustion precedent. Once the proper boundaries of the patent right are understood, it becomes evident that Monsanto has transgressed those boundaries and therefore must answer for its misuse of the patent.

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“McFarling put the invention he bought to its only reasonable use. He purchased seeds; he planted them in the ground; and they grew into soybean plants, which naturally produce new seeds. The Federal Circuit held that, merely by planting the seeds he purchased, McFarling has made infringing copies of its patented invention, since planting the seeds generated new seeds. But the new seeds cannot be infringing under this Court's long-established principle of patent exhaustion because they are - literally - the natural result of putting the purchased invention to its only reasonable use. As a result, the Federal Circuit erred in rejecting McFarling's patent-misuse claim on the basis that [patentee] Monsanto was merely acting within the scope of its patent rights. It was not.”

The grant of *certiorari* in *Quanta* occurred after the petition was filed in *McFarling*. In the Reply Brief to the Opposition to grant of *certiorari* in *McFarling*, Petitioner McFarling seeks to piggyback its case for *certiorari* onto *Quanta* with three reasons being given:

“*First*, the cases present striking parallels. In each case, a patented invention purchased from a licensee was put to its only reasonable use. The Intel computer components in *Quanta* were combined with non-Intel components, since the only other function those components could have served was to take up space. Likewise, the seeds in this case were planted in the ground, the natural use that farmers make of those seeds. Monsanto claims that *Quanta* presents is different because soybeans can be sold as a commodity, rather than being put to their only reasonable use in farming. Opp. 19. But this distinction fails: computer components, like soybeans, can be bought and sold on the open market. This does not change the fact that the only reasonable use of the computer components in *Quanta* was their combination with non-Intel computer components, or the fact that the only reasonable use of the seeds in this case is planting them in the ground. No farmer buys 50-pound quantities of soybean seeds to eat at home.

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“*Second*, the differences that do exist between the two cases would allow the Court a comprehensive view of the patent-exhaustion issue. Unlike computer components, seeds replicate themselves when put to their only reasonable use. For this reason, there can be no reasonable ‘us[e]’ of the seeds without ‘making’ new seeds. 35 U.S.C. §154(a). This Court should review this case in the same term as *Quanta* because only by considering both types of cases can it get a complete picture of the circumstances in which exhaustion arises.

“*Third*, the law of patent exhaustion in the lower courts has developed along radical lines since this Court's most recent opportunity to speak on the issue in *United States v. Univis Lens Co*, 316 U.S. 241 (1942). In the line of cases represented by *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), the Federal Circuit has unmoored post-sale restrictions on patented goods from their legitimate basis in contract law and instead has allowed unilateral post-sale restrictions to be enforced through patent remedies. Because the decision below is the product of this straying, almost any result that this Court reaches in *Quanta* is likely to affect the legal standard applied below in this case. Indeed, in the very same week in which Monsanto filed its brief arguing that *Quanta* would *not* affect the outcome of this case, the Biotechnology Industry Organization (‘BIO’) - of which Monsanto is among the largest members - argued in its brief in the *Quanta* case that this Court needed to draw a careful line in *Quanta* because of the effect that the exhaustion decision there could have on seed-saving cases like *McFarling*. Brief of the BIO as *Amicus Curiae* in Support of Neither Party, *Quanta* (No. 06-937). Given BIO's acknowledgment that the cases are conceptually linked, the Court should at least hold this case until the same issues are resolved in *Quanta*.”

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(3) *In re Kubin, Biotech Obviousness; Enzo Disclosure*

In re Kubin, Fed. Cir. App. No. _____, *opinion below, Ex parte Kubin*, 2007 WL 2070495 (PTO Bd. App. & Int. 2007)(Linck, APJ).

In re Kubin is an appeal from an expanded panel of the Board authored by perhaps the best known Administrative Patent Judge – a former Solicitor and later Vice-President of a pharmaceutical company. *Kubin* is simply one of the most important Board opinions in recent years, and by far the most important decision for biotechnology, which is discussed in more detail in Wegner, *Post-KSR Patent Procurement* [August 7, 2008], *attached* as a republished version, highlight marked in turquoise to show portions relevant to *Kubin*, including an introductory portion at pp. 3-4, a discussion of the PTO's repudiation of *In re Deuel*, 51 F.3d 1552 (Fed. Cir.1995)(Lourie, J.), at pp. 29-32, and the at least equally important question of the expansion of the "written description" line of case law at pp. 39-44.

Ex parte Kubin was recognized by the PTO itself at the time as being of very great importance for a variety of reasons beyond its noted author, including the virtually unprecedented action of having the decision ratified by the Board as "precedential" and the expansion of the Board to include six members including the Chief Administrative Patent Judge.

It remains to be seen whether the PTO requests an *en banc* hearing in light of the position the Board has taken that repudiates a Federal Circuit opinion – *Deuel*.

(4) *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.

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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: Awaiting decision (argument was held August 8, 2007)(Newman, Moore, Farnan, Jr., JJ.)

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 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.

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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. * * *

“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

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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.

(5) *Convolve – Review of In re Seagate*

Convolve, Inc. v. Seagate Technology, No. 07-656, *opinion below*, *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007)(*en banc*).

Issues: Three “Questions Presented” are stated in the Petition for *certiorari*:

1. Whether [35 USC § 284], which confers discretion on district courts to “increase the damages up to three times the amount found or assessed” for patent infringement, requires a finding of willful infringement, where the statute does not use the term “willful”, is not conditioned on culpable

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conduct or confined to exceptional cases, and is devoid of any standard for awarding increased damages. ...

2. Whether [35 USC § 284], which confers discretion on district courts to award increased damages for patent infringement, is compatible with a categorical rule precluding an entire class of patentees from accruing increased damages based on the infringers' conduct occurring solely after litigation began.

3. Whether there should be a special rule in patent cases permitting selective waiver of attorney-client privilege and work-product protection by accused infringers who assert an advice-of-counsel defense to a charge of willful patent infringement.

Status: The winning party below has until January 22, 2008, to file its Opposition to the petition.

Discussion: This is the famous *en banc* case of *In re Seagate*, which has generated a large amount of interest.

Chances for Grant of Certiorari: Because of the *en banc* notoriety gained by the opinion below and the numerous commentaries about the law dealt with in *In re Seagate*, this case coming out of the block has a better than average chance of success for grant of *certiorari*. However, the failure of petitioner to focus on one clear issue and to point to a conflict with regional circuit case law in the first Question Presented greatly diminishes whatever chance of success Petitioner may otherwise have for grant of review. It also remains to be seen what type of opposition the winning party below will present in this case.

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(6) *Bilski* – Patent-Eligibility under § 101

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

Status: Awaiting decision; argument October 1, 2007 (Bryson, Clevenger, Moore, JJ.)

Discussion: This case may be considered “Comiskey II”. It is difficult to create a line of distinction over *Comiskey* that will permit survival of the claims of this case. See *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007)(Dyk, J.)

(7) *Sanofi-Synthelabo* – The *Plavix* Case

Sanofi-Synthelabo v. Apotex, Inc., No. 2007-1438, *opinion below*, 492 F.Supp.2d 353 (S.D.N.Y. 2007), *earlier proceedings sustaining preliminary injunction*, 470 F.3d 1368 (Fed. Cir. 2006)(Lourie, Bryson, Clevenger, JJ.).
Sanofi-Synthelabo v. Teva Pharm. USA, Inc., No. 2007-1521

Status: Oral argument is likely during Court Week in the time frame March/April/May 2008.

Issues (*per Appellant*): The accused infringer-appellant focuses upon two issues:

1. Whether the ... claims are invalid for anticipation where (1) the prior art patents described the compound of which [Plavix] is an enantiomer, described those enantiomeric forms, and disclosed the salts claimed, and (2) the techniques used to separate this enantiomer and to make these salts were very well known to those of ordinary skill in the art.
2. Whether the ... claims directed to [Plavix] and its salts including the bisulfate would have been obvious to a person of ordinary skill in the art where the prior art taught at least the racemate comprising [Plavix], suggested separating the racemate into its enantiomers to isolate the therapeutically active enantiomer, if present, and taught reacting the active enantiomer with a strong, mineral acid, such as hydrochloric acid, sulfuric acid, and hyrdobromic acid, to form pharmaceutically acceptable salts, the properties of which were good, but not surprising.

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Issues (per Appellee): Patentee-appellee rephrases the case as having three issues:

1. Whether the District Court clearly erred in concluding that Apotex had failed to show by clear and convincing evidence that the patent-in-suit's claim to clopidogrel bisulfate [Plavix] was anticipated by a prior U.S. patent, or its very similar Canadian counterpart, which did not disclose [Plavix] or its bisulfate salt, or indicate how bisulfate could be prepared.

2. Whether the District Court clearly erred in concluding that Apotex had failed to show by clear and convincing evidence that the patent-in-suit's claim to clopidogrel bisulfate was obvious in light of the prior art, when the prior art failed to afford a person of ordinary skill in the art ("POSA") any basis for expectation that:

(i) clopidogrel would have all of the antiplatelet activity of the prior art racemate from which it was derived ("PCR 4099") while its opposite enantiomer (the "levorotatory enantiomer") would have none;

(ii) [Plavix] would have no neurotoxicity, in contrast with PCR 4099 and its levorotatory enantiomer, which did; and

(iii) the bisulfate salt of clopidogrel [Plavix] would have a uniquely favorable combination of properties rendering it, alone among more than 20 tested pharmacological salts, suitable for manufacture as a tablet.

(8) *Sang Su Lee II* – Post-KSR Motivation

In re Sang Su Lee II, Fed. Cir. 2007-119, *earlier proceedings*, 277 F.3d 1338 (Fed. Cir. 2002)(Newman, Cleverger, Dyk, JJ.)(*Sang Su Lee I*)

Status: On Tuesday morning, January 8, 2008, perhaps the longest running *ex parte* appeal in the recent history of the patent system will reappear at the Federal Circuit for a second argument.

Discussion: *Sang Su Lee II* revisits one of the oldest pending appeals in the history of *ex parte* patent appeals, rivaling the longest reexamination and interference proceedings. (*The first Board opinion is dated 1994 – fourteen (14) years ago.*)

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The Solicitor in *Sang Su Lee II* challenges the legal underpinnings of the earlier panel opinion, invoking *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006), and – particularly – *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

The 2002 *Sang Su Lee* Opinion:

The panel “vacate[d] the Board's decision for failure to meet the adjudicative standards for review under the Administrative Procedure Act, and remand[ed] for further proceedings.”

The failure of the Board to specify the motivation for the combination of prior art references was critical to the decision to remand the case to the Board: “As applied to the determination of patentability *vel non* when the issue is obviousness, ‘it is fundamental that rejections under 35 U.S.C. § 103 must be based on evidence comprehended by the language of that section.’ *In re Grasselli*, 713 F.2d 731, 739 (Fed.Cir.1983). The essential factual evidence on the issue of obviousness is set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52 (Fed.Cir.2001) (‘the central question is whether there is reason to combine [the] references,’ a question of fact drawing on the *Graham* factors).

“‘The factual inquiry whether to combine references must be thorough and searching.’ *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25 (Fed.Cir.2000) (‘a showing of a suggestion, teaching, or motivation to combine the prior art references is an ‘essential component of an obviousness holding’ ‘) (quoting *C.R. Bard, Inc., v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed.Cir.1998)); *In re Dembiczak*, 175 F.3d 994, 999 (Fed.Cir.1999) (‘Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based

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obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.’); *In re Dance*, 160 F.3d 1339, 1343 (Fed.Cir.1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075 (Fed.Cir.1988) (‘teachings of references can be combined *only* if there is some suggestion or incentive to do so.’) (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed.Cir.1984)). ‘The need for specificity pervades this authority. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371 (Fed.Cir.2000) (‘particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed’); *In re Rouffet*, 149 F.3d 1350, 1359 (Fed.Cir.1998) (‘even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.’); *In re Fritch*, 972 F.2d 1260, 1265 (Fed.Cir.1992) (the examiner can satisfy the burden of showing obviousness of the combination ‘only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references’).”
Sang Su Lee I, 277 F3d. at 1342-43.

The Solicitor’s Current Defense of the Board’s Decision on Remand

Further prior art is cited in the proceedings between the 2002 Federal Circuit opinion and the return to the court in the present incarnation. Of particular interest are the Solicitor’s argument that modern case law trumps the 2002 opinion, *see Following Kahn Instead of the earlier Panel Opinion*, and the special reliance on *KSR*, *see KSR – Argued to Trump the Panel’s Rationale*:

Following *Kahn* Instead of the earlier Panel Opinion: “The Board's explanation of its rationale for combining the references ... meets the Federal Circuit teaching-suggestion-motivation test for an obviousness determination. *See In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006) (‘[T]he Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.’); *KSR Intern. Co. v. Teleflex*

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Inc., 127 S. Ct. 1727, 1741 (2007) (endorsing Federal Circuit's teaching-suggestion-motivation test as one method for showing obviousness). “[T]he nature of the of the problem to be solved likewise provides motivation for the combination. . . . *See In re Kotzab*, 217 F.3d at 1370 (‘The test for an implicit showing [of teaching-suggestion-motivation] 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.’). The result would have been the claimed invention.”

KSR – Argued to Trump the Panel’s Rationale: “While the Board in this case held the claimed invention obvious based on its finding that the prior art provided clear teachings that would have motivated one with skill in the art to make the proposed combination, the Supreme Court has since pointed out additional bases under which a claimed invention might be found obvious. Most pertinent here:

“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. ***For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.***

KSR Intern. Co. v. Teleflex Inc., 127 S. Ct. at 1740 (emphasis added).

“Given that the ‘technique’ of providing a demonstration mode had been ‘been used to improve’ multiple prior art ‘device[s]’ (two of which used TV screens for their demonstrations), a person of ordinary skill in the art would have recognized that adding a demonstration mode to a TV would improve the TV in the same way. Accordingly, adding the demonstration mode to Nortrup ‘is obvious unless its actual application is beyond his or her skill.’ *See KSR*, 127 U.S. at 1740. In this case Lee does not assert that it would have been difficult to add a demonstration mode to Nortrup's TV set. Therefore, under *KSR*, the USPTO has plainly established a prima facie case of obviousness that Lee must overcome.”

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(9) *Ferguson* – Method of Marketing a Product

In re Ferguson, Appeal No. 2007-1232

The opinion of the Board below is not available; neither is any brief available on Westlaw. The PTO in *Bilski, supra*, 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.”

Status: Oral argument was held December 5, 2007 (Newman, Mayer, Gajarsa, JJ.).

Issue: Per appellants, “[a]re the claims ... properly rejected as being under 35 USC § 101, based on the so called ‘Abstract Idea’ exception to patentability[?]”

The claims are to a marketing method. From a request for reconsideration of a 2004 Board decision that entered a new ground of rejection under 35 USC § 101, an expanded eight member panel issued an expansive decision on reconsideration on July 27, 2006, that expands upon negative patent-eligibility decisions (J. Smith, J., with Barrett, J., and Dixon, J., each concurring in separate opinions), *subsequent proceeding*, Decision on Request for Rehearing (December 18, 2006)(J. Smith, J.).

(10) Egyptian Goddess – Design Patent Infringement

Egyptian Goddess, Inc. v. Swisa, Inc., No. 2006-152, *order granting reh'g en banc*, 2007 WL 4179111 (Fed. Cir. 2007)(*en banc*)(order), *vacating panel opinion*, 498 F.3d 1354 (2007)(Moore, J.)

Issues: The order for *en banc* briefing sets forth three questions:

“1) Should ‘point of novelty’ be a test for infringement of design patent?

“2) If so, (a) should the court adopt the non-trivial advance test adopted by the panel majority in this case; (b) should the point of novelty test be part of the patentee's burden on infringement or should it be an available defense; (c) should a design patentee, in defining a point of novelty, be permitted to divide closely related or ornamentally integrated features of the patented design to match features contained in an accused design; (d) should it be permissible to find more than one “point of novelty” in a patented design; and (e) should the overall appearance of a design be permitted to be a point of novelty? *See Lawman Armor Corp. v. Winner Int'l, LLC*, 449 F.3d 1190 (Fed. Cir. 2006).

“3) Should claim construction apply to design patents, and, if so, what role should that construction play in the infringement analysis? *See Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1577 (Fed.Cir.1995).”

Status: The appeal is now in the briefing stage; absent any extension, appellant's brief falls due January 25, 2008, with supporting and neutral *amici* having briefs due in early February. A Summer 2008 oral argument is anticipated with a decision likely Fall 2008.

Amici Briefing for the En Banc Argument: The Order spells out the grounds rules for *amici* briefing as being “entertained in accordance with Federal Rules of Appellate Procedure 29 and Federal Circuit Rule 29.” Such Briefs which are either neutral or in support of appellant will, absent any extension, be due in early February. (Rule 29(e) sets the deadline at seven days of the filing of the appellant's brief, now due January 25, 2008.)

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Discussion: The past few years have seen public policy concerns voiced about the scope of patent protection and providing support for patent owners versus freedom for industry to operate in a more patent-free environment. Here, in the context of design patent infringement, the same question is being played out with design patent law, first with a tightening of the “point of novelty” infringement test two years ago in *Lawman Armor Corp. v. Winner Int'l, LLC*, 449 F.3d 1190 (Fed.Cir.2006), and the further extension of *Lawman Armor* in *Egyptian Goddess*. Both sides of the debate have valid public policy points which should be weighed by the legislature; in an extreme case where there is a consensus for change, at that point consideration might be given to the judicial legislation envisioned in *Lawman Armor* in *Egyptian Goddess*. Indeed, it will be interesting to see who weighs in for and against the new trend as manifested by the panel opinion in *Egyptian Goddess*.

The New Test of the Panel Opinion Majority: The panel majority introduces a test specific to combination patents that requires for “a combination of individually known design elements to constitute a point of novelty, the combination must be a non-trivial advance over the prior art.” Or, as part of the longer passage from which this quotation is taken –

“Because the point of novelty determination is part of the infringement analysis, the initial burden is on the patentee to ‘present, in some form, its contentions as to points of novelty.’ [*Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1383 (Fed.Cir.2004)] The point of novelty can be either a single novel design element or a combination of elements that are individually known in the prior art. *See Lawman Armor Corp. v. Winner Int'l, LLC*, 449 F.3d 1190, 1192 (Fed.Cir.2006) (supplemental opinion on petition for rehearing); *Litton [Sys., Inc. v. Whirlpool Corp.]*, 728 F.2d 1423, 1443-44 (Fed. Cir. 1984)]. The patentee is not free to set forth any combination of elements as the point of novelty, rather, the point of novelty must include features of the claimed design that distinguish it from the prior art. *Litton*, 728 F.2d at 1444; *Goodyear Tire & Rubber Co. v. Hercules Tire & Rubber Co.*, 162 F.3d 1113, 1118 (Fed.Cir.1998).

“For a combination of individually known design elements to constitute a point of novelty, the combination must be a non-trivial advance

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over the prior art. See *Smith v. Whitman Saddle Co.*, 148 U.S. 674, 682 (1893) (analyzing whether the accused device contained the aspects of the claimed design that ‘rendered it patentable as a complete and integral whole’); *Bernhardt*, 386 F.3d at 1384 (noting that the point of novelty determination ‘is not especially different from the factual determinations that the district courts routinely undertake’ in performing the obviousness inquiry); cf. *Litton*, 728 F.2d at 1444 (applying the results of the obviousness analysis when determining the point of novelty of the claimed design); *Goodyear*, 162 F.3d at 1119, 1121 (noting that the court ‘adopted the same points of novelty that it had relied on in determining that the ‘080 patent was not invalid for obviousness,’ and holding that ‘the district court did not clearly err in giving weight to those aspects of the ‘080 tread that were necessary design aspects in sustaining the validity of the patent’).” *Egyptian Goddess*, 498 F.3d at 1357-58; emphasis added; footnotes omitted.

Concerns Raised by the Dissent: A detailed dissent provides a rebuttal to the panel majority’s new test, *Egyptian Goddess, Inc. v. Swisa, Inc.*, 498 F.3d 1354, 1359-60 (Fed. Cir. 2007)(Dyk, J., dissenting).

The dissent first focuses upon the new “non-trivial advance” test for the point of novelty to determine infringement: It is concluded that “the majority opinion departs from our precedent in fashioning a new rule—that a combination of elements cannot constitute a point of novelty in design patent cases unless the combination constitutes a ‘non-trivial advance’ over the prior art. The majority equates its newly-fashioned non-trivial advance test with the requirement that a design patent be nonobvious over the prior art. It then appears to limit the application of that test to cases in which the point of novelty involves a combination of prior art elements.” *Egyptian Goddess*, 498 F.3d at 1359.

The dissent cautions that the panel majority’s test “conflate[es] the criteria for infringement and obviousness, [so that] the test eviscerates the statutory presumption of validity by requiring the patentee to affirmatively prove nonobviousness. *Id.* (citing 35 U.S.C. § 282). But, by statute, “[t]he burden of proof on obviousness rests with the accused infringer and must be established by clear and convincing evidence. Under the majority’s test,

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however, the patentee would have to prove nonobviousness in order to establish infringement.” *Id.*

As a *second* critique, “the majority's approach is at the same time too narrow and too broad. It is too narrow because it applies a special test only to designs which involve a combination of design elements. It is clear to me that a single point of novelty test must apply to all points of novelty, not just those involving combinations. That has invariably been the approach of our past cases. The majority's approach is also too broad because it extends an obviousness-like test to each point of novelty, not merely the overall design (which is presently the sole focus of the obviousness analysis).” *Id.*

The third point emphasizes that the new “non-trivial advance” test “requires a difficult and restrictive inquiry in design patent cases.” *Id.* How does a judge – or expert – focus upon a particular point of novelty? The dissent notes that “[p]oints of novelty in design patents are often not dramatically different from the prior art. It is difficult enough to assess whether an overall design would have been obvious; it is almost impossible to determine whether a particular design feature represents a trivial or substantial advance over the prior art.” *Id.*

Beyond the policy and practical concerns, the dissent argues that majority’s approach deviates from the case law. *Egyptian Goddess*, 498 F.3d at 1359-60.

Is an *Egyptian Goddess*-based standard Workable? Heretofore, design patent enforcement has been one bright spot in the patent law where Markman hearings and complex determinations were *not* needed. The court has itself recognized that the new case law under review creates a standard that is far more difficult for the courts and litigants to follow with great predictability. This is implied from the third question presented by the court in its order for briefing: “Should claim construction apply to design patents, and, if so, what role should that construction play in the infringement analysis?”

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Policy Contrasts to a Japanese Pro-Patentee Tool for Anti-Counterfeiting:

The United States has taken a back seat to Japan in terms of use of the design patent law as a weapon against copyist infringers and counterfeiters. An earlier note, *Designed Patent Reform: Japan versus the Egyptian Goddess Case*, summarizes differences between the United States and Japan design law and practice and, particularly, the policy choice Japan has made to *strengthen* its design law particularly as a weapon for its pioneer industries against counterfeiters.