TOP TEN PATENT CASES

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Top Ten No. (1) Impression Products (Patent Exhaustion)
Top Ten No. (2) Samsung v. Apple: Certiorari Granted
Top Ten No. (10) Is Metallizing Engineering Viable?

Rank	♦ = certiorari granted ♦ = CVSG order pending
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	Patent Exhaustion
2	Sequenom v. Ariosa Diagnostics; response due April 20, 2016
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•	Willful Infringement (§ 284)
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	Whether <i>Metallizing Engineering</i> was overruled by statute

<u>Recommended Citation</u>: Harold C. Wegner, *Top Ten Patent Cases* (Mar. 25, 2016), available at "Wegner's Writings" on the website of the Los Angeles Intellectual Property Law Association: www.laipla.net/category/wegners-writings/

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Appendix: The Helsinn Healthcare Case

(1) Patent Exhaustion (Kirtsaeng; Quanta Computer)

<u>Current case</u>: Impression Products, Inc. v. Lexmark International, Inc., Supreme Ct. No. 15-1189, petitioner challenges the denial of patent exhaustion at the Federal Circuit, Lexmark Int'l, Inc. v. Impression Prods., Inc., __ F.3d __ (Fed. Cir. Feb. 12, 2016)(en banc)(Taranto, J.).

<u>Status</u>: The Response to the Petition is due April 21, 2016. A vote whether to grant *certiorari* is expected before the end of June before the end of the current Term. If *certiorari* is granted, the case would be briefed over the Spring and Summer; an oral argument would likely take place in late Fall or early Winter, with a merits decision before the end of June 2017.

Questions Presented: "The 'patent exhaustion doctrine'—also known as the 'first sale doctrine'—holds that 'the initial authorized sale of a patented item terminates all patent rights to that item.' Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617, 625 (2008). This case presents two questions of great practical significance regarding the scope of this doctrine on which the *en banc* Federal Circuit divided below:

- "1. Whether a 'conditional sale' that transfers title to the patented item while specifying post-sale restrictions on the article's use or resale avoids application of the patent exhaustion doctrine and therefore permits the enforcement of such post-sale restrictions through the patent law's infringement remedy.
- "2. Whether, in light of this Court's holding in *Kirtsaeng* v. *John Wiley & Sons*, *Inc.*, 133 S. Ct. 1351, 1363 (2013), that the common law doctrine barring restraints on alienation that is the basis of exhaustion doctrine 'makes no geographical distinctions,' a sale of a patented article—authorized by the U.S. patentee—that takes place outside of the United States exhausts the U.S. patent rights in that article."

A Case Destined for Supreme Court Review: Remarkably, the majority (Taranto, J., joined by Newman, Lourie, Moore, O'Malley, Reyna, Wallach, Chen, Stoll, JJ.), maintains its broad denial of exhaustion, distinguishing international intellectual property exhaustion in Kirtsaeng v. John Wiley & Sons, Inc., 133 S. Ct. 1351 (2013), maintaining its denial of exhaustion in Jazz Photo Corp. v. International Trade Comm'n, 264 F.3d 1094 (Fed. Cir. 2001), and maintaining contractual restrictions to block exhaustion in the questionable Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992), and, particularly, distinguishing Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008).

Clearly, *certiorari* is never certain, but if ever a case called for grant of review, this case is it.

<u>International Patent Exhaustion</u>: Although the *Kirtsaeng* issue is the *second* Question Presented, this appears to have the greater appeal, given the sharp distinction between the Federal Circuit denial of international intellectual property exhaustion versus the Supreme Court grant of international intellectual property exhaustion in the context of copyright law.

Notwithstanding *Kirtsaeng*, the majority "adhere[s] to the holding of *Jazz Photo Corp. v. International Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001), that a U.S. patentee, merely by selling or authorizing the sale of a U.S.-patented article abroad, does not authorize the buyer to import the article and sell and use it in the United States, which are infringing acts in the absence of patentee-conferred authority." Two members of the Court in dissent "would retain *Jazz Photo* insofar

as it holds that a foreign sale does not in all circumstances lead to exhaustion of United States patent rights. But, in my view, a foreign sale does result in exhaustion if an authorized seller has not explicitly reserved the United States patent rights." *Lexmark*, __ F.3d at __, slip op. at 101 (Dyk, J., joined by Hughes, J., dissenting).

Conditional Sales to Avoid Exahustion: Notwithstanding Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008), the same majority "adhere[s] to [its] holding of Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992), that a patentee, when selling a patented article subject to a single-use/no-resale restriction that is lawful and clearly communicated to the purchaser, does not by that sale give the buyer, or downstream buyers, the resale/reuse authority that has been expressly denied. Such resale or reuse, when contrary to the known, lawful limits on the authority conferred at the time of the original sale, remains unauthorized and therefore remains infringing conduct under the terms of § 271." The same dissent "agree[s] with the government that *Mallinckrodt*[, *Inc.* v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992)], was wrong when decided, and in any event cannot be reconciled with the Supreme Court's recent decision in *Quanta* Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008). We exceed our role as a subordinate court by declining to follow the explicit domestic exhaustion rule announced by the Supreme Court." *Lexmark*, __ F.3d at __, slip op. at 101 (Dyk, J., joined by Hughes, J., dissenting).

(2) Section 101 Patent-Eligibility: Is a method to determine the presence in a blood sample of a known substance (*here*, DNA) patent-eligible under 35 USC § 101 where that substance, *as such*, is known and not in any event patent-eligible?

<u>Current Case</u>: Sequenom, Inc. v. Ariosa Diagnostics, Inc., Supreme Court No. 15-1182, proceedings below sub nom Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

Status: A Response to the petition is due April 20, 2016.

<u>Question Presented</u>: "Whether a novel method is patent-eligible where; (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery."

(The discussion, below, is a shortened version of a paper, The Sequenom Certiorari Petition: Whither Patent-Eligibility? (Feb. 19, 2016):

(The *Question Presented* is keyed to the statement of the case set substantially different from the theory set forth in this paper. Whether the current approach is successful in gaining *certiorari* remains to be seen.)

The law of patent-eligibility is in a state of flux with the important case involving the genetic testing method of Sequenom on the verge of a deision whether to grant certiorari in a case styled as *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, Supreme Court No. 15-1182, *proceedings below sub nom Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). A response to the petition is due April 20, 2016, after which a vote whether to grant *certiorari* is expected before the end of June when the current Term ends.

A "Microscope" Invention to Identify a Known Substance: Like a

"microscope" a blood test is a way of identifying the presence of material in a sample. Here, the claimed invention is "[a] method for detecting a paternally inherited nucleic acid[, i.e., DNA,] of fetal origin performed on a maternal serum or plasma sample from a pregnant female ***." The DNA, per se, is *known* and thus unpatentable, but, in any event, it is the object of *identification* of the DNA in the sample of the claimed invention. Grant of a patent would thus not preclude any method of making or using the DNA.

A Method to *Identify* a Known DNA that does not Claim the DNA: Patent-eligibility involving microorganism inventions has not even been in controversy where the microorganism is not claimed nor is there a composition claimed involving the microorganism. *In re Bergy*, 596 F.2d 952, 976-77 (CCPA 1979)(Rich, J.), *aff'd as to Chakrabarty sub nom Diamond v. Chakrabarty*, 447 U.S. 303 (1980)(*citing Cochrane v. Deener*, 94 U.S. 780 (1876); *Risdon Iron & Locomotive Works v. Medart*, 158 U.S. 68 (1895); *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (2nd Cir. 1908); *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628 (S.D.N.Y.1930))("[The Patent Office] contends that the [microorganism] invention of the Weizmann patent is unpatentable since it is for

^{*} Claim 1: "A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises [(a)] amplifying a paternally inherited nucleic acid from the serum or plasma sample and [(b)] detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."

the life process of a living organism. Were the patent for bacteria per se, a different situation would be presented. As before stated, the patent is not for bacteria per se. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. Undoubtedly there is patentable subject-matter in the invention.")(original emphasis). Patent-eligibility was denied in *Funk v. Kalo* because the product was claimed, as distinguished from a patent-eligible method of testing. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)(citing *Telephone Cases*, 126 U.S. 1, 532, 533 (1888); *De Forest Radio Co. v. General Electric Co.*, 283 U.S. 664, 684, 685 (1931); *Mackay Radio & Tel. Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939); *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F. 453, 462, 463 (2nd Cir. 1908.)("We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. ***. If there is to be invention [here], it must come from the application of the law of nature to a new and useful end.")

Claims to *Identify* DNA in a Sample do not Implication § 101: It has never before been seriously suggested that a method of several process steps to identify DNA lacks patent-eligibility. See Schering Corp. v. Amgen, Inc., 18 F.Supp.2d 372, 387 (D. Del. 1998) ("hybridization was used in this invention to identify DNA segments structurally similar to both RNA segments and DNA segments found to code on expression for proteins with the anti-viral characteristics of interferon."). It also cannot be seriously contemplated that a method of testing for DNA in a civil litigation could be denied patent-eligibility, a daily occurrence. See Franson v. Micelli, 645 N.E.2d 404, 411 (Ill. App. 1 Dist. 1994)(paternity suit)("The procedures used to 'match' or 'identify' DNA strands...."); see also Allen v. State of Florida, 62 So.3d 1199, 1200 (Fla. App. 2011)(criminal lawsuit)("[H]er lab uses the polymerase chain reaction (PCR) process to identify DNA."); State of Utah v. Maestas, 2012 UT 46, ¶ 124 (Utah S.Ct. 2012)(PCR evidence to sustain capital murder conviction)("[Expert witness] Dr. Wrigley testified that the Y-STR DNA analysis uses the same process and technology to extract, amplify, and identify DNA that is generally employed with polymerase chain reaction (PCR) STR DNA tests. *** Dr. Wrigley testified that because all males in the same paternal lineage have the same forensic markers, *** the Y-STR analysis indicates whether an individual and all of his paternal relatives can be excluded as possible contributors as the source of a DNA sample."); People v. Golub, 601 N.Y.S.2d 502, 503 (N.Y.A.D. 2 Dept. 1993)(second degree murder conviction)("The bloodstains were tested using a then relatively new scientific technique known as 'DNA fingerprinting.'").

An "Adams Battery" Combination Invention: The invention is a combination invention, including all of its elements in the combination of the claim that is to be evaluated for patent-eligibility and nonobviousness: The claim is not to be dissected element by element. As explained in the Adams Battery case, "it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention[.]" United States v. Adams, 383 U.S. 39, 48-49 (1966)(citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 547 (1871); Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 312 U.S. 654 (1940); Schering Corp. v. Gilbert, 153 F.2d 428 (2nd Cir. 1946)).

As explained in the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966): "While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, *Burns v. Meyer*, 100 U.S. 671, 672 (1880); *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116 (1895), it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention, *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 547 (1871); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 312 U.S. 654 (1940); *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946)."

Borrowing Mayo Dictate to Create a Conflict with Established Law: Taking dicta from Mayo, in vacuo, leads to an unnecessary conflict within the case law of the Supreme Court that has uniformly required consideration of the invention as a whole, "all elements" of the claimed invention in their combination defined by the patentee. In the context of patent infringement, the cases repeatedly spoke of the judicial requirement to construe the subject matter under the "all elements" rule. There is a rich history of precedent more from more than one hundred years ago that established the rule that was established by Justice Story. See Barrett v. Hall, 2 F.Cas. 914, 924 (No. 1047)(D. Mass. 1818)(Story, J., riding circuit)("the patent [is] for the combination only[;] it is no infringement of the patent to use any of the machines separately, if the whole combination be not used; for in such a case the thing patented is not the separate machines, but the combination; and the statute gives no remedy, except for a violation of the thing patented."); see also Prouty v. Draper, 20 F.Cas. 11, 12 (No. 11,446) (D. Mass. 1841) (Story, J.; riding circuit), aff'd, 41 U.S. (16 Pet.) 336 (1842)(Taney, C.J.)(" "The plaintiffs' patent is for an entire combination of all the three things, and not for a combination of any two of them. A patent for a combination of A, B and C, cannot be technically or legally deemed at once a combination of A, B and C, and of A and B alone."); Eames v. Godfrey, 68 U.S. (1 Wall.) 78, 79 (1864)("[T]here is no infringement of a patent

which claims mechanical powers in combination unless all the parts have been substantially used. The use of a part less than the whole is no infringement."); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879)("It is a well-known doctrine of patent law, that the claim of a combination is not infringed if any of the material parts of the combination are omitted. ***").

The quoted cases are merely illustrative of the many "all elements" cases from the nineteenth century that include, *inter alia, Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Gould v. Rees*, 82 U.S. (15 Wall.) 187 (1872); *Dunbar v. Myers*, 94 U.S. (4 Otto) 187, 202 (1876); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *Case v. Brown*, 69 U.S. (2 Wall.) 320, 327-28 (1864); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 26-30 (1874); *Fuller v. Yentzer*, 94 U.S. (4 Otto) 288, 297 (1876); *Gage v. Herring*, 107 U.S. (17 Otto) 640, 648 (1882); *Fay v. Cordesman*, 109 U.S. 408, 420-21 (1883); *Rowell v. Lindsay*, 113 U.S. 97, 102 (1885); *Sargent v. Hall Safe & Lock Co.*, 114 U.S. 63, 86 (1885); *Brown v. Davis*, 116 U.S. 237, 252 (1886); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 373, 378 (1886); *McClain v. Ortmayer*, 141 U.S. 419, 425 (1891); *Wright v. Yuengling*, 155 U.S. 47, 52(1894); *Black Diamond Coal Mining Co. v. Excelsior Coal Co.*, 156 U.S. 611, 617-18 (1895); *Cimiotti Unhairing Co. v. American Fur Ref. Co.*, 198 U.S. 399, 410 (1905)).

The Aberrant Flook Case: To the extent that Parker v. Flook, 437 U.S. 584 (1978), stands for the proposition that one may dissect a claim into its constituent elements to determine patent-eligibility based upon the patent-eligibility of one of the components, Flook was cabined by Diamond v. Diehr, 450 U.S. 175 (1981).

In *Diehr* the Court expressly stated that "[i]n determining the eligibility of [the patent applicants'] claimed process for patent protection under § 101, their *claims must be considered as a whole*. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Diehr*, 450 U.S. at 188.

Misapplication of the Law of the Mayo Case: In voting to deny rehearing en banc in Ariosa, the second most senior active member of the Federal Circuit who has been on the bench for twenty-five years manifests a misunderstanding of precedent in the following passage: "In Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012), the Supreme Court set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." Ariosa Diagnostics, Inc. v. Sequenom, Inc. __ F.3d __, __(Fed. Cir. Dec. 2, 2015)(Lourie, J., joined by Moore, J., concurring in den. reh'g en

banc). Precisely. Mayo deals with claims to "laws of nature, natural phenomena", but the invention, *here*, has no such claim.

♦ (3) Design patent infringement; damages keyed to component

Current Case: Samsung Electronics Co., Ltd. v. Apple Inc., No. 15-777 opinion below, Apple Inc. v. Samsung Electronics Co., Ltd., __ F.3d __ (Fed. Cir. May 18, 2015)(Prost, C.J.), asks whether design patent damages should be limited to profits attributable to a component of a patented design, where the design is applied to only that component.

Status: Certiorari was granted March 21, 2016, but only as to the second Question Presented. The case will be briefed in the coming months with a Fall or early Winter argument and a decision in the Term that expires at the end of June 2017.

Questions Presented: "***The [Federal Circuit] held that a design-patent holder is entitled to an infringer's entire profits from sales of any product found to contain a patented design, without any regard to the design's contribution to that product's value or sales. The *** effect of [this holding] is to reward design patents far beyond the value of any inventive contribution. The questions presented are: * * *

"2. Where a design patent is applied to only a component of a product, should an award of infringer's profits be limited to those profits attributable to the component?"

A Damages Pandora's Box for "Regular" Patents: If the Court determines that a particular feature of the patented design is responsible for the success of the infringing product and it accounts for, say, ten percent of the profits, what lesson would a ruling limiting the design patentee to ten percent of the profits in this case have on "regular" patent infringement cases?

Opening the Door to Future Design Patent Grants of Certiorari: One reason why design patents have not been accepted for review by the Supreme Court is because the Court may have been reluctant to grant certiorari in an area of law unfamiliar to the members of the Court. This situation is now dramatically changed with Samsung Electronics v. Apple providing a "tutorial" to the Supreme Court on design patent law. What's next?

Historic First Grant of Certiorari in a Design Patent Case: Never since the Evarts Act of 1891 gave the Court discretion whether to accept an appeal has the Court previously issued a merits decision on design patent law. The leading design patent case came a generation before the Evarts Act in Gorham Co. v. White, 81 U.S. (14 Wall.) 511 (1871), where an appeal could be taken directly from the trial court as a matter of right. (To be sure, discussion of design patent law is found in dictum in Mazer v. Stein, 347 U.S. 201, 215-16 (1954)(copyright case discussing design patents)(" Gorham Co. v. White, 81 U.S. (14 Wall.) 511 (1871), interpret[s] the design patent law of 1842, 5 Stat. 544, granting a patent to anyone who by 'their own industry, genius, efforts, and expense, may have invented or produced any new and original design for a manufacture * * *.' A pattern for flat silver was there upheld. The intermediate and present law differs little. 'Whoever invents any new, original and ornamental design for an article of manufacture may obtain a patent therefor, * * *' subject generally to the provisions concerning patents for invention. § 171, 66 Stat. 805, 35 U.S.C.A. § 171.")(footnote omitted).

Federal Circuit Activity in Design Patents: To be sure, the Federal Circuit has had a major *en banc* review of a design patent issue. *See Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008)(en banc)(Bryson, J.).

(4) "Broadest Reasonable Interpretation" Post-Grant Claim Construction

<u>Current Case</u>: Cuozzo Speed Technologies LLC v. Lee, Supreme Court No. 15-446: The first Question Presented asks whether the Federal Circuit erred in concluding that in an inter partes review post-grant proceeding, the PTAB may construe claims in an issued patent according to the "broadest reasonable interpretation" standard used for ex parte examination as well as pre-Leahy Smith post grant proceedings versus the claims' "plain and ordinary meaning". The decision below is styled as Apotex Inc. v. Daiichi Sankyo, Inc., __ F.3d __ (Fed. Cir. 2015)(Taranto, J.)

Status: Merits briefing stage. (Cert. granted January 15, 2016.)

Sham "Consolidated Proceedings", a Second Issue: The Patent Office in theory permits a patent challenger to file parallel ex parte reexamination and a post-grant proceeding under the Leahy Smith America Invents Act and then to seek "consolidation" of the two proceedings under 35 U.S.C. 315(d), 37 C.F.R. 42.122(a). As explained in the Final Rules, the "consolidated" proceeding would result in "a single inter partes review proceeding." 77 Fed. Reg. at 48,697.

The consolidation approach may be played out, for example, in the odd circumstance of double patenting where this *is* a ground for a patent challenge in *ex parte* reexamination but not (per the current Board interpretation of the law) in a post-grant review under the *Leahy Smith America Invents Act. See Apple Inc. v. SightSound Technologies, LLC*, CBM2013-00021, slip op. at 23-25 (PTAB 2013)(Arbes, APJ).

(i) Sham "Consolidation" Rule: But, the right to "consolidate" parallel reexamination and other post-grant review proceedings is an entirely theoretical right in the sense that the PTAB has never granted "consolidated" proceedings. Thus, the PTAB has never exercised its "consolidation" authority under 35 U.S.C. 315(d), 37 C.F.R. 42.122(a). As Cuozzo points out in its opening merits brief to the Supreme Court, "[t]he Government has <u>not pointed to a single instance</u> in which the Board has consolidated an IPR with a reexamination or reissue proceeding." Cuozzo Br. at 44 (emphasis added). The issue is important in the pending Supreme Court case because the PTO and the Federal Circuit have both cited the possibility of a consolidated reexamination/IPR proceeding as a justification for the "broadest reasonable interpretation" standard in IPR. See id.

- (ii) Double Patenting in a Consolidated Proceeding: One of the implications of the sham practice is that whereas the PTAB in Apple Inc. v. SightSound Technologies, LLC, CBM2013-00021, slip op. at 23-25 (PTAB 2013)(Arbes, APJ), has denied consideration of double patenting in a Covered Business Method (CBM) proceeding, suggesting the same result in a post-grant review under the Leahy Smith America Invents Act, a patent challenger in an ex parte reexamination is permitted bring such a challenge. It makes no sense to deny consolidation in such a case.
- (5) Public vs. Experimental Use; Whether Patents "Preempt" Future Research: Does a patent "preempt" research using the subject matter of the claimed invention for the purpose of study or improvement upon the patented technology?
- <u>Current Cases:</u> (1) <u>Public vs. Experimental Use</u>: The Medicines Co. v. Hospira, Inc., Fed. Cir. 2014-1469, vacated panel opinion, __ F.3d __ (Fed. Cir. 2015)(Hughes, J.)
- (2) Sequenom: Sequenom, (supra, case (1)) (Supreme Court view that there is no experimental use exception to permit research on a patented invention).

(1) Public vs. Experimental Use The Medicines Co. v. Hospira

Issues to be Briefed in Medicines Company: "(a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?

- "(i) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?
- "(ii) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?
- (b) Should this court overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no 'supplier exception' to the on-sale bar of 35 U.S.C. § 102(b)?"

(The now vacated panel opinion quote with approval from *Special Devices*: "A 'sale' under th[e on-sale bar] occurs when the parties offer or agree to reach 'a contract . . . to give and pass rights of property for consideration which the buyer

pays or promises to pay the seller for the thing bought or sold." *Special Devices*, 270 F.3d at 1355 (quoting *Zacharin v. United States*, 213 F.3d 1366, 1370 (Fed. Cir. 2000))).

Status: The Hospira opening brief is due Dec 28, 2015; the Medicines Company's responsive brief is Due Jan. 27, 2016; the Hospira Reply Brief is due 15 days later. Oral argument will be at some point in 2016.

Significance of Medicines Company for Newly Drafted Patent Applications: Medicines v. Hospira deals with a fact pattern under the old law prior to the Leahy Smith America Invents Act. It is thus not an interpretation of the present statute that denies novelty where an invention "was * * * in public use * * * or otherwise available to the public before the [applicant's] effective filing date[.]" Leahy Smith America Invents Act, 35 USC § 102(a)(1).

A Technology-Free cert. -worthy case: For a technologically-challenged Court that nevertheless wants to stay involved in patent issues, "experimental use" and related themes are policy-rich areas that are apt to be explored by the Supreme Court, as seen when it revised the standard for "public use", denying an "experimental" exception in its less than landmark "ready for patenting" decision in *Pfaff v. Wells Elecs.*, *Inc.*, 525 U.S. 55, 67-68 (1998), a seemingly unique case in the context of the Federal Circuit dealing with patentability where the Federal Circuit had reached a conclusion of invalidity that was then *affirmed*, albeit with a different rationale.

Double, double, toil and trouble: Surprisingly, the panel opinion was *unanimous*, hardly the type of scenario to attract *en banc* review. To the extent that the *en banc* court now issues a highly divided opinion, this might be just the seasoning to this case to create basis for grant of *certiorari*.

The Federal Circuit's Difficulty with understanding "Experimental Use":

"Experimental use" in any context, but including "public use", has long troubled the Federal Circuit, yet the *en banc* court has refrained from clarification, particularly in the very troubling progeny of the *Deuterium* case; *see Federal Circuit Case Law that Patents Do Preempt Research, infra.*

(2) Research Preemption (Ariosa)

<u>Current Case</u>: Sequenom, Inc. v. Ariosa Diagnostics, Inc., is the styling of the expected certiorari petition due April 1, 2016, from Ariosa Diagnostics, Inc. v. Sequenom, Inc., __ F.3d __ (Fed. Cir. Dec. 2, 2015)(Order denying en banc review), panel proceedings, 788 F.3d 1371 (Fed. Cir. 2015) (Supreme Court view that there is no experimental use exception to permit research on a patented invention).

Prior Case Law that Patents do not Preempt Research: Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.)(riding circuit) ("[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for [scientific] experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.").

Federal Circuit Case Law that Patents Do Preempt Research: See PATENT-ELIGIBILITY, § 3[c], Deuterium Ghost at the Federal Circuit (citing Deuterium Corp. v. United States, 19 Cl.Ct. 624 (Cl.Ct.1990)(Rader, J.), followed, Embrex v. Service Eng'g Corp., 216 F.3d 1343 (Fed.Cir.2000) (Rader, J., concurring); see also Madey v. Duke Univ., 307 F.3d 1351 (Fed.Cir.2002)(Gajarsa, J.)(dictum); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 863 n.2 (Fed. Cir. 2003), rev'd sub nom Merck KGaA v Integra Lifesciences I, Ltd., 545 U.S. 193 (2005)(discussed in Wegner, Post-Merck Experimental Use and the "Safe Harbor," 15 Fed. Cir. B.J. 1 (2005)).

<u>Implications</u>: If the answer to the question is "no" – that patents do <u>not</u> preempt research – then the argument in *Mayo*, *Alice* and other recent cases vanishes that a patent "preempts" research.

(6) Willful Infringement (§ 284): Should a Willful Patent Infringement Determination be based upon a Rigid Two Part test?

Current Cases now at the Supreme Court: Halo Electronics, Inc. v. Pulse Electronics, Inc., S.Ct. No. 14-1513; Stryker Corp. v. Zimmer, Inc., No. 14-1520.

Status: Awaiting decision (consolidated argument was held February 23, 2016; merits decision by the end of June 2016.

First Question Presented in Halo: "Whether the Federal Circuit erred by applying a rigid, two-part test for enhancing patent infringement damages under 35 U.S.C. § 284, that is the same as the rigid, two part test this Court rejected last term in Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749 (2014) for imposing attorney fees under the similarly worded 35 U.S.C. § 285."

First Question Presented in Stryker Corp. v. Zimmer, Inc., No. 14-1520:

"The Patent Act provides that district courts "may increase . . . damages up to three times the amount found or assessed." 35 U.S.C. § 284. Despite this permissive and discretionary language, the Federal Circuit requires, as a prerequisite to awarding enhanced damages under § 284, that a patentee prove by clear and convincing evidence that infringement was "willful," meaning both that (1) there was an objectively high likelihood that the infringer's actions constituted infringement, and (2) this likelihood was either known or so obvious that it should have been known to the accused infringer.

"The [first question presented is] Has the Federal Circuit improperly abrogated the plain meaning of 35 U.S.C. § 284 by forbidding any award of enhanced damages unless there is a finding of willfulness under a rigid, two-part test, when this Court recently rejected an analogous framework imposed on 35 U.S.C. § 285, the statute providing for attorneys' fee awards in exceptional cases?"

<u>Implications</u>: Reversal of the current Federal Circuit case law will make it easier to award enhanced damages for willful infringement.

♦ (7) "Active Inducement" to Infringe (§ 271(f)(1)): Can a single party who creates one component of a patented combination in the United States and then that same single party creates the patented combination offshore be guilty of infringement of the combination under a theory of "active inducement" under 35 USC § 271(f)(1)?

<u>Current Case</u>: Life Techs. Corp. v. Promega Corp., Supreme Court No. 14-1538, opinion below, Promega Corp. v. Life Techs. Corp., 773 F.3d 1338 (Fed. Cir., 2014)(Chen, J.). Tthe first Question Presented is "[w]hether the Federal Circuit erred in holding that a single entity can 'actively induce' <u>itself</u> to infringe a patent under 35 U.S.C. § 271(f)(1)." (emphasis added)

<u>Status</u>: The Solicitor General was asked for his views in a CVSG order dated October 5, 2015. It is likely that the Solicitor General's brief will be filed in Spring 2016, perhaps in time for a vote before the end of the Term at the end of June 2016.

Prior Case Law: Contributory infringement was spawned more than 140 years ago in *Wallace v. Holmes*, 29 F.Cas. 74 (No. 17,100) (CC Conn.1871), as a court-fashioned way for a patentee to sue a third party who supplies a component of the patented invention to numerous third parties, because it would be impossible or next to impossible as a practical matter to sue each of the individual direct infringers. There has never been a prior appellate holding of active inducement other where a third party is induced to infringe.

<u>Implications</u>: This case represents yet another bold stroke by the Federal Circuit to expand the scope of American patent rights to cover extraterritorial activity.

(8) Laches, Federal Circuit case law

<u>Current Case</u>: SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods.,LLC, S.Ct. No. 15-927, opinion below, __ F.3d __ (Fed. Cir. Sept. 18, 2015)(en banc), asks whether Federal Circuit patent laches law consistent with the Supreme Court copyright laches case, Petrella v. Metro-Goldwyn-Mayer, Inc., 134 S.Ct. 1962 (2014).

Status: Response to the petition is due March 23, 2016 (once extended).

Split En Banc Opinion interpreting *Petrella*: The 6-5 *en banc* majority opinion split the court between a majority opinion of Prost, C.J. (joined by Newman, Lourie, Dyk, O'Malley, Reyna, JJ.), and an opinion by Hughes, J. (joined by Moore, Wallach, Taranto, Chen, JJ., concurring-in-part and dissenting-in-part).

The majority opinion explains that the en banc court was convened "to resolve whether, in light of the Supreme Court's recent decision in *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 134 S. Ct. 1962 (2014), laches remains a defense to legal relief in a patent infringement suit. We conclude that Congress codified a laches defense in 35 U.S.C. § 282(b)(1) that may bar legal remedies. Accordingly, we have no judicial authority to question the law's propriety. Whether Congress considered the quandary in *Petrella* is irrelevant—in the 1952 Patent Act, Congress settled that laches and a time limitation on the recovery of damages can coexist in patent law. We must respect that statutory law."

<u>Implications</u>: No matter the outcome, *SCA Hygience* is a black eye for the Federal Circuit as a court established to provide a uniform body of case law in the patent field. It reaches a conclusion as to laches that differs from *Petrella v. Metro-Goldwyn-Mayer*, *Inc.*, 134 S.Ct. 1962 (2014)(copyright law) and does so in badly split *en banc* decision with a six vote majority opinion (Prost, C.J., joined by Newman, Lourie, Dyk, O'Malley, Reyna, JJ.) balanced by a five vote minority opinion (Hughes, J., joined by Moore, Wallach, Taranto, Chen, JJ., concurring in part, dissenting in part).

The majority ruled that "laches remains a defense to legal relief in a patent infringement suit after *Petrella* [v. Metro-Goldwyn-Mayer, Inc., 134 S.Ct. 1962 (2014)]. Laches bars legal relief, and courts must weigh the facts underlying

laches in the *eBay* framework when considering an injunction. However, absent extraordinary circumstances, laches does not preclude an ongoing royalty."

The dissent disagreed with "the majority [which] adopts a patent-specific approach to the equitable doctrine of laches. In doing so, the majority overlooks Congress' intent and Supreme Court precedent, which demonstrate that laches is no defense to a claim for damages filed within the statutory limitations period established by 35 U.S.C. § 286."

(9) Extraterritorial Patent Infringement

<u>Current Case</u>: WesternGeco L.L.C. v. Ion Geophysical Corp., Supreme Court No. 15-1085, proceedings below, __ Fed. App'x __ (Fed. Cir. 2015)(on pet. for reh'g en banc)(Wallach, J., joined by Newman, Reyna, JJ., dissenting from den. of reh'g en banc), panel opinion, __ F.3d __ (Fed. Cir. 2015)(Dyk, J.), and __ F.3d at __ (Wallach, J., dissenting-in-part).

Status: Response due March 28, 2016.

Issue: This case has an interesting issue concerning extraterritorial patent infringement damages.

In the course of deciding a variety of issues relating to offshore activities governed by 35 USC § 271(f), the panel majority denied infringement damages based upon certain overseas activities. On rehearing en banc, a unique view of extraterritorial patent relief is posited by the three dissenting members keyed to the copyright "predicate doctrine":

"The predicate act doctrine holds that a copyright owner 'is entitled to recover damages flowing from the exploitation abroad of . . . domestic acts of infringement.' L.A. News Serv. v. Reuters Television Int'l, Ltd., 149 F.3d 987, 991-92 (9th Cir. 1998) (tracing the predicate act doctrine to Judge Learned Hand's opinion in Sheldon v. Metro-Goldwyn Pictures Corp., 106 F.2d 45 (2d Cir. 1939), aff'd, 309 U.S. 390 (1940)); see also Tire Eng'g & Distrib., LLC v. Shandong Linglong Rubber Co., 682 F.3d 292, 306 (4th Cir. 2012) ('We adopt the predicate-act doctrine, which posits that a plaintiff may collect damages from foreign violations of the Copyright Act so long as the foreign conduct stems from a domestic infringement.'); Update Art, Inc. v. Modiin Publ'g, Ltd., 843 F.2d 67, 73 (2d Cir. 1988) ('It is well established that copyright laws generally do not have extraterritorial application. There is an exception—when the type of infringement

permits further reproduction abroad — such as the unauthorized manufacture of copyrighted material in the United States.').

"In this case, [the patentee]'s damages flowed from the exploitation abroad of domestic acts of patent infringement under § 271(f). The court's denial of rehearing en banc unfortunately prevents consideration of the predicate act doctrine, which is of particular import given 'the historic kinship between patent law and copyright law.' *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 439 (1984)."

(10) Secret Commecialization as Prior Art

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Fed. Cir. 2016-1284 Whether the Leahy Smith America Invents Act overrules Metallizing Engineering.

This case is considered in detail in the APPENDIX.

Other Cases and Issues

(not ranked by immediacy nor importance)

Propriety of Post-Grant Proceedings Raising § 101 Issue

Retirement Capital Access v. U.S. Bancorp)

Patent-Eligibility Denial exclusive of §§102, 103, 112 denials

cf. Mayo v. Prometheus (no active pending case)

Claim Indefiniteness with Broad and Narrow Constructions

Ex Parte Miyazaki; see also Inre Packard (Plager, J., concurring).

Nautilus v. Biosig

"Nautilus II": Claim Indefiniteness; certiorari denied

OIP v. Amazon.com

Section 101 Patent-Eligibility; certiorari denied.

Patent-Eligibility Denial exclusive of §§102, 103, 112 denials

cf. Mayo v. Prometheus (no active pending case)

SpeedTrack v. Office Depot

Federal Circuit standard for res judicata vs. other circuits

Certiorari denied January 11, 2016.

Fivetech Tech. v. Southco

"lexicography and disavowal" standard for claim construction; Certiorari denied

Medtronic Sofamor Danek v. NuVasive

GVR sought Petition granted with GVR remand. in view of Commil v. Cisco

ITC Jurisdiction Beyond "Articles" (Electronic transmissions):

Whether ITC can exclude as infringing "articles" the exclusion of "electronic transmission of digital data". No current case.

Allergan PLC v. State of New York

Antitrust violation for refusal to continue sale of soon to expire patented formulation; (Case withdrawn before *certiorari* decision)

MCM Portfolio v. Hewlett-Packard

Constitutional challenge to inter partes review; Certiorari petition due March 1, 2016

Antitrust, Removal of Patented Drug from the Market

Allergan PLC v. State of New York; (Case withdrawn before certiorari decision).

"Broadest Reasonable Interpretation" Standard

Interval Licensing v. Lee

Response to petition due March 4, 2016

District Court Jurisdiction of Section 146 Appeals

Biogen MA v. Japanese Foundation for Cancer Research

Conference March 18, 2016; certiorari DENIED.

Injunction following PTAB Invalidation of the Patent

ePlus v. Lawson Software; cert. DENIED February 29, 2016

Propriety of Post-Grant Proceedings Raising § 101 Issue

Current Case: Retirement Capital Access Management Co. LLC v. U.S. Bancorp, No. 15-591, proceedings below, __ Fed App'x __ (Fed. Cir. 2015)(Rule 36 affirmance)(Lourie, Bryson, O'Malley, JJ.)

Status: Awaiting Conference.

Questions Presented: "In 2011, Congress enacted the Leahy-Smith America Invents Act [], Pub. L. No. 112-29, 125 Stat. 284 (2011). The Act created three new post-grant administrative proceedings for challenging the validity of patents. It also created within the Patent and Trademark Office [] a new tribunal called the Patent Trial and Appeal Board (hereinafter the "Board") to preside over these new proceedings. One of the newly created proceedings is the transitional post-grant review, also known as "covered business method" or "CBM" review, for patents directed to a financial product or service. The AIA limits the Board's jurisdiction with respect to CBM review to challenges based on any ground that could be raised under paragraph (2) or (3) of 35 U.S.C. § 282(b). Paragraph 2 provides that a party may seek to invalidate a patent or claim on any ground specified in part II of Title 35 as a condition for patentability.

"The questions presented arise from the Federal Circuit affirming, without comment, the Board's holding that 35 U.S.C. § 101 is a ground specified in part II of Title 35 as a condition for patentability and therefore constitutes a proper basis for review in a CBM proceeding, and from the Federal Circuit affirming the Board's application of § 101 to the patent claims at issue. They are:

- "1. Whether subject matter eligibility under 35 U.S.C. § 101 is a ground specified as a condition for patentability under 35 U.S.C. § 282(b)(2).
- "2. Whether the Board errs when it invalidates issued patent claims posing no risk of preemption under the abstract idea exception to patent eligibility."

Note: The Question(s) Presented quoted here come from Patent Law and the Supreme Court: Certiorari Petitions Pending, https://www.wilmerhale.com/pages/publicationsandnewsdetail.aspx?NewsPubId=1 0737419834

Patent-Eligibility Denial exclusive of §§102, 103, 112 denials:

Is there subject matter within the statutory categories of § 101 that should be denied patent-eligibility under §101 case law that is not also denied under patentability provisions of §§ 102, 103, 112? Should the Patent Office confine its initial § 101 determination until after full examination under §§102, 103, 112?

Current Case: None.

Prior Case: In Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S.Ct. 1289 (2012), the Court declined the Government view that it should focus a validity determination on patentability issues under 35 USC §§ 102, 103, 112 instead of Section 101:

"[T]he Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. Brief for United States as *Amicus Curiae*. The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U. S. C. §102, that it not be 'obvious in light of prior art,' §103, and that it be 'full[y], clear[ly], concise[ly], and exact[ly]' described, §112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under §102.

"This approach, however, would make the 'law of nature' exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections. [citing *Bilski*; *Diehr; Flook; Benson*] See also H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) ('A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101* unless the conditions of the title are fulfilled' (emphasis added[by the Court])).

"We recognize that, in evaluating the significance of additional steps, the \$101 patent-eligibility inquiry and, say, the \$102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do."

<u>Implications</u>: The approach suggested by the Government would provide a more objective determination of patentability. Independent of the Supreme Court preference for a Section 101 determination, quare, should the Patent Office as a first step examine claims for patentability (§§ 102, 103, 112) *before* any consideration of Section 101?

"Nautilus II": Claim Indefiniteness

No Current Case: Certiorari was denied in Nautilus, Inc. v. Biosig Instruments, Inc., Supreme Ct. 15-561, where petitioner had challenged the validity of claims under 35 USC § 112 ¶ 2 which had been upheld by the Federal Circuit on remand from the first appeal to the Supreme Court, Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014).

<u>Discussion</u>: In this case – "Nautilus II" – petitioner challenges the validity of claims under 35 USC § 112 ¶ 2 which had been upheld by the Federal Circuit on remand from the *first* appeal to the Supreme Court, *Nautilus*, *Inc.* v. *Biosig Instruments*, *Inc.*, 134 S. Ct. 2120 (2014).

In a first *Question Presented*, petitioner-patent challenger asks whether "a patent claim [is] invalid for indefiniteness if its scope is not reasonably certain the day the patent issues, even if statements in later Patent Office proceedings clarify it?"

Questions Presented: "The Patent Act's particular-and-distinct claiming mandate gives innovators the reasonable certainty they need to invent confidently near a patent claim's boundary, but not over it. See 35 U.S.C. § 112, ¶ 2 (2006 ed.). To perform this public-notice function, a patent claim must be clear the day it issues. This Court accordingly rejected the Federal Circuit's post hoc 'amenable to construction' standard: 'It cannot be sufficient that a court can ascribe some meaning to a patent's claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc.' Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2130 (2014). But, the remand panel again did the opposite. It copied and pasted much of its opinion this Court had vacated. It did not even mention the original prosecution history. Instead, it again viewed the claim post hoc in view of statements made in Patent Office proceedings 15 years after the patent issued. And, it again relied upon a purely functional distinction over a structurally identical prior-art design as supposedly providing sufficient clarity. The questions presented are:

- "1. Is a patent claim invalid for indefiniteness if its scope is not reasonably certain the day the patent issues, even if statements in later Patent Office proceedings clarify it?
- "2. Is a patent claim invalid for indefiniteness if its scope is distinguished from prior art solely by a functional requirement, rather than by any structural difference?"

OIP Technologies: Section 101 Patent-Eligibility

No Current Case: *OIP Technologies, Inc. v. Amazon.com, Inc.*, Supreme Court No. 15-642, proceedings below, 788 F.3d 1359 (Fed. Cir. 2015)(Hughes, J.), *certiorari denied.*

First Question Presented: "Whether all methods that improve existing technological processes are equally eligible for patent protection under 35 USC § 101, and the Federal Circuit erred by distinguishing a method of testing demand to improve a pricing process from Diehr's method [in Diamond v. Diehr, 450 U.S. 175 (1981),] of testing temperature to improve the timing of a rubber curing process by finding that only the business-related process was ineligible."

Res Judicata, Federal Circuit Standards

Current Case: None

<u>Previous Case</u>: *SpeedTrack, Inc. v. Office Depot, Inc., Inc.*, No. 15-461: Petitioner questions the Federal Circuit standard for res judicata. <u>Certiorari</u> was <u>denied</u> on January 11, 2016.

"Question Presented: In Taylor v. Sturgell, 553 U.S. 880 (2008), this Court confirmed that there are "uniform federal rule[s]" of res judicata.' 553 U.S. at 891. In the decision below, however, the Federal Circuit adopted its own unique form of patent-specific preclusion. This new form of preclusion bars entirely new issues and claims that no court has ever resolved. The Federal Circuit grounded this unique legal doctrine in its reading of Kessler v. Eldred, 206 U.S. 285 (1907), an anti-suit injunction case decided during 'the heyday of the federal mutuality of estoppel rule." MGA, Inc. v. Gen. Motors Corp., 827 F.2d 729, 733 (Fed. Cir. 1987). The Federal Circuit has directly acknowledged that its departure from generally applicable legal principles is 'questionable' (Brain Life, LLC v. Elekta Inc., 746 F.3d 1045, 1057-1058 (Fed. Cir. 2014)), but the court has nevertheless now twice confirmed that it will not apply traditional preclusion rules 'unless and until the Supreme Court overrules [Kessler].' App., infra, 23a; Brain Life, 746 F.3d at 1058. The rules of preclusion are accordingly '[dis]uniform' in the Federal Circuit alone.

"The question presented is: Whether, in direct conflict with the Third and Fourth Circuits, the Federal Circuit erred in construing *Kessler* to bar new issues and new claims that would survive the 'uniform' rules of preclusion applied by every other circuit in all non-patent cases."

Note: The *Question(s) Presented* quoted here come from *Patent Law and the Supreme Court: Certiorari Petitions Pending*,

 $https://www.wilmerhale.com/pages/publications and news detail.aspx? \\ News PubId=10737419834$

Intrinsic Evidence to Determine Claim Construction

Current Case: None.

<u>Previous case</u>: Fivetech Technology Inc. v. Southco, Inc., Supreme Court No. 15-381: Petitioner in the first Question Presented asks whether it is proper for the Federal Circuit to limit the role of the intrinsic evidence in construing patent claims under the exacting 'lexicography and disavowal' standard. The petition was denied on December 4, 2015.

Questions Presented in Fivetech case: In United States v. Adams, 383 U.S. 39, 49 (1966), this Court stated that 'it is fundamental that [patent] claims are to be construed in light of the specifications, and both are to be read with a view to ascertaining the invention.' In Markman v. Westview Instruments, Inc., 517 U.S. 370, 389 (1996), this Court referenced the required 'standard construction rule that a [claim] term can be defined only in a way that comports with the instrument as a whole.' (Emphasis added). In Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc), the Federal Circuit rejected a line of Federal Circuit opinions that limited the role of the specification in defining claim terms only to instances of explicit redefinitions or explicit disavowals of claim scope. However, since *Phillips*, the Federal Circuit remains divided as to the role of the specification and file history (intrinsic evidence) in construing claim terms. Specifically, some panels of the Federal Circuit have adopted a rigid standard of 'lexicography and disavowal' for defining claim terms which limits the relevance of the intrinsic evidence only to those instances of explicit redefinition of a claim term or explicit disavowal of claim scope. See, e.g., GE Lighting Solutions, LLC v. Agilight, Inc., 750 F.3d 1304,1308-09 (Fed. Cir. 2014) ('The standards for finding lexicography and disavowal are exacting.'). This has raised the following questions for this Court.

- "1. Whether it is proper for the Federal Circuit to limit the role of the intrinsic evidence in construing patent claims under the exacting 'lexicography and disavowal' standard.
- "2. Whether the Federal Circuit's exacting 'lexicography and disavowal' standard improperly circumscribes the objective standard of the person of ordinary skill in the art in construing claim terms."

Note: The Question(s) Presented quoted here come from Patent Law and the Supreme Court: Certiorari Petitions Pending,

https://www.wilmerhale.com/pages/publications and news detail.aspx? News Pub Id = 10737419834

Knowledge Requirement for Indirect Infringement

<u>Current Case:</u> <u>Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.</u>, Supreme Ct. No. 15-85: Petitioner seeks to have the case sent back to the Federal Circuit in view of <u>Commil USA, LLC v. Cisco Systems, Inc.</u>, 135 S. Ct. 1920 (2015). i.e., petitioner seeks a GVR.

Status: Petition GRANTED. Judgment VACATED and case REMANDED for further consideration in light of *Commil USA*, *LLC v. Cisco Systems*, *Inc.*, 575 U.S. ____ (2015).

"Questions Presented: In this case, the Federal Circuit affirmed a judgment of indirect infringement, solely on the ground that defendant Medtronic was aware of the patent and instructed doctors to use its products in a manner that was later determined to be infringing. The Federal Circuit did not discuss whether Medtronic's reading of the patent claims—under which it did not infringe—was reasonable.

"Two months later, this Court decided *Commil USA*, *LLC v. Cisco Systems*, *Inc.*, 135 S. Ct. 1920 (2015). That decision rejected the proposition that 'even if the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable, he would still be liable because he knew the acts might infringe,' and held that a plaintiff asserting a claim of indirect infringement must provide 'proof the defendant knew the acts were infringing.'

"The question presented is: Whether the Court should grant the petition, vacate the judgment below, and remand to the Federal Circuit for further consideration in light of *Commil USA*, *LLC v. Cisco Systems*, *Inc.*, 135 S. Ct. 1920 (2015)."

Note: The Question(s) Presented quoted here come from Patent Law and the Supreme Court: Certiorari Petitions Pending, https://www.wilmerhale.com/pages/publicationsandnewsdetail.aspx?NewsPubId=1 0737419834

ITC Jurisdiction Beyond "Articles" (Electronic transmissions): The appellate court determined that the ITC, having has jurisdiction to exclude infringing "articles", does not permit exclusion of instant "electronic transmission of digital data".

No current case.

<u>Previous Case</u>: ClearConnect Operating, LLC v. U.S. Int'l Trade Comm'n, __ F.3d __ (Fed. Cir. Nov. 10, 2015)(Prost, C.J.).

Discussion: "Today's culture, as well as today's economy, are founded on advances in science and technology. As the Industrial Revolution advanced, and recognizing the importance to the nation of technology-based industry, the Tariff Acts of 1922 and 1930 were enacted to provide additional support to domestic industries that dealt in new and creative commerce, by providing an efficient safeguard against unfair competition by imports that infringe United States patents or copyrights. The International Trade Commission correctly applied the Tariff Act and precedent to encompass today's forms of infringing technology.

"The new technologies of the Information Age focus on computer-implemented methods and systems, whose applications of digital science provide benefits and conveniences not imagined in 1922 and 1930. Throughout this evolution, Section 337 served its statutory purpose of facilitating remedy against unfair competition, by providing for exclusion of imports that infringe United States intellectual property rights."

ClearConnect, __ F.3d at __ (Newman, J., dissenting)

Antitrust, Removal of Patented Drug from the Market

: Is the patentee's removal from the market of a patented formulation from the market in favor of the continued marketing of a second patented formulation with a longer patent life an antitrust violation?

No Current Case: Allergan PLC v. State of New York, Supreme Ct. No. 15-587, opinion below, People of the State of New York v. Actavis PLC, 787 F.3d 638 (2nd Cir. 2015): Can it be an antitrust violation for a branded drug manufacturer to remove one patented formulation in favor of maintaining on the market a second patented formulation? Stipulation to dismiss the petition for writ of certiorari pursuant to Rule 46; petition dismissed (Rule 46).

Pharma Under Fire: Both Top Ten No. (2) Allergan v. State of New York (antitrust violation for removing drug from the market) and Top Ten No. (6) Lexmark v. Impression Products (international exhaustion) represent serious threats to the pharmaceutical industry.

<u>Questions Presented</u>: "Brand drug manufacturers seeking to market a new prescription drug must undergo a long and expensive process to obtain FDA approval. Under the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman, generic drug manufacturers can obtain FDA approval for a 'bioequivalent' generic drug more easily, by piggy-backing on the brand's approval efforts. Once the brand drug's patent and other exclusivities expire and generic versions enter the market, state drug substitution laws permit or require pharmacists to dispense lower-priced, therapeutically equivalent generic drugs in place of brand drugs, unless the prescriber directs otherwise. Under most (but not all) states' definitions of therapeutic equivalence, however, pharmacists may not substitute a generic drug that has a different dose than the prescribed brand without the physician's approval.

"The Second Circuit held below that brand drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws so as to maximize the future sales of their generic competitors. Petitioners are a brand drug manufacturer and its subsidiary, who sought to exercise their rights under the Patent Act to limit distribution of an outdated version of their patented Alzheimer's drug in favor of an innovative new formulation with different dosing and longer patent protection. The Second Circuit held that so doing would violate section 2 of the Sherman Antitrust Act because it would reduce the number of prescriptions most state substitution laws would automatically hand over to Petitioners' generic rivals once the old drug's exclusivities ended. The questions presented are:

- "1. Whether exercising rights granted by the Patent Act—in particular, not selling one patented product and selling a different patented product instead—can violate the Sherman Antitrust Act?
- "2. Whether drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws to maximize competitors' sales?"

<u>Background</u>: Various state laws have differing reimbursement policies for prescription medications which may make it impossible to prescribe (with refund) new versions of old drugs. Here, a prescription for the patented single daily dose

version of a drug (the once-a-day "Namenda XR" form) could not in some states permit substitution of the by now off-patent older version (the twice-daily "Namenda IR" form).

The factual background is further explained in the *certiorari* petition:

"The Second Circuit affirmed an unprecedented antitrust injunction forcing a brand drug manufacturer to continue making and selling an outdated patented drug it wanted to replace with a new and improved version. The court held that withdrawing twice-daily Namenda IR in favor of innovative [i.e., patented] once-daily Namenda XR violated section 2 of the Sherman Act because certain state pharmacy laws treat the two drugs differently. In particular, most states allow or require pharmacists to dispense a generic version of IR in place of brand IR, but not in place of brand XR. The Second Circuit held that instead of maximizing their own sales and profits, Petitioners had to keep selling IR to maximize the sales state drug laws would automatically hand over to Petitioners' generic rivals.

* * *

"Under the Hatch-Waxman amendments to the FDCA, once the FDA approves a brand drug for marketing, generic manufacturers can obtain similar marketing approval far more easily. In particular, "a generic competitor [may] file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Caraco Pharm. Labs.*, *Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.* (citing 21 U.S.C. § 355(j)(2)(A)(ii), (iv))."

"Broadest Reasonable Interpretation" Standard

Interval Licensing LLC v. Lee, No. 15-716, proceedings below, __ Fed. App'x __ (Fed. Cir. April 17, 2015)(per curiam affirmance without opinion under Rule 36)(Newman, Lourie, O'Malley, JJ.)

Status: Response to petition due March 4, 2016 (once extended)

<u>Question Presented</u>: Can the Patent and Trademark Office appropriately apply the "broadest reasonable interpretation" standard in construing patent claims in post-grant validity challenges?

Note: The Question Presented quoted here comes from Patent Law and the Supreme Court: Certiorari Petitions Pending, https://www.wilmerhale.com/pages/publicationsandnewsdetail.aspx?

District Court Jurisdiction of Section 146 Appeals

Current Case: None.

<u>Earlier case</u> (certiorari denied March 21, 2016): Biogen MA, Inc. v. Japanese Foundation for Cancer Research, No. 15-607, opinion below, __ F.3d __ (Fed. Cir. May 7, 2015) (questioning whether the Leahy-Smith America Invents Act "eliminated federal district courts' jurisdiction over patent interference actions under 35 U.S.C. § 146."

Injunction following PTAB Invalidation of the Patent

Current Case: None.

Recent Case: ePlus, Inc. v. Lawson Software, Inc., No. 15-639, opinion below, ___ F.3d __ (Fed. Cir. 2015)(Dyk, J.), with O'Malley, J., dissenting. (This case is "ePlus II", following an earlier case, "ePlus I", 700 F.3d 509 (Fed. Cir. 2012).

Status: Certiorari denied February 29, 2016.

<u>The Dissent (O, Malley, J.)</u>: The dissent (O'Malley, J.) points to the issue in controversy at the Supreme Court:

"[An ongoing injunction was *prospectively* terminated upon the Patent Office cancellation of the relevant claim in a post grant proceeding.] That conclusion comes easily ***. The more difficult question is whether Appellees are relieved of all penalties for having violated the injunction during the four years it was in place before the PTO's cancellation was affirmed.

"On this second question, the majority concludes that '[t]his case does not require us to decide whether civil contempt sanctions would survive if the injunction had been final at the time the district court imposed civil contempt sanctions,' because, under *Fresenius USA, Inc. v. Baxter International, Inc.*, 721 F.3d 1330 (Fed. Cir. 2013) ('*Fresenius II'*), cancellation of claims by the Patent and Trademark Office ("PTO") "requires that non-final judgments be set aside.' *Id.* Because it finds the judgment in this case non-final, the majority—on the strength

of *Fresenius II*—renders all aspects of the earlier judgment against Lawson, including the injunction premised thereon, a nullity. *** *Fresenius II* is distinguishable from, and I do not believe governs, the present appeal. I write separately, moreover, to note that, if we are bound by *Fresenius II* on these facts, I find *Fresenius II* even more troubling than I initially believed. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 733 F.3d 1369, 1373-81 (Fed. Cir. 2013) (O'Malley, J., dissenting from denial of petition for rehearing en banc)[]. If *Fresenius II* compels the conclusion here, it should be reconsidered."

Questions Presented: "Following a jury trial, the district court permanently enjoined respondent Lawson Software, Inc., from infringing patent claims owned by petitioner ePlus, Inc. Lawson then abandoned its challenge to the validity of the key patent claim (claim 26). The Federal Circuit affirmed the judgment that Lawson infringed claim 26, and it upheld the injunction; it reversed with respect to some other patent claims.

"Lawson flagrantly violated the injunction, and after a hearing, the district court entered an order of civil contempt. While Lawson's second appeal was pending, the U.S. Patent and Trademark Office cancelled claim 26 based on an invalidity ground that Lawson had not pursued in litigation. A divided Federal Circuit panel held that the cancellation order retroactively invalidated the contempt judgment.

"The questions presented are as follows:

- "1. Whether civil contempt of a permanent injunction order that has been affirmed on appeal and is binding on the litigants under the law of judgments, may be set aside based on a legal development that came after both the permanent injunction and the contumacious conduct, and that did not call into question the correctness of the injunction when it was entered.
- "2. Whether, under *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211 (1995), the PTO, an administrative agency, may issue an order that retroactively overrides a federal court's judgment on a question of law that is not subject to further judicial review, so long as some other part of the litigation is pending."

Free* Information Sources

<u>Supreme Court Patent Filings, Proceedings and Analysis</u> <u>Supreme Court Official website, supremecourt.gov/</u>

The official government website is the primary source for obtaining the latest information, *other than* copies of briefs and statement of *Questions Presented*.

<u>Docket Sheet</u>: If a person knows the names of the parties or the Case Number, the Docket Sheet is easily accessible for each case at http://www.supremecourt.gov/docket/docket.aspx

<u>An "Orders List"</u> showing whether certiorari has been granted, http://www.supremecourt.gov/orders/ordersofthecourt/15

Generally, a decision whether to grant *certiorari* is part of an Orders List that is electronically published at 9:30 AM on the first "red" or "blue" day (usually a Monday) following the Conference where the case is under consideration (a "green" day, generally the previous Friday). But, in the early months of each Term beginning in October, if *certiorari* is granted, then a special Orders List is issued in the afternoon of the day of the Conference indicating cases where *certiorari* has been granted.

The calendar with the "red", "blue" and "green" days is available at http://www.supremecourt.gov/oral_arguments/2015TermCourtCalendar.pdf For the date of the Conference for an individual case, see the Docket Sheet for that case.

<u>New Opinions</u>: Latest slip opinions are released at http://www.supremecourt.gov/opinions/slipopinion/15

Shortcomings of the Official Website: The website does not provide access to court documents, e.g., briefs, petitions, and nowhere states the *Question Presented*.

^{*}A variety of fee-based resources provide excellent information including Westlaw (which electronically publishes all Supreme Court *certiorari* petitions), Law360 (which is often fed the latest information from interested parties and then provides a link to briefs and other documents) and the Patent Trademark and Copyright Journal, a daily source of on line information.

Top Free* **Private Blogsters**

Full time academics and practitioners who have an active appellate practice at either the Federal Circuit or Supreme Court are listed here, *alphabetically*:

<u>Courtenay C. Brinckerhoff</u>, Pharmapatents Blog pharmapatentsblog.com/

Appellate expert Courtenay C. Brinckerhoff provides in depth expert analysis of all issues relating to pharmaceutical patents.

*** * ***

<u>Prof. Dennis Crouch</u> *et al.*, Patently-O blog patentlyo.com

Prof. Crouch provides by far the most comprehensive treatment of all patent issues, including Supreme Court cases.

*** * ***

<u>Tom Goldstein</u>, SCOTUSblog http://www.scotusblog.com/

SCOTUSblog is by far the most compressive website for Supreme Court information. It is the most convenient source to obtain briefs in any case where *certiorari* has been granted. Its only real drawback is an absence of input from an active patent practitioner.

*** * ***

Dr. Kevin Noonan et al., Patent Docs blog,

^{*} See the note on the previous page.

http://www.patentdocs.org/

This website selectively considers *biotechnology* and related patent Supreme Court petitions and merits cases with in depth analysis of the cases it considers. It also provides links to briefs.

*** * ***

Professor Jason Rantanen, see Prof. Dennis Crouch et al., Patently-O blog

♦ ♦ ♦

<u>WilmerHale</u>, Patent Law and the Supreme Court: Certiorari Petitions Granted, https://www.wilmerhale.com/pages/publicationsandnewsdetail.aspx?NewsPubId=1 0737419833

Authored by Joseph J. Mueller, Leslie Pearlson and Thomas G. Saunders, this website is useful to identify all patent cases at the Supreme Court <u>after grant of certiorari</u> with a statement of the <u>Question Presented</u> and links to documents. It is not updated as frequently as SCOTUSblog.

*** * ***

Warren D. Woessner, Patents4life blog

http://www.patents4life.com/

This blog presents the views of a senior, experienced patent practitioner for the field of biotechnology.

*** * ***

Dr. Donald Zuhn, see Kevin Noonan et al., Patent Docs blog

About the List

This listing represents the opinion of the author and has been created probono without sponsorship by any other person or organization.

This listing differs from the previous *Top Ten Patent Cases* that ran for several years through the end of 2014 in that it is in the first instance *issue* driven – whether or not there is a pending case for that issue – while the pendency or likely pendency of a test case that is at or may reach the Supreme Court is also given weight.

Suggestions for inclusion of issues or cases is gratefully appreciated and may be sent to hwegner@gmail.com, with the subject heading, "Suggestions for The List.

Public Access to Documents of this Writer

This paper and also other papers by the author are made available to the public as "Wegner's Writings" on the website of the Los Angeles Intellectual Property Law Association: www.laipla.net/category/wegners-writings/

Any citations to PATENT DRAFTING and PATENT ELIGIBILITY are to monographs of this writer now in draft form, which are available under "Wegner's Writings"

About the Author



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Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

§ 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

- § 1[a][7][C][i] The Literal Wording of the Statute
- § 1[a][7][C][ii] Changed Circumstances since Metallizing Engineering
- § 1[a][7][C][iii] Danger a Third Party May Patent the Process
- § 1[a][7][C][iv] Prior User Rights under the New Patent Law
- § 1[a][7][C][v] "[O]r otherwise available to the public"
- § 1[a][7][C][vi] Legislative History, the Harmonization Goal
- § 1[a][7][C][vii] Helsinn Healthcare Amicus Challenge, a New Twist

This appendix is an excerpt from the writer's monograph, FIRST TO FILE PATENT DRAFTING (March 22, 2016). Pagination to the original version is indicated, e.g. [*29].

§ 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

[*29] Prior to the *Leahy Smith America Invents Act* under *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir.1946)(L. Hand, J.), the commercialization of the product of a secret process created a statutory bar under 35 USC § 102(b) as a "public use" of the invention – even though the process remained secret. Where the patentee uses a patentable process to make a commercial product where the sale of that product does not reveal the identity of the product of that patentable process, does the patentee forfeit his right to a patent on the patentable process if he fails to file a patent application to that process within one year from his first commercialization?

[*30] Prior to the *Leahy Smith America Invents Act*, the answer has been "yes", there is a bar. This is based upon the interpretation of the "on sale" bar in *Metallizing Engineering*: "[I]t is a condition upon the inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 149 (1989)(quoting *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir.1946)(L. Hand, J.).

Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

The question now is whether *Metallizing Engineering* remains the law as part of the *Leahy Smith America Invents Act*, an issue now before the Federal Circuit in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, Fed. Cir. 2016-1284.

Until there is a decision in *Helsinn Healthcare* or some future case, the safest approach in establishing a patent portfolio is to file a patent application on the patentable process *prior to* the one year anniversary of the first "on sale" event of the product made by that process.

The Federal Circuit explained the law of *Metallizing Engineering* in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983): Budd and Cropper were involved in prior art activities for the *sale* of a product (a tape) where the prior art activities did *not* permit identification of the process used to make that product. Here, the sale of the product would have been a patent-defeating bar against a patent to the product, but not to the secret process, *except* against the party who had commercialized the tape:

"If Budd [and Cropper] offered and sold anything, it was only tape, not whatever process was used in producing [the tape]. *** [T]here was no evidence[] that the public could learn the claimed process by examining the tape. If Budd and Cropper commercialized the tape, that could result in a forfeiture of a patent granted them for their process on an application filed by them more than a year later. *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147-48 (Fed.Cir.1983); See *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir.1946). There is no reason or statutory basis, however, on which Budd's and Cropper's secret commercialization of a process, if established, could be held a bar to the grant of a patent to Gore on that process."

W.L. Gore, 721 F.2d at 1550.

Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

[*31] § 1[a][7][C][i] The Literal Wording of the Statute

Whether *Metallizing Engineering* has survived the *Leahy Smith America Invents Act* depends in the first instance upon a change in the wording of the law

The basis for the bar to secret commercialization is the "public use" and "on sale" language of 35 USC § 102(b) which in *Metallizing Engineering* was judicially expanded to include *secret* commercialization.

35 USC § 102(b)(pre-*Leahy Smith America Invents Act*)(An invention was barred where more than one year before the United States filing date "the invention was *** in public use or on sale in this country ***").

But, in the *Leahy Smith America Invents Act*, instead of merely repeating "public use" and "on sale" activities as a bar, this language is *qualified* and limited to acts "available to the public." Thus, an invention today s barred for such activities where "the claimed invention was *** in public use, on sale, *or otherwise available to the public*[.]"35 USC § 102(a)(1)(*Leahy Smith America Invents Act*)(emphasis added).

§ 1[a][7][C][ii] Changed Circumstances since Metallizing Engineering

There are completely different public policy considerations today vis a vis the time of the *Metallizing Engineering* decision.

Today, policy arguments for or against a patent policy for the United States necessarily must consider how that policy will impact United States domestic industry vis a vis China, Japan, Germany and other leading industrial countries of the world. *Metallizing Engineering* was decided in a completely different era of *domestic* competition. It was a world without global economic competition, where the American manufacturing community was dealing with essentially only domestic competition. The trial case was decided on March 28, 1945, during the final months of World War II, and was considered by the Second Circuit in the months following that war. (The Circuit Court decision was handed down March 28, 1945.)

Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

Whereas in 1946 China, Germany and Japan posed absolutely no threat as manufacturing competitors to the United States, the world has literally been turned upside down as today it is the United States that is having difficulty competing [*32] particularly with Asian countries. Countless stories are found in the business literature where American technology is copied by foreign concerns. In the case where it is impossible or at least time consuming and difficult to reverse engineer a product without knowledge of its manufacturing details, trade secret protection may in some cases be more important than gaining a patent. Americans should be *encouraged* to use trade secret protection to maintain American manufacturing jobs by blocking competition based upon trade secrecy.

One of the incentives to use trade secret protection would be the ability to *patent* the trade secret even years after use of the trade secret. But, this incentive is thwarted by *Metallizing Engineering* that blocks an American patent more than one year after secret commercialization.

To the contrary, foreign companies have this encouragement in their laws by virtue of the *absence* of *Metallizing Engineering*: When a foreign company recognizes that its trade secret process may well be reverse engineered in the near future, the foreign company will file a patent application at that time and thus transition to patent protection. (To be sure, an American company in a like situation may still obtain European and Asian patent protection even after secret commercialization, assuming there has been no public divulgation up this point.) Another aspect of public policy favoring *Metallizing Enginnering* is that without this safeguard, an inventor may gain a prolonged exclusive right by piggybacking patent protection on top of several years of trade secret protection. Indeed, this is a point that must be weighed vis a vis the benefit of encouraging trade secret protection at the early point of commercialization.

§ 1[a][7][C][iii] Danger a Third Party May Patent the Process

The theory of *Metallizing Engineering* was that an inventor could in essence multiply the length of its exclusive rights without this case, because then the inventor could maintain his monopoly through trade secret protection and then, much later, file a patent application to the once secret process invention and thus start a new patent term.

Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

This theory is flawed because if the inventor sits on his trade secret process it is not part of the prior art as to *third parties* and once a *third party* discovered the trade secret process that third party could obtain a dominant patent that would compromise the original inventor's rights to practice the invention.

[§ 33] § 1[a][7][C][iv] Prior User Rights under the New Patent Law

More important perhaps in the context of the *Leahy Smith America Invents Act* is the fact that even assuming, *arguendo*, that one in 1946 (the date of *Metallizing Engineering*) one could first protect an invention as a trade secret and then much later file a patent application, today, failure to file a patent application would permit a third party who discovered the "secret" of the commercial process could be exempt from liability under the prior user right statute that did not exist in 1946 but is now a vibrant element of the *Leahy Smith America Invents Act* as 35 U.S.C. 273(a):

- "A person shall be entitled to a defense under [35 USC § 282(b)] with respect to subject matter consisting of a process *** that would otherwise infringe a claimed invention being asserted against the person if—
- "(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use; and
- "(2) such commercial use occurred at least 1 year before *** (A) the effective filing date of the claimed invention[.]"

§ 1[a][7][C][v] "[O]r otherwise available to the public"

To say that "public use" or "on sale" events are *maintained* unchanged in the *Leahy Smith America Invents Act* overlooks the overall sentence that states that "the claimed invention was *** in public use, on sale, *or otherwise available to the public*[.]"35 USC § 102(a)(1)(*Leahy Smith America Invents Act*)(emphasis added). To be sure, the *original* language used in the earliest version of the legislation that wound up as the *Leahy Smith America Invents Act* had more explicit language that would have clearly and unmistakably overruled *Metallizing Engineering*. *See* Dmitry Karshtedt, *Did Learned Hand Get it Wrong? The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Villanova L. Rev. 261, 332 n.435

Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

(2012)(quoting Wegner, THE 201 PATENT LAW; LAW AND PRACTICE, § 155 at 108-09 (2nd ed. 2011))

The prime author of the text leading up to the *Leahy Smith America Invents Act* firmly sees *Metallizing Engineering* as having been overruled by the wording of the new law. *See* Robert A. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, § III-C-5, *Step Four: Clarifying the "Available* [*34] *to the Public" Standard*, 40 AIPLA Q. J. 1, 58-60 (2012). He explains that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible." *Id.* at 58 (citing statement of Sen. Jon Kyl, 157 Cong.rec. S1335, 1370 (daily ed. Mar. 8, 2011)). Thus, "[p] *ublic disclosures* will represent prior art and will be disclosures, made by any means or method, that have become *publicly accessible*, *i.e.* made *available to the public* ***." *Id.* at 59 (original emphasis).

To say that *Metallizing Engineering* survives the *Leahy Smith America Invents Act* by focusing on the specific wording "public use" and "on sale" overlooks the entire context of the statute which in the same sense refers to "otherwise available to the public". The more complete statement is that there is a bar against a "claimed invention [which] was *** in public use, on sale, *or otherwise available to the public*[.]"35 USC § 102(a)(1). To say that "public use" and "on sale" should be interpreted as prior to the *Leahy Smith America Invents Act* is to deny the context and "all words" of the statute.

Ignoring words, e.g., "or otherwise available to the public", simply cannot be ignored: "[T]he Court will avoid a reading which renders some words altogether redundant." *Texas Dept. of Housing and Community Affairs v. Inclusive Communities Project, Inc.*, __ U.S. __, __, slip op. at 19 (2015)(quoting *Gustafson v. Alloyd Co.*, 513 U. S. 561, 574 (1995)). *See also Ford Motor Co. v. United States*, 715 F.3d 906, 920 (Fed. Cir.2013) (characterizing *Glover v. West*, 185 F.3d 1328, 1332 (Fed.Cir.1999), as "explaining that courts must 'attempt to give full effect to all words contained within th[e] statute [and] regulation[s], thereby rendering superfluous as little of the statutory or regulatory language as possible'."); *Sullivan v. McDonald*, __ F.3d __, __ slip op. at 5 (Fed. Cir. Mar. 8, 2016)(same).

Appendix: Wegner, First to File Patent Drafting [2016] § 1[a][7][C] Inventor's Secret Commercialization as Personalized Prior Art

It requires a linguistic genius to unravel and find specific meaning in the phrase "or otherwise available to the public" to conclude that a secret disclosure is "otherwise available to the public." A leading proponent of the view that a secret use is "public" makes the point loud and clear both in his Testimony before the Patent Office, Robert P. Merges, Comments on "Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act", § 3[a], Meaning of "Or Otherwise Available to the Public" under AIA § 102(a)(1), pp. 3-4, Letter to Mary Till, Legal Advisor, Office of Patent Legal Administration, U.S. Patent and Trademark Office (October 12, 2012)("Testimony"), and in his law review article, Robert P. Merges, Priority and Novelty under the AIA, 27 Berkeley Tech. L.J. 1023, 1035 (2012)(with Research Assistance from Puneet Kohli)("Law Review Article").

[*35] In his testimony, and to his credit, this leading academic candidly admits that the lack of clarity of the statutory wording. "[He] recognize[s] that [his] case would be stronger if the statute read: 'patented, or described in a printed publication, or in public use, on sale, or otherwise available to the public. *** [He] also recognize[s] that a semicolon, in [his] preferred alternative [reading], would have sent a clearer signal that the two phrases *** were meant to be read as separate and distinct." Testimony at p.4 n.6. The author's scholarly treatment of the same issue speaks for itself. Indeed, the scholar candidly states that "[t]here is an obvious textual problem, so it would seem, with an argument that the word 'disclosure' is meant to include confidential sales, and the use in public of things that are made by but which in no way reveal the details of the underlying invention. Put simply, these sales and uses are in some sense secret. They are not open, widely discoverable, or easily accessible. So how can they be construed to be part of the general class of 'disclosures'? Isn't a disclosure something that is open or widely available?" Law Review Article at 1035-36.

The scholar extricates himself from this dilemma not through citation of a Supreme Court or Federal Circuit case, but instead by turning to the definition of "disclose" in the Oxford English Dictionary, citing, *inter alia*, "[e]xamples of 'disclosure in the [Oxford English Dictionary] include watching an egg hatch or watching a caterpillar emerge from its cocoon." Law Review Article at 1036.

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§ 1[a][7][C][vi] Legislative History, the Harmonization Goal

As it is clear that the wording of the statute limits "public use" and "on sale" bars to *public* disclosure that does not retain the secrecy of an invention, resort to legislative history is unnecessary. But even assuming, *arguendo*, that there is at least ambiguity sufficient to open the door to a consideration of the legislative history it is even more clear that it was the intention of Congress to harmonize and to eliminate "on sale" or "public use" events which retained the secrecyof an invention. In the first instance, it is clear that the legislative history shows that harmonization of patent laws was a goal.

There is a mountain of legislative history that demonstrates that a driving overall purpose of what became the *Leahy Smith America Invents Act* is the harmonization of patent laws for the benefit of the United States industrial circles so that it would be easier and more reliable to obtain for American innovation parallel patent rights in Asia and Europe. At the time of *Metallizing Engineering* the world was either embroiled in the final stages of World War II (at the District Court level) or in the immediate recovery period after that conflict (at the appellate [*36] level). Beyond the *economic* state of the world where Japan and much of Europe lay in waste and the immediate concerns were domestic economic recovery without realistic immediate thoughts of economic competition with the United States, the state of the patent laws of the world was one of great disharmony with each of the United States, Germany, the United Kingdom, France and Japan have widely different patent laws making it difficult to obtain global patent rights. Individually tailored patent applications had to be crafted for divergent and often inconsistent national patent laws.

At the time of *Metallizing Engineering* one could not even agree on how to define an invention given, for example, the fact that Germany had a "central" system where claim language was mere guidance where the bounds of protection could be stretched to the full scope of the "general inventive thoughts" expressed in the patent, the United Kingdom and Japan had claiming systems with extremely narrow protection essentially void of a doctrine of equivalents and Italy at the other end of the spectrum provided for patents without *any* claims of any kind.

The European Patent Convention that would result in common patent provisions was more than a generation away; so, too, was the Patent Cooperation Treaty a vision yet to be born (and a generation away from accomplishment).

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With the gross divergence of patent laws and the economic reality of a war ravaged Europe and Japan, it is not surprising that *Metallizing Engineering* in 1946 had a narrow domestic focus.

In the debates in international for a to create a uniform patent law, Metallizing Engineering was a center stage issue of disharmonization. During the WIPO Patent Harmonization debates, *public disclosure* was the near consensus view of an essential element for prior art: "The prior art shall consist of everything which *** has been made available to the public anywhere in the world." See Wegner, PATENT HARMONIZATION § 800, Patentability: Novelty; Nonobviousness [Art. 11], pp. 77 (London: Sweet & Maxwell 1993)(quoting Art. 11(2)(b)). Because the United States law of *Metallizing Engineering* did not comport with this provision, the United State unsuccessfully sought to amend the treaty to accommodate this unique American position: "Art. 9^{bis}(1), PLT/CD/40, was proposed by the United States to provide in part for a bar based on *Metallizing* Engineering This measure 'did not receive general support' at the Hague [Diplomatic Conference], although "there was general agreement *** that nothing in the Treaty precluded' U.S. retention of this current bar." Wegner, PATENT HARMONIZATION, supra, § 814, U.S. Secret Commercialization Bar, p. 78 [*37](quoting CA/H 8/92, Comment by the EPO to Art. 9^{bis} of the Basic Proposal.).

Whereas there were major divergent principles of patent law amongst the major countries of the world, in the wake of the European Patent Convention and the Patent Cooperation Treaty, there was substantial harmonization of patent laws around the world with one big asterisk: Whereas the other countries of the world created a largely harmonized patent law, the United States stood pat with a law focused on its unique domestic focus. What changed this focus in the United States? In the first instance, during the period beginning in 1984 there was a multi-year United Nations drafting of a substantive patent law treaty that sought to iron out remaining differences amongst the member states. Wegner, PATENT HARMONIZATION (London: Sweet & Maxwell 1993). In the end, the Geneva effort through WIPO died, fueled by the unilateral repudiation of the treaty by Harry Manbeck, the leader of the Patent Office just before and during the Diplomatic Conference. *Id.*, § 612, *Treaty Disintegration* (1989-1991), p. 39.

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But, in part inspired by the initial progress that was made, the United States in the 1980's successfully launched parallel proceedings that by 1994 had resulted in the TRIPS Agreement that imposed substantive patent standards on all countries, with a particular focus on developing countries. The United States played a key leadership role in this effort, which helped spawn concern for an overall reform of United States patent law consistent with what had become the "international system". The American Intellectual Property Law Association under the leadership of its late past President, Robert Benson, and its prime leader for patent harmonization of the era, Robert A. Armitage, forged a pathway to Introduction of domestic legislation where the common denominators behind this legislation were to simplify the American patent system and to make the American patent system compatible with the global realities of the "international system". These dual features would be expected to make it easier for American to obtain overseas patent rights to spread the development costs of American innovations to the global marketplace and avoid the booby-traps created by divergent legal systems.

There are numerous article and debates within the American Intellectual Property Law Association pointing to these dual goals as well as statements within the legislative record that demonstrate support for the harmonization goals of the legislation.

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[*38] There is a rich body of legislative history supporting *both* the fact that the legislation from a macroscopic approach is designed to *harmonize* American with overseas patent laws *and* that the legislation was designed to limit public uses and sales of an invention as prior art *only* if they make the invention available to the public.

In terms of the macroscopic goal of harmonization, there is a rich body of evidence supporting this point. In 2007 Senators Leahy and Hatch both explained the harmonization objective of the legislation: "Both [Senator Leahy] and Senator Hatch made affirmative arguments in favor of the first-to-file system, noting that it would produce greater international harmonization * * *." Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 22 Federal Circuit B. J. 435, 453-54 n.129 (2012)(citing 153 Cong. Rec. S4685 (daily ed. Apr. 18,

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2007) (statement of Sen. Leahy); *id.* at S4691 (statement of Sen. Hatch). *See also* the statement of Rep. Johnson that the reform legislation will further harmonize U.S. patent law with that of other industrialized nations. See 157 Cong. Rec. E1273 (daily ed. July 8, 2011) (statement of Rep. Johnson).

In terms of limiting public uses and sales of an invention as prior art *only* if they make the invention available to the public one may refer to the statement of Senator Kyl: Prior to Senate enactment of the *Leahy Smith America Invents Act*, Senator Kyl explained that "[p]ublic uses and sales of an invention will remain prior art, but only if they make the invention available to the public. * * * Only the sale or offer for sale of the invention to the relevant public or its use *in a way that makes it publicly accessible* will constitute prior art." Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 22 Federal Circuit B. J. 435, 472-73 (2012)(quoting statement of Senator Kyl addressing the bill's provision of "prior art", 157 Cong. Rec. S5319-21 (daily ed. Sept. 6, 2011)(emphasis added, footnote omitted).

§ 1[a][7][C][vii] Helsinn Healthcare Amicus Challenge, a New Twist

Interestingly, forty-two (42) law professors as amici curiae are represented by two leading patent academics including the author of the testimony and law review article cited in § 1[a][7][C][v], "[O]r otherwise available to the public", have created a theory unrecognizable in the testimony or law review article. See Mark Lemley & Robert P. Merges, *Helsinn Healthcare S.A. v. Teva* [*39] Pharmaceuticals USA, Inc., Fed. Cir. 2016-1284, Brief of Amici Curiae 42 Intellectual Property Professors in Support of Appellant, March 14, 2016. The brief is written on behalf of amici Professor John R. Allison; Professor Clark Asay; Professor Margot A. Bagley; Professor Ann Bartow; Professor Jeremy Bock; Professor Dan L. Burk; Professor Michael A. Carrier; Professor Andrew Chin; Professor Ralph D. Clifford; Professor Kevin Collins; Professor Christopher A. Cotropia; Professor Thomas Cotter; Professor Robin Feldman; Professor William Gallagher; Professor Shuba Ghosh; Professor Yaniv Heled; Professor Timothy Holbrook; Professor Camilla Hrdy; Professor Dennis S. Karjala; Professor Dmitry Karshtedt; Professor Amy L. Landers; Professor Mark A. Lemley; Professor Lee Ann Lockridge; Professor Brian J. Love; Professor Stephen Mcjohn; Professor Mark P. Mckenna; Professor Robert P. Merges; Professor Joseph Scott Miller; Professor Mike Mireles; Professor Craig Allan Nard; Professor Tyler T. Ochoa;

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Professor David S. Olson; Professor Michael Risch; Professor Sharon Sandeen; Professor Joshua D. Sarnoff; Professor Katherine J. Strandburg; Professor Kurt M. Saunders; Professor Sean B. Seymour; Professor Ted Sichelman; Professor Brenda Simon; Professor David O. Taylor; Professor R. Polk Wagner.

The *amici* treat *Metallizing Engineering* as a well-crafted cornerstone of the patent system, while in fact the Supreme Court has cited but never adopted the holding in the case nor do *amici* recognize the inherent weakness of the opinion itself. George Washington University Law School Professor Karshtedt makes this point clear:

"The patent forfeiture rule of *Metallizing* is unsupported by precedent or statute, and is inequitable on the actual facts of the case. *** The disclosure and extension-of-monopoly rationales for the rule are questionable, and all the more so because the most important policy rationale for the existence of the patent system – to provide incentives to invest and engage in inventive activities – might not be well served by the *Metallizing* rule. In addition, the rule likely contributes to overpatenting, which can in turn lead to patent thickets that stifle competition. *** While the Supreme Court cited the *Metallizing* case in three separate opinions, it has never endorsed the forfeiture rule. Moreover, the Supreme Court in recent patent cass has hewed closely to the language of the Patent Act and accepted rules that seemingly diverged from the patent statutes only as long as they have been supported by long-standing Supreme Court precedent. There are no such precedents for the Metallizing rule – Pennock v. Dialogue and Woodbridge v. *United States* are clearly distinguishable from *Metallizing* on their facts, and *Bates* v. Coe speaks directly against the rule by focusing on truly public uses as patentinvalidating activities. *** [T]he textualist orientation of the current Court seems [*40] to militate against 'policy polymorphism' of distinguishing first and third parties in a statute that, in its plain language, makes no such distinction. It appears that the *Metallizing* rule, whose justification and scope courts and commentators are still trying to understand, has remained on the books for as long as it did partly out of respect for a great judge. But should we always defer to Judge Learned Hand? Perhaps not. In the biting words of Judge Alex Kozinski, Judge Hand 'was very knowledgable about everything except how the world works."" Dmitry Karshtedt, Did Learned Hand Get it Wrong? The Questionable Patent

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While there is a wealth of literature cited in their brief, there are several key authorities that have been overlooked, including the work of undoubtedly the most important draftsman of the legislation, Robert A. Armitage, as well as a law review article by one of the authors of the amicus effort as well as his testimony before the Patent Office. See Robert A. Armitage, Understanding the America Invents Act and its Implications for Patenting, § III-C-5, Step Four: Clarifying the "Available to the Public" Standard, 40 AIPLA Q. J. 1, 58-60 (2012); Robert P. Merges, Priority and Novelty under the AIA, 27 Berkeley Tech. L.J. 1023, 1036 (2012); Robert P. Merges, Comments on "Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act", § 3[a], *Meaning of "Or Otherwise Available to the Public" under AIA § 102(a)(1)*, pp. 3-4, Letter to Mary Till, Legal Advisor, Office of Patent Legal Administration, U.S. Patent and Trademark Office (October 12, 2012)). See also the detailed analysis of the legislation by George Washington University Law School Professor Dmitry Karshtedt, Did Learned Hand Get it Wrong? The Questionable Patent Forfeiture Rule of Metallizing Engineering, 57 Villanova L. Rev. 261 (2012).

What do *amici* say about the analysis of the legislation by Armitage, a principal draftsman of the *Leahy Smith America Invents Act* and by far the most prominent person on the stage throughout the planning for the legislation dating back to the mid-1990's up through the entire six year legislative process? How do the *amici* answer the Armitage analysis of this legislation? They don't. Instead, the *amici* law professors at pp. 2-5 of their brief spin a fantastic linguistic analysis that does not square with the picture painted Armitage, *supra*.

[*41] The *amici* ignore not only the prime work of Armitage but also their own previous law review article and testimony before the Patent Office, each of which paints entirely different approaches to justify the result they seek in their brief. (To be sure, while the Merges law review article is not cited in the bodyof the brief, there is a footnote citation to the article, p. 11 n. 11.)

Perhaps the most radically different argument is one that was previously made by one of the coauthors of the brief that focuses upon a dictionary definition of "disclose" as "includ[ing] watching an egg hatch or watching a caterpillar emerge from its cocoon." Merges, 27 Berkeley Tech. L.J. at 1036. The testimony

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before the Patent Office is also of interest. *See* § 1[a][7][C][v](citing Merges' testimony before the Patent Office).

Legislative history on the macroscopic scale as to harmonization is found repeatedly. *See id.* (citing 153 Cong. Rec. S4685 (daily ed. Apr. 18, 2007) (statement of Sen. Leahy); *id.* at S4691 (statement of Sen. Hatch); 57 Cong. Rec. E1273 (daily ed. July 8, 2011) (statement of Rep. Johnson)). Clearly, one of the major points for American reforms to harmonize its patent law with the mainstream view of essentially every other major country of the world was the elimination of *Metallizing Engineering* from the American patent law. What, precisely, do these 42 *amici* have to say about the legislative purpose of the *Leahy Smith America Invent Act* to *harmonize* and *simplify* American patent law, and the fact that overruling *Metallizing Engineering* clearly is within the purview of harmonization and simplification? *See* § 1[a][7][C][vi], *Legislative History, the Harmonization Goal*.

Nothing.

Absolutely nothing.

The *amici* implicitly argue that there is no real legislative history but instead only "faux legislative history" in the sense that statements made on the floor of the House or Senate after enactment do not constitute real legislative history. But, the legislative history cited in this monograph is hardly "faux" but focuses upon legislative history prior to Congressional passage. See § 1[a][7][C][vi], Legislative History, the Harmonization Goal. Amici thus argue that "those who claim the [America Invents Act] overruled Metallizing [Engineering] offer only a [*42] relatively weak form of legislative history – the statements of individual Senators. The basis of the argument is a "colloquy" on the floor of the Senate the day after the Senate had passed the [America Invents Act.]" p. 7. While it is true that there was such a "colloquy" and this post-passage discussion is, indeed, faux legislative history, the amici ignore "real" legislative history taking a macroscopic view of the legislation, see § 1[a][7][C][vi], Legislative History, the Harmonization Goal, as well as the specific legislative history dealing with Metallizing Engineering, see id. (citing, e.g., Joe Matal, A Guide to the Legislative

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History of the America Invents Act: Part I of II, 22 Federal Circuit B. J. 435, 472-73 (2012)(quoting statement of Senator Kyl addressing the bill's provision of "prior art", 157 Cong. Rec. S5319-21 (daily ed. Sept. 6, 2011)). See also § 1[a][7][C][v], "[O]r otherwise available to the public" (citing Robert A. Armitage, Understanding the America Invents Act and its Implications for Patenting, § III-C-5, Step Four: Clarifying the "Available to the Public" Standard, 40 AIPLA Q. J. 1, 58 (2012)(explaining that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible.")(citing statement of Sen. Jon Kyl, 157 Cong. Rec. S1335, 1370 (daily ed. Mar. 8, 2011)).

Beyond consideration of whether *Metallizing Engineering* survives the new patent law, the amici fail to address complexities that arise through maintaining Metallizing Engineering as explained by George Washington University Law School Professor Dmitry Karshtedt. He points out that "Professors Robert Merges and John Duffy offer a number of reasons why [the view that Metallizing Engineering was not abrogated] is the better view; for example, they argue that it was made during a colloquy devoted primarily to another issue – what kinds of disclosures by the inventor qualify for the one-year grace period under new Section 102(b)(1). The two issues are related, however: if the *Metallizing* bar continues in force, a question arises whether commercial exploitation of a secret invention is 'disclosure' within the meaning of Section 102(b)(1), in which case the one-year grace period applies, or whether it is not a 'disclosure', in which case the bar would appear to cause a forfeiture of the patent if the exploitation precedes the effective filing date even by a day. It remains for the Federal Circuit to answer these questions[.]" Dmitry Karshtedt, Did Learned Hand Get it Wrong? The [*43]Questionable Patent Forfeiture Rule of Metallizing Engineering, 57 Villanova L. Rev. 261, 332-33 (2012)(footnotes omitted)