TOP TEN PATENT CASES

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***Arthrex v. Smith & Nephew* Conference this Friday**
indirect infringement based upon belief that patent is invalid
(cf. *Commil v. Cisco*)(*see* pp. 19-20)

Top Ten Patent Cases (*list, summary*)
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Rank	**Top Ten List** ♦ = ***certiorari* granted** ♦ = **CVSG order pending**
1	International Patent Exhaustion *Lexmark v. Impression Products (en banc)* *Certiorari* Petition due May 12, 2016
2	"All Elements" Determination of §101 Patent-Eligibility *Sequenom v. Ariosa Diagnostics* is the expected certiorari petition *Certiorari* Petition is due March 1, 2016
3 ♦	"Broadest Reasonable Interpretation" Rule *Cuozzo Speed v. Lee* Merits Briefing stage, argument late Spring 2016
4	(1) Public Use vs. Experimental Use *The Medicines Co. v. Hospira, En banc* briefing (2) Whether Patents "Preempt" Future Research *Sequenom v. Ariosa Diagnostics* is the expected certiorari petition Petition is due March 1, 2016
5a ♦	Willful Infringement (§ 284) *Halo Electronics v. Pulse Electronics., cert.* granted; argument February 23, 2016; ; decision by June 2016.
5b ♦	Willful Infringement (§ 284) *Stryker v. Zimmer, cert.* granted; argument February 23, 2016; decision by June 2016.
6	Contractual Proscription Barring Exhaustion *Lexmark v. Impression Products (en banc)* Petition due May 12, 2016
7 ♦	Active Inducement to Infringe (§ 271(f)(1)) *Life v. Promega* ; awaiting Solicitor General's response to CVSG
8	Medical diagnostics patent-eligibility *Sequenom v. Ariosa Diagnostics* is the expected certiorari petition Petition is due March 1, 2016
9	ITC Infringement Jurisdiction over "electronic transmissions" *ClearConnect v. U.S. ITC*; cert. petition due February 10, 2016
10	Laches, Federal Circuit case law *SCA Hygiene v. First Quality Baby Prods* Response to the petition is due February 22, 2016.

Other Cases and Issues (not ranked by immediacy nor importance
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*)
"Knowledge" for Indirect Infringement *Arthrex, Inc. v. Smith & Nephew Inc.* Conference February 19, 2016
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 distributed for conference December 4, 2015
Medtronic Sofamor Danek v. NuVasive GVR sought Petition granted with GVR remand. in view of *Commil v. Cisco*
WesternGeco v. Ion Geophysical 35 USC § 271(f) extraterritorial patent infringement *Cert.* petition due Feb. 26, 2015 (extended)

continued on the next page

Other Cases and Issues (*con'd*) (not ranked by immediacy nor importance
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
ePlus, Inc. v. Lawson Software Injunction following PTAB Invalidation of the Patent Response to Petition due February 19, 2016
Retirement Capital Access Management v. U.S. Bancorp Post-Grant Proceedings Raising § 101 Issue: Response to the 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).
Design Patent Infringement: *Samsung Electronics v. Apple* Awaiting Conference
"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* Awaiting Conference.

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(1) International Patent Exhaustion: *Is the patent right be "exhausted" upon the first sale by the patentee of a patented item when that item is sold by the patentee anywhere in the world* ("international patent exhaustion") or only where that item is sold in the United States (the current Federal Circuit practice).

Current Case: *Lexmark International, Inc. v. Impression Products, Inc*., __ F.3d __ (Fed. Cir. Feb. 12, 2016)(en banc)(Taranto, J.).

***Status**:* Petition due May 12, 2016 (unless extended).

Prior Case Law: *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S.Ct. 1351 (2012)(establishing international *copyright* exhaustion); cf. *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094 (Fed.Cir.2001) (Newman, J.)(denying international patent exhaustion based upon *Boesch v. Graff*, 133 U.S. 697 (1890)(dicta)(holding had to do with an overseas first party sale by a third party and not by the patentee)).

Implications: Establishment of international patent exhaustion would result in severe consequences for the pharmaceutical industry where United States drug prices for patented medicines are far higher than in some other countries which would result in either an increased flow of lower priced "parallel import" drugs or diminishment of sales in other countries to diminish parallel import challenge.

The *en banc* Federal Circuit in *Lexmark* determined that there is *no* international patent exhaustion, despite the Supreme Court holding that there *is* international *copyright* exhaustion in the recent *Kirtsaeng* case.

Twenty seven thousand words! The majority opinion in *Lexmark* is a difficult to swallow, nearly 27,000 words – roughly three times the maximum word length for a petition for *certiorari* (which is only 9000 words.)

The Flawed *Jazz Photo* Precedent: The holding in *Lexmark* is keyed to the Federal Circuit *Jazz Photo* panel opinion, not one of the finest examples of judicial writing. The *Lexmark* majority opinion with its frequent citation to *Jazz Photo* implies that this case of first impression was carefully thought out and its result was compelled by a *holding* of patent exhaustion from a Supreme Court decision, *Boesch v. Graff*, 133 U.S. 697 (1890)). *See Lexmark*, __ F.3d at __, slip op. at 64

("Nor did [the Supreme Court in *Kirtsaeng*] cite, even to distinguish, its own leading case on exhaustion and foreign sales in the patent area, namely, *Boesch*…")

As to any careful reflection or policy arguments entertained by the court in *Jazz Photo*, the answer is that there was *absolutely no discussion whatsoever* of any policy basis or case law other than the *Boesch v. Graff* case which implicitly was cited as a holding for denial of international patent exhaustion.

In fact, the sole basis given for the *Jazz Photo* denial of international patent exhaustion is found in a single sentence constituting less than 50words:

"United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent. *See Boesch v. Graff*, 133 U.S. 697, 701-703 (1890) (*a lawful foreign purchase does not obviate the need for license from the United States patentee before importation into and sale in the United States*)." *Jazz Photo Corp v. International Trade Commission*, 264 F.3d 1094, 1105 (Fed. Cir. 2001)(rationale emphasized).

As to the value of the *holding* in *Boesch v. Graff* the case has absolutely nothing to do with patent exhaustion but instead deals with a first sale by a party having no patent right of any kind. Indeed, the facts of *Boesch v. Graff* have absolutely nothing to do with exhaustion but instead relate to a sale by a prior inventor of patented burners who had no opportunity to gain a patent following the filing of the patentee under the first-to-file patent law of Germany, where a true first inventor who failed to file or was second to file could not obtain a patent but could have a right to make, use and sell the patented invention *independent from the patentee* under Germany's Prior User Right statute.

If anything, the *Lexmark* quotation from *Boesch v. Graff* explains that the sale in Germany of the patented burners was by someone other than the patentee who "*was allowed [to sell the burners] under the laws of [Germany].*" *Lexmark*, __ F.3d at __, slip op. at 78 (quoting *Boesch v. Graff*, 133 U.S. 697, 703 (1890))("The right which [the German seller] had to make and sell the [patented] burners in Germany *was allowed him under the laws of that country,* and

purchasers from him could not be thereby authorized to sell the articles in the United States in defiance of the rights of patentees under a United States patent.").

Common Law Roots: The majority opinion spends a great deal of time focusing upon the writings of Lord Coke, which were relied upon by the Supreme Court in *Kirtsaeng* to establish international copyright exhaustion. The Federal Circuit has had difficulty in recent years in understanding English precedent as foundation for how the American patent law should be decided. *See* Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565 (2015).

(2) "All Elements" Determination of §101 Patent-Eligibility: *Should determination whether "inventive" subject matter is patent-eligible be determined under the "all elements" rule or may the claimed subject matter be focused upon a single element of the claim?*

Current Case: *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, is the styling of the expected *certiorari* petition due March 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).

Prior Case Law – (a) § 101: *See* PATENT-ELIGIBILITY, § 8[b][1], *Flook versus the "All Elements" Rule* (discussing *Diamond v. Diehr*, 450 U.S. 175, 188 (1981), distinguishing *Parker v. Flook*, 437 U.S. 584 (1978)).

Prior Case Law – (b) "All Elements" Rule: "All elements" rule, in PATENT ELIGIBILITY, § 8[b][1], *Flook versus the "All Elements" Rule* (citing *Barrett v. Hall*, 2 F.Cas. 914, 924 (No. 1047)(D. Mass. 1818)(Story, J., riding circuit); *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.); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *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.Se. (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).)

Implications: If a claimed invention including all elements is nonobvious, i.e., "inventive", then grant of a patent does not preempt fundamental or "abstract" technology (apart from the claimed "inventive" combination).

(3) ***"Broadest Reasonable Interpretation"*** **Post-Grant Claim Construction**

Current Case**:** *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.)

(4) 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?

Current Cases: (1) Public vs. Experimental Use: *The Medicines Co. v. Hospira, Inc.*, Fed. Cir. 2014-1469, *vacated panel opinion*, __ F.3d __ (Fed. Cir. 2015)(Hughes, J.)

(2) *Sequenom*: *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, is the styling of the expected *certiorari* petition due March 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).

(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*)

Current Case: *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, is the styling of the expected *certiorari* petition due March 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)).

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

(5) 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 (*cert.* granted); *Stryker Corp. v. Zimmer, Inc.*, No. 14-1520 (*cert*. granted). Consolidated oral argument is scheduled for 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?"

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

(6) Contractual Provision to Block Exhaustion:

Current Case: *Lexmark International, Inc. v. Impression Products, Inc*., __ F.3d __ (Fed. Cir. Feb. 12, 2016)(en banc)(Taranto, J.); *see* Top Ten No. (1),, *supra*.

Status*:* Petition due May 12, 2016 (unless extended).

(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)?*

Current Case: *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' ***itself*** to infringe a patent under 35 U.S.C. § 271(f)(1)." (emphasis added)

Status: 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.

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

(8) Medical diagnostics patent-eligibility: *To what extent should patent eligibility include medical diagnostics?*

Current Case: *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, is the styling of the expected *certiorari* petition.

Status: Petition is due March 1, 2016

(9) 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".*

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

Status: Petition for *certiorari* was due February 10, 2016.

Discussion: Likelihood of *certiorari* review is heightened by the spirited dissent of the third member of the panel:

"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)

(10) Medical diagnostics patent-eligibility: *To what extent should patent eligibility include medical diagnostics?* .

Current Case: *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, is the styling of the expected *certiorari* petition due March 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)

Other Cases and Issues

This is *the beginning* of a *separate* list of important issues with a particular focus upon cases at the Supreme Court that are pending but where *certiorari* has not so far been granted.

Issues before the Supreme Court *on petition* are generally (but not always) included in *this* section and not the "Top Ten" because, absent extraordinary circumstances, the chances for grant of review are slim. (Issues which stand as important, with or without grant of review, are included in the main list.)

Merely because an issue is very important does not mean that either the Supreme Court will grant *certiorari* or even that the *en banc* Federal Circuit will hear an appeal:

In the first instance, the issue must be properly framed, either as a *Question Presented* in a *certiorari* petition (or as an issue in a petition for Federal Circuit rehearing *en banc*). Many cases involve the failure of the petitioner to properly frame the issue in a *Question Presented.* Too often, *multiple* issues are presented

in plural *Questions Presented* to dilute an important issue. Even where there is a conflict amongst decisions, the split is not properly identified.

Even where Supreme Court counsel are involved, the Supreme Court never grants more than a handful of petitions each year – less than one hundred – out of the many thousands that are presented. If success is measured by the grant of a petition, the success rate is at the one percent order of magnitude.

Even where a brilliant Supreme Court team puts together what seems to be the best possible petition, one that is definitely *certiorari* worthy, the Court may deny review, as it did in the case of *Eolas Technologies Inc. v. Microsoft Corp*., 399 F.3d 1325 (2005); subsequently, in a slightly different presentation of the issues certiorari *was* granted and the appeal was successful in *Microsoft Corp. v. AT & T Corp*., 550 U.S. 437 (2007).

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."

Implications: 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?

Laches, Federal Circuit case law

Current Case*: *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 February 22, 2016.

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."

Implications: 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."

"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).

Discussion: 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."

Good Faith Invalidity Belief to Negate Indirect Infringement

Current Case: *Arthrex, Inc. v. Smith & Nephew Inc.*, Supreme Court No. 15-559, *proceedings below*, *Smith & Nephew Inc. v. Arthrex, Inc.*, __ Fed. App'x __ (Fed. Cir. 2015)(Taranto, J.): Is indirect infringement negated by a good faith belief that the patent is invalid?

Status: Conference February 19, 2016.

Question Presented: "Whether a[n accused infringer] may be held liable under a 'knowledge' standard where its actions were consistent with an understanding of relevant legal requirements that was not objectively unreasonable." Thus, where the accused infringer has knowledge that its acts will lead to direct infringement of a patent, *if that patent is valid*, does a good faith belief in the invalidity of the patent mean that the accused infringer does not meet the "knowledge" requirement for indirect infringement?

Status: Distributed for Conference February 19, 2016.

The *Commil* Hurdle: Less than a year ago, the Supreme Court in *Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920 (2015), stated: "The question the Court confronts [in this case] concerns whether a [defendant-accused infringer]'s

belief regarding patent validity is a defense to a claim of induced infringement. It is not. The scienter element for induced infringement concerns infringement; that is a different issue than validity.").

History of Indirect Infringement: Historically, indirect infringement requires knowledge that the accused indirect infringer has knowledge that his actions will induce the acts constituting direct infringement. *See Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176, 187-89 (1980)(discussing the 'Oil Lamp Burner' case, *Wallace v. Holmes*, 29 F.Cas. 74 (No. 17,100) (C.C. Conn.1871)). As explained in *Dawson*, "[t]he *Wallace* case demonstrates * * * the reason for the contributory infringement doctrine. It exists to protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others. This protection is of particular importance in situations, like the [*Wallace*] oil lamp case itself, where enforcement against direct infringers would be difficult, and where the technicalities of patent law make it relatively easy to profit from another's invention without risking a charge of direct infringement." *Dawson. v. Rohm and Haas*, 448 U.S. at 188.

***Res Judicata*, Federal Circuit Standards**

Current Case: None

Previous Case: *SpeedTrack, Inc. v. Office Depot, Inc., Inc.*, No. 15-461: Petitioner questions the Federal Circuit standard for res judicata. Certiorari was **denied** 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/publicationsandnewsdetail.aspx?\NewsPubId=10737419834

Intrinsic Evidence to Determine Claim Construction

Current Case: None.

Previous case: *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/publicationsandnewsdetail.aspx?NewsPubId=10737419834

Knowledge Requirement for Indirect Infringement

Current Case: *Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.*, Supreme Ct. No. 15-85: Petitioner seeks to have the case sent back to the Federal Circuit in view of *Commil USA, LLC v. Cisco Systems, Inc.*, 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=10737419834

Extraterritorial Patent Infringement

***Current Case**: WesternGeco L.L.C. v. Ion Geophysical Corp*., Supreme Court No. 15A736, *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: The petition is due February 26, 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)."

Injunction following PTAB Invalidation of the Patent

***Current 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: Conference February 19, 2016.

***The Dissent (O,Malley, J.)*:** 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."

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: Response to the petition due March 1, 2016

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=10737419834

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.

Questions Presented: "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?"

***Background*:** 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))."

Design Patent Infringement:

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.)

Status: Awaiting Conference.

Questions Presented: "Design patents are limited to 'any new, original and ornamental design for an article of manufacture.' 35 U.S.C. 171. A design-patent holder may elect infringer's profits as a remedy under 35 U.S.C. 289, which provides that one who 'applies the patented design . . . to any article of

manufacture . . . shall be liable to the owner to the extent of his total profit, . . . but [the owner] shall not twice recover the profit made from the infringement.'
The Federal Circuit held that a district court need not exclude unprotected conceptual or functional features from a design patent's protected ornamental scope. The court also 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 combined effect of these two holdings is to reward design patents far beyond the value of any inventive contribution. The questions presented are:
"1. Where a design patent includes unprotected non-ornamental features, should a district court be required to limit that patent to its protected ornamental scope?
"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?"

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

"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)

Question Presented: 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 Appeals7

Biogen MA, Inc. v. Japanese Foundation for Cancer Research, No. 15-607, *opinion below*, __ F.3d __ (Fed. Cir. May 7, 2015).

Status: Awaiting Conference.

Question Presented: Whether the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), eliminated federal district courts' jurisdiction over patent interference actions under 35 U.S.C. § 146.

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

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Free* Information Sources

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

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

Docket Sheet: 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

An "Orders List" 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.

New Opinions: 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*.

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*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.

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Prof. Dennis Crouch *et al.*, Patently-O blog
patentlyo.com

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

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Tom Goldstein, 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.

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* See the note on the previous page.

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

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.

♦ ♦ ♦

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

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WilmerHale, *Patent Law and the Supreme Court: Certiorari Petitions Granted,* https://www.wilmerhale.com/pages/publicationsandnewsdetail.aspx?NewsPubId=10737419833

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

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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.

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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 pro bono 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

HAROLD C. WEGNER is an independent Expert Patent Consultant available to cooperate with corporate and law firm colleagues on matters involving patent drafting and procurement strategies, appellate matters and opinions.

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