The Chisum Patent Academy is pleased to announce the September 2015 publication by Wolters Kluwer Law & Business of the annual Update for Volume I (Patentability and Validity) of the practitioner treatise, Mueller on Patent Law, authored by our co-founder, Janice M. Mueller

The two-volume Mueller on Patent Law treatise was first published in 2012. Volume I addresses patentability, validity, and prosecution procedures; Volume II covers patent infringement, USPTO post-issuance procedures, design patents, and international patenting issues. For detailed tables of contents for both volumes, click here.

The full text of the 2015 Update for Volume I (Patentability and Validity) is available electronically on Wolters Kluwer's Intelliconnect electronic platform. By examining in detail each of the cases highlighted below (plus many others), the 2015 Update adds extensive and important new matter to Volume I.

Highlights of the September 2015 Update:

• Undoubtedly the most significant and troubling change in U.S. patent law in the past five years surrounds the unsettled question of which inventions qualify as patent-eligible subject matter under 35 U.S.C. §101 and what subject matter is excluded from that statutory provision as "laws of nature," "natural phenomena," or "abstract ideas." In a four-year period following its 2010 decision in Bilski v. Kappos, the Supreme Court has issued three additional decisions on the §101 eligibility issue: Mayo Collaborative Servs. v. Prometheus Labs., Inc. (2012); Association for Molecular Pathology v. Myriad Genetics, Inc. (2013); and Alice Corp. Pty. Ltd. v. CLS Bank Int'l (2014).

• Association for Molecular Pathology, decided in 2013, significantly limited the patenting of genetic material. The Supreme Court held that Myriad's patent claims to isolated DNA recited naturally-occurring subject matter that was not patent eligible under §101; rather, the claims were directed to a "natural phenomenon," a "law of nature," or a "product of nature." However, the Court also held that Myriad's claims to complimentary DNA ("cDNA") were patent eligible subject matter under §101. In the Court's view, the cDNA claims were within §101 because they were drawn to synthetic DNA created in the laboratory. See §3.04[C][2].

• The Supreme Court's pivotal 2012 Mayo decision announced a two-step framework for determining if a claimed invention falls within one of three enumerated exceptions to patent-eligible subject matter. Step one of the Mayo framework asks "whether the claims at issue are directed to one of those patent-ineligible concepts." If the answer is yes, step two of the Mayo framework asks "'[w]hat else is there in the claims before us?'" To answer the second Mayo question, courts should "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." The second step of the Mayo framework can be described as "a search for an 'inventive concept'—i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" Especially troubling is the Court's reliance on antiquated terminology such as "inventive" as an eligibility requirement. See §3.02[D][4][c].

• In 2014, the Supreme Court applied the Mayo framework in Alice to determine that claims drawn to a method using computers to minimize settlement risk in financial transactions were attempts to patent an "abstract idea" (a nebulous concept the Court has never clearly defined) and thus not patent eligible under 35 U.S.C. §101. See §3.02[D][4][d].

• As of August 2015, the Federal Circuit had issued eleven decisions addressing the issue of patent eligibility since the Supreme Court's 2014 Alice decision. In the nine Federal Circuit cases that concerned software-implemented inventions or business methods, only one, DDR Holdings, LLC v. Hotels.com, L.P., found patent-eligible subject matter. See §3.02[D][4][e].

• The Federal Circuit's two post-Alice decisions involving chemical/biotechnological subject matter held the claimed inventions ineligible in both cases. In the Federal Circuit's 2014 decision in In re BRCA1- & BRCA2- Based Hereditary Cancer Test Patent Litigation (a follow-on to the Supreme Court's 2013 decision in Ass'n for Molecular Pathology), the Circuit held that claims to primers ("short, synthetic, single-stranded DNA molecule[s] that bind [ ] specifically to ... intended target nucleotide sequence[s]") were not patent-eligible compositions of matter under 35 U.S.C. §101 because the primers had "DNA structure[s] with a function similar to that found in nature," and those structures were not "unique" or "different from anything found in nature." See §3.04[C][2][b].

• In Ariosa Diagnostics, Inc. v. Sequenom, Inc., the Federal Circuit in 2015 professed itself compelled by the Supreme Court's 2012 Mayo decision to affirm the invalidation under 35 U.S.C. §101 of a groundbreaking patent on methods of non-invasive prenatal testing. The Circuit considered the claimed methods patent-ineligible "natural phenomena," although the "natural phenomena" (i.e., the presence of certain DNA in maternal plasma and serum) was previously unknown and had never before been measured, assayed, or amplified. See §3.02[E][2][c].

• The Supreme Court has taken an interest in critical aspects of patent claiming, a task central to every aspect of patent practice. In its 2014 decision Nautilus, Inc. v. Biosig Instruments, Inc., the Court rejected the Federal Circuit's overly-lenient and uncertain formulation of the patent claim definiteness standard and replaced it with a new standard turning on "reasonable certainty" of claim scope to a skilled artisan. See §2.04[C]. The Federal Circuit has applied the new standard in several cases, sometimes sustaining claim validity against indefiniteness challenges and sometimes invalidating. See §2.04[D].

• In a June 2015 partially en banc decision, the Federal Circuit in Williamson v. Citrix Online, LLC, focused on the treatment of means-plus-function claim elements under 35 U.S.C. §112, para. 6. The Circuit had previously recognized a "negative" proposition that the absence of the word "means" in a claim limitation creates a presumption that the claim element is not to be treated as a means-plus-function element. Certain of the Circuit's earlier decisions had raised the bar required to overcome the negative presumption by characterizing it as a "strong" one (against application of §112, para. 6). The en banc court in Williamson rejected this heightened burden. Rather, the correct standard post-Williamson for assessing whether a claim element lacking the word "means" should nevertheless be interpreted as a §112, para. 6 element asks "whether the words of the claim are understood by person of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." Thus it appears more probable post-Williamson that

functional claim language will be deemed within the scope-narrowing strictures of §112, para. 6 even when the word "means" is absent. See §2.05[A][4].

• The Federal Circuit's July 2014 decision in AbbVie Deutschland GMH & Co. v. Janssen Biotech, Inc. extended to antibody technology the reasoning of the Federal Circuit's controversial 1997 decision in Regents of Univ. of Cal. v. Eli Lilly and Co., which concerned claims to genuses of gene sequences. (Antibodies are proteins that bind to unwanted foreign substances called "antigens" in order to remove them from the body.) The AbbVie decision calls into question the continued viability of antibody claims reciting a genus based on functionality (rather than structure). In an opinion authored by Judge Lourie, the Federal Circuit majority in AbbVie affirmed a jury's invalidation based, inter alia, on failure to satisfy the written description of the invention requirement with respect to the asserted claims in two AbbVie patents directed to a genus of human antibodies. See §6.07[F].

• The Federal Circuit continues to debate the timing of "unexpected results" evidence proffered in support of nonobviousness. In a controversial 2014 decision, the Circuit affirmed a district court's invalidation of pharmaceutical patent claims for obviousness in Bristol-Myers Squibb Co. v. Teva Pharms. USA Inc. The appellate court stated that "[t]o be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention" (emphasis added). Dissenting from denial of rehearing en banc in Bristol-Myers Squibb, four Circuit judges posited important (but as yet unanswered) questions about the relevance of unexpected results evidence obtained after the invention date (for AIA patents, after the effective filing date). See §§9.07[B][2], 9.07[D][2].

• The Federal Circuit in 2014 invalidated four biotechnology patents for want of enablement in Promega Corp. v. Life Techs. Corp. The Promega patents in suit concerned "multiplex amplification" of "short tandem repeats" (STR) loci. The Circuit's invalidation turned on the failure to enable the full scope of the "broad" claim construction sought by the patentee, which construction neither party contested on appeal. See §4.02[C].

• The Federal Circuit in 2015 confirmed that even an unauthorized use by third parties will not trigger the public use bar of 35 U.S.C. §102(b) (2006) if the individuals maintain the invention as confidential. In Delano Farms Co. v. California Table Grape Comm'n, the Federal Circuit affirmed a district court's judgment sustaining the validity of two plant patents against a §102(b) public use invalidity challenge. The Circuit sustained the district court's findings that the actions of two third party individuals (non-inventors) who obtained samples of two unreleased but later-patented table grape varieties from the government and planted them in their own fields did not constitute a §102(b) invalidating public use. See §7.06[F][2].

• In its 2014 decision Novartis AG v. Lee, the Federal Circuit reviewed a challenge to the USPTO's patent term adjustment (PTA) computations with respect to requests for continued examination (RCEs) filed by Novartis in certain of its patent prosecutions. Siding in part with the government, the Federal Circuit held firstly that "any time consumed by continued examination," no matter when initiated, does not count toward depleting the allotment of three years the USPTO has before any adjustment time begins to accrue. Agreeing in part with Novartis, however, the Circuit also held that time consumed by continued examination, for which no PTA

is available, should run only until allowance of the application, not until its later issuance as a patent (so long as no examination actually occurs following allowance). The Circuit's decision in Novartis AG will likely result in the receipt of additional PTA for a large number of recently issued patents that included an RCE in their prosecution. See §11.05[C].

• In its 2015 decision The Medicines Co. v. Hospira, Inc., the Federal Circuit held that an on sale bar-triggering "commercial offer for sale" under 35 U.S.C. §102(b) (2006) can occur based on the sale of services to the patentee when the seller's performance of those services results in manufacture of the patented product, even though title to the product does not change hands. See §7.06[G][4].

• A divided panel of the Federal Circuit held in Solvay S.A. v. Honeywell Int'l Inc., a 2014 decision stemming from an infringement suit, that 35 U.S.C. §102(g)(2) (2006) allows the inventor of the prior art invention to conceive the invention outside the United States. However, the reduction to practice of that prior art invention must occur in the United States for the invention to count as §102(g)(2) "made in this country" prior art. See §7.11[D][4].

• In early 2013, Congress passed a "technical corrections" bill to implement certain fixes to the America Invents Act of 2011. The changes made by the Leahy-Smith America Invents Technical Corrections Act relate to patent prosecution, including an inventor's oath/declaration; post-grant proceedings including IPRs, derivation proceedings, and interference proceedings; litigation, including advice of counsel; and patent term adjustment. See §7A (Chapter Explanatory Note).

• Concern for potential harassment by multiple assignees drove the Federal Circuit's 2013 double patenting decision in In re Hubbell. There a divided panel of the Circuit affirmed a USPTO obviousness-type double patenting rejection of an application in view of an issued patent owned by a completely separate entity. Notably, the rejected application and the reference patent shared two common inventors but lacked identical inventorship (each had two other, different inventors). In holding that the double patenting rejection was properly entered, the Circuit majority blessed the USPTO's position that obviousness-type double patenting does not require either common ownership or the identical inventive entity between a rejected application and a reference patent; some overlap in inventorship is enough (see MPEP §804(I)(A)). In so doing, the Hubbell majority approved the USPTO position that the Circuit had specifically declined to adopt in its 2009 decision In re Fallaux. See §12.03[B].

• In its 2015 decision Biogen MA, Inc. v. Japanese Foundation for Cancer Research, the Federal Circuit observed that under the AIA's effective date provision, AIA §3(n)(1), "interference proceedings are to continue with respect to . . . applications filed before March 16, 2013," with the single exception of AIA §6(f)(3)(A), which provides that the USPTO Director may dismiss a pending interference in favor of a post-grant review. See §7A.03[C].

• The Federal Circuit's 2013 divided decision in Dawson v. Dawson and Bowman illustrates the complexities of determining, often many years after the fact, whether an inventor had conceived a claimed invention by a certain date, or whether at that time he merely possessed a "general goal or research plan." The Dawson decision also reinforces that historic pre-AIA concepts such as conception and reduction to practice remain relevant post-AIA. The parties disputed whether Dr. Dawson conceived his invention while employed at a major public university or instead after he

joined a private pharmaceutical manufacturer. The Circuit majority agreed with the pharmaceutical manufacturer, affirming an interference decision by the USPTO. See §8.02[A][1][a].

• Sufficient nexus was not established with respect to licensing activity to support nonobviousness in the Federal Circuit's 2013 decision, Soverain Software LLC v. Newegg Inc. The Circuit reversed a district court's judgment, entered on a jury verdict, that had sustained the validity of two Soverain Software patents. See §9.06[E][2].

• In its 2015 decision Daiichi Sankyo Co. v. Lee, the Federal Circuit upheld the USPTO's February 1, 2010 Interim Procedure for patent term adjustment (PTA), including the Optional Interim Procedure providing a 180 day-post issuance time period for seeking PTA recalculation for patents issuing before March 2, 2010. The agency had acted within its discretion in promulgating the challenged PTA regulations. See §11.05[B].

• The Federal Circuit articulated standards in its 2013 decision, In re Biedermann, for determining whether the USPTO Board of Appeals has improperly entered a new ground of rejection on appeal. The central issue was "whether the Board and the examiner properly relied on the same articulated reasoning and factual underpinnings in rejecting [the applicant's] claims or whether the Board made new findings and adopted different reasons to support a new ground of rejection, thus depriving [the applicant] of both notice and an opportunity to respond." The Federal Circuit agreed with the applicant and accordingly vacated and remanded the Board's decision for further proceedings. See §11.09[C].

• The Federal Circuit remains divided on the question whether "secondary considerations" evidence (such as commercial success, failure of others, etc.) must be considered in an obviousness-type double patenting analysis. For example, the court in its 2003 decision Geneva Pharms., Inc. v. Glaxo SmithKline PLC stated that "[o]bviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not," and other Circuit decisions followed Geneva. However, the court's 2012 double patenting decision in Eli Lilly and Co. v. Teva Parenteral Medicines, Inc. stated that "[w]hen offered, such evidence [of secondary considerations] should be considered." A district court had erred in "categorical[ly] repudiat[ing]" patentee Eli Lilly's evidence of the "unexpected clinical properties" and "considerable" commercial success of its patented drug. See §12.06[C].

• A 2013 Federal Circuit decision showed that the court remains undecided on the question whether intentional concealment is required for a best mode violation. Answering in the affirmative, a divided panel in Ateliers de la Haute-Garonne v. Broetje Automation USA Inc. reversed a district court's grant of summary judgment that Ateliers de la Haute-Garonne's (AHG's) two patents in suit were invalid for failure to satisfy the best mode requirement. See §5.06[B][5].

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About the Author:

Janice M. Mueller is a registered U.S. patent attorney and chemical engineer. She was the first woman to serve as a judicial law clerk for Judge Giles S. Rich, U.S. Court of Appeals for the Federal Circuit, from 1990-1992. Janice litigated patent and copyright infringement cases as an Honors Program Trial Attorney in the U.S. Department of Justice before entering legal academia. From 2004-2011 Janice was a tenured full Professor at the University of Pittsburgh School of

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