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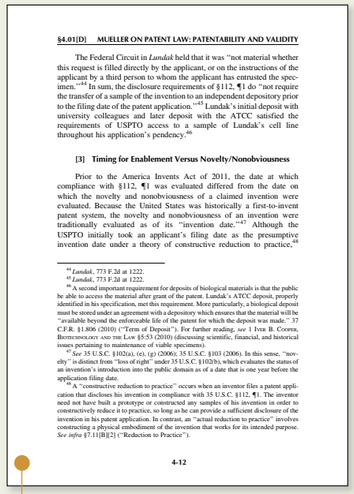

§4.01[D] MUELLER ON PATENT LAW: PATENTABILITY AND VALIDITY

The Federal Circuit in *Lundak* held that it was "not material whether this request is filled directly by the applicant, or on the instructions of the applicant by a third person to whom the applicant has entrusted the specimen."[44] In sum, the disclosure requirements of §112, ¶1 do "not require the transfer of a sample of the invention to an independent depository prior to the filing date of the patent application."[45] Lundak's initial deposit with university colleagues and later deposit with the ATCC satisfied the requirements of USPTO access to a sample of Lundak's cell line throughout his application's pendency.[46]

[3] Timing for Enablement Versus Novelty/Nonobviousness

Prior to the America Invents Act of 2011, the date at which compliance with §112, ¶1 was evaluated differed from the date on which the novelty and nonobviousness of a claimed invention were evaluated. Because the United States was historically a first-to-invent patent system, the novelty and nonobviousness of an invention were traditionally evaluated as of its "invention date."[47] Although the USPTO initially took an applicant's filing date as the presumptive invention date under a theory of constructive reduction to practice,[48]

[44] *Lundak*, 773 F.2d at 1222.
[45] *Lundak*, 773 F.2d at 1222.
[46] A second important requirement for deposits of biological materials is that the public be able to access the material after grant of the patent. Lundak's ATCC deposit, properly identified in his specification, met this requirement. More particularly, a biological deposit must be stored under an agreement with a depository which ensures that the material will be "available beyond the enforceable life of the patent for which the deposit was made." 37 C.F.R. §1.806 (2010) ("Term of Deposit"). For further reading, *see* 1 Ivor B. Cooper, Biotechnology and the Law §5:53 (2010) (discussing scientific, financial, and historical issues pertaining to maintenance of viable specimens).
[47] *See* 35 U.S.C. §102(a), (e), (g) (2006); 35 U.S.C. §103 (2006). In this sense, "novelty" is distinct from "loss of right" under 35 U.S.C. §102(b), which evaluates the status of an invention's introduction into the public domain as of a date that is one year before the application filing date.
[48] A "constructive reduction to practice" occurs when an inventor files a patent application that discloses his invention in compliance with 35 U.S.C. §112, ¶1. The inventor need not have built a prototype or constructed any samples of his invention in order to constructively reduce it to practice, so long as he can provide a sufficient disclosure of the invention in his patent application. In contrast, an "actual reduction to practice" involves constructing a physical embodiment of the invention that works for its intended purpose. *See infra* §7.11[B][2] ("Reduction to Practice").

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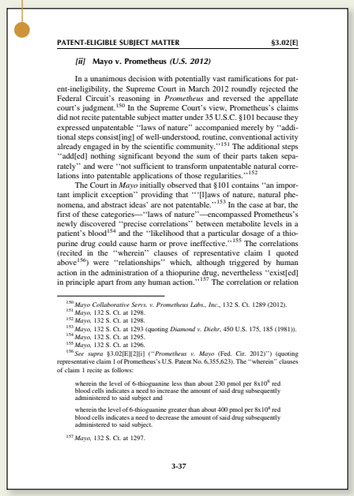
Clear, concise explanations of patent law concepts, such as effective compliance date with enablement requirement

Allows quick reference to the most important case law by topic



PATENT-ELIGIBLE SUBJECT MATTER §3.02[E]

[ii] Mayo v. Prometheus *(U.S. 2012)*

In a unanimous decision with potentially vast ramifications for patent-ineligibility, the Supreme Court in March 2012 roundly rejected the Federal Circuit's reasoning in *Prometheus* and reversed the appellate court's judgment.[150] In the Supreme Court's view, Prometheus's claims did not recite patentable subject matter under 35 U.S.C. §101 because they expressed unpatentable "laws of nature" accompanied merely by "additional steps consist[ing] of well-understood, routine, conventional activity already engaged in by the scientific community."[151] The additional steps "add[ed] nothing significant beyond the sum of their parts taken separately" and were "not sufficient to transform unpatentable natural correlations into patentable applications of those regularities."[152]

The Court in *Mayo* initially observed that §101 contains "an important implicit exception" providing that "'[l]aws of nature, natural phenomena, and abstract ideas' are not patentable."[153] In the case at bar, the first of these categories—"laws of nature"—encompassed Prometheus's newly discovered "precise correlations" between metabolite levels in a patient's blood[154] and the "likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective."[155] The correlations (recited in the "wherein" clauses of representative claim 1 quoted above[156]) were "relationships" which, although triggered by human action in the administration of a thiopurine drug, nevertheless "exist[ed] in principle apart from any human action."[157] The correlation or relation

[150] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).
[151] *Mayo*, 132 S. Ct. at 1298.
[152] *Mayo*, 132 S. Ct. at 1298.
[153] *Mayo*, 132 S. Ct. at 1293 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).
[154] *Mayo*, 132 S. Ct. at 1295.
[155] *Mayo*, 132 S. Ct. at 1296.
[156] *See supra* §3.02[E][2][i] ("*Prometheus v. Mayo* (Fed. Cir. 2012)") (quoting representative claim 1 of Prometheus's U.S. Patent No. 6,355,623). The "wherein" clauses of claim 1 recite as follows:

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

[157] *Mayo*, 132 S. Ct. at 1297.

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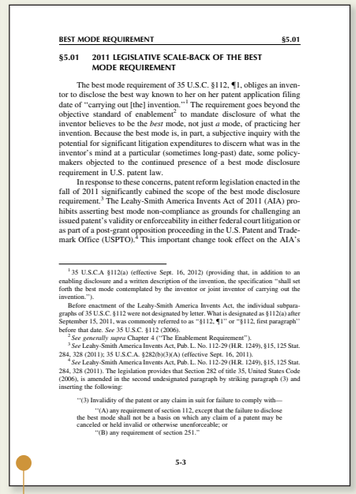

BEST MODE REQUIREMENT §5.01

§5.01 2011 LEGISLATIVE SCALE-BACK OF THE BEST MODE REQUIREMENT

The best mode requirement of 35 U.S.C. §112, ¶1, obliges an inventor to disclose the best way known to her on her patent application filing date of "carrying out [the] invention."[1] The requirement goes beyond the objective standard of enablement[2] to mandate disclosure of what the inventor believes to be the *best* mode, not just *a* mode, of practicing her invention. Because the best mode is, in part, a subjective inquiry with the potential for significant litigation expenditures to discern what was in the inventor's mind at a particular (sometimes long-past) date, some policymakers objected to the continued presence of a best mode disclosure requirement in U.S. patent law.

In response to these concerns, patent reform legislation enacted in the fall of 2011 significantly cabined the scope of the best mode disclosure requirement.[3] The Leahy-Smith America Invents Act of 2011 (AIA) prohibits asserting best mode non-compliance as grounds for challenging an issued patent's validity or enforceability in either federal court litigation or as part of a post-grant opposition proceeding in the U.S. Patent and Trademark Office (USPTO).[4] This important change took effect on the AIA's

[1] 35 U.S.C.A §112(a) (effective Sept. 16, 2012) (providing that, in addition to an enabling disclosure and a written description of the invention, the specification "shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.").
Before enactment of the Leahy-Smith America Invents Act, the individual subparagraphs of 35 U.S.C. §112 were not designated by letter. What is designated as §112(a) after September 15, 2011, was commonly referred to as "§112, ¶1" or "§112, first paragraph" before that date. *See* 35 U.S.C. §112 (2006).
[2] *See generally supra* Chapter 4 ("The Enablement Requirement").
[3] *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29 (H.R. 1249), §15, 125 Stat. 284, 328 (2011); 35 U.S.C.A. §282(b)(3)(A) (effective Sept. 16, 2011).
[4] *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29 (H.R. 1249), §15, 125 Stat. 284, 328 (2011). The legislation provides that Section 282 of title 35, United States Code (2006), is amended in the second undesignated paragraph by striking paragraph (3) and inserting the following:

"(3) Invalidity of the patent or any claim in suit for failure to comply with—

"(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or
"(B) any requirement of section 251."

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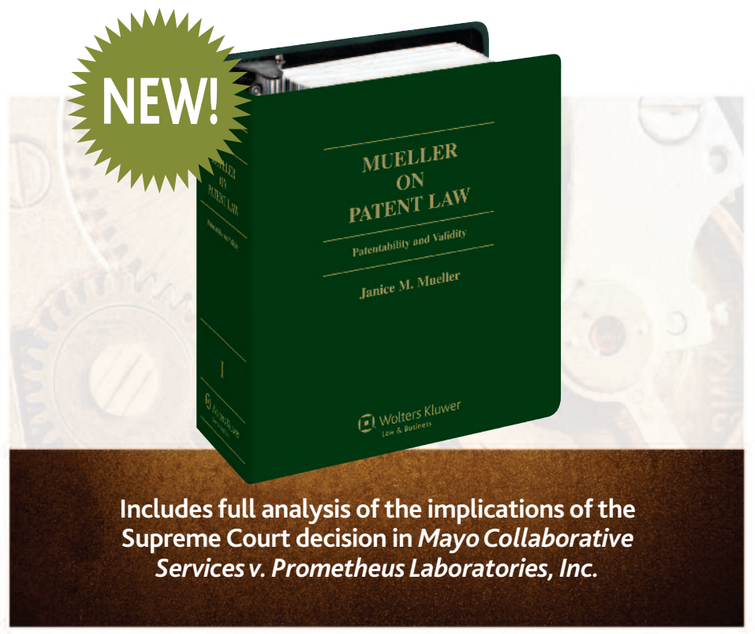

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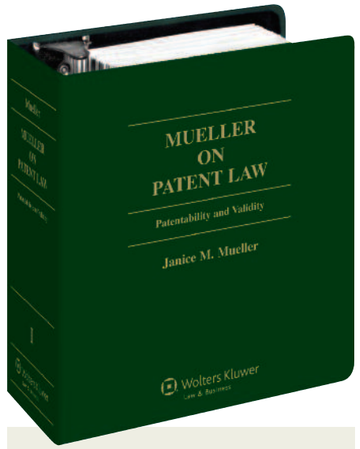

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About the Author

Janice M. Mueller, a registered patent attorney and chemical engineer, 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. Ms. Mueller 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 she was a tenured full Professor at the University of Pittsburgh School of Law, where she taught and wrote in the field of intellectual property law with an emphasis in U.S. and comparative patent law. Ms. Mueller has also taught at John Marshall Law School, Suffolk University, the University of Kentucky, the University of Washington, Seattle University, Santa Clara University, and William Mitchell College of Law. Aspen Publishers issued the third edition of her student text, *Patent Law,* which received a 5-star review in 2009, and she has published numerous scholarly articles. In 2009, Ms. Mueller co-founded the Chisum Patent Academy, Inc. with Donald S. Chisum, providing patent law educational services in a unique small-group seminar format.

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