# FIRST TO FILE PATENT DRAFTING

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Guidelines is not properly before us in this appeal. See 35 U.S.C. § 141(a) (stating that an applicant 'dissatisfied with the final *decision*' of the Board may appeal that decision to the Federal Circuit). As the Interim Eligibility Guidance itself states, it 'is not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is *these rejections* that are appealable.' Interim Eligibility Guidance, Vol. 79 Fed. Reg. 74618, 74619 (Dec. 16, 2014). And even if the Applicants had properly challenged the Guidance, we have previously determined that such Guidance is 'not binding on this Court.' See In re Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005). Thus we decline to consider Applicants' argument regarding the Interim Eligibility Guidance."

*In re Smith*, \_\_\_\_\_ F.3d \_\_\_\_, slip op. at 6-7 (Fed. Cir. March 11, 2016)(Stoll, J.)(emphasis added by the court).

#### § 1[b][8] New Approach in a New Administration in 2017

This book focuses upon drafting the first, priority application "today" which will receive a first action on the merits two or more years from now, at a time when there is a new President and a new Under Secretary of Commerce in charge of running the Patent Office. No matter which party wins the election, it is difficult to think that the new leadership of the Patent Office could be any less friendly toward patent applicants in the area of "abstract" technology under 35 USC § 101.

#### § 1[b][8][A] Statutory Requirements for Patentability, Repudiating Mayo

There are many ways that a new Administration could take a fresh approach to examination of "abstract" innovations. Perhaps the most important approach would be to treat "abstract" innovations in the same manner as any other subject matter area, to provide a complete examination on the merits of every case, including an examination for novelty, nonobviousness and formalities. 35 USC §§ 102, 103, 112. Perhaps the examiner should be required in the first instance to examine *only* under these standard statutory criteria and *not* in the first instance consider patent-eligibility under 35 USC § 101. After all, if the invention is "obvious", then there is no "inventive step" to consider under Section 101. And, if there *is* a nonobvious invention, then there *is* an "inventive step" present.

To be sure, there may be skeptics who think that there is some gray area where an invention may be nonobvious but still should be subject to rejection under 35 USC § 101. For such a case, the Patent Office should detail and embed I the relevant Technology Centers several Administrative Patent Judges who would take over an application with such an issue: They would then decide whether there

is in the first instance merit in a further rejection, and, if so, promptly push the case up the appellate ladder acting as Examiners, followed by an expedited hearing at the Patent Trial and Appeal Board.

It is recognized that the Supreme Court in its evaluation of patent-eligibility declined the Government's suggestion in *Mayo Collaborative Services v*. *Prometheus Laboratories, Inc.,* 132 S.Ct. 1289 (2012), to focus a validity determination on patentability issues under 35 USC §§ 102, 103, 112:

[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)).

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.

#### Mayo v. Prometheus, 132 S.Ct. at 1304

There is nothing inconsistent with the proposal, here, and the statement quoted from *Mayo v. Prometheus*. In the first instance, the guidance in *Mayo* speaks in the context of validity determinations in the courts and not about examination. Secondly, the proposal, here, does not preclude an examination under Section 101: Only the *order* of examination follows the classic patentability determination that has been the hallmark of the Patent Office since it opened its doors nearly 180 years ago in 1836.

(No hint or suggestion should be even remotely implied as to the incumbent leadership of any influence from Google. Years from now, the legacy of the incumbent leader of the Office will be viewed in the context of history as perhaps the most anti-patentee leader of in its entire history. The fact that the incumbent Under Secretary spent much of her career in a leadership position at Google is important only from the standpoint that Google during her tenure was constantly in a position of defending patent infringement charges so that her anecdotal, actual patent experience has been focused on this point of view. In terms of whether Google has any political influence over the Under Secretary, there is no evidence of any kind that this has occurred: To the contrary, her departure from Google was under circumstances that, if anything, would suggest a hostility toward Google.)

#### § 1[b][8][B] Eli Lilly et al Sequenom Amicus Filing, Mayo Déjà vu

In the end, the approach taken by the Government in *Mayo* discussed in the previous section must be revisited: The policy concerns that have created judicial hyperactivity in the interpretation of 35 USC § 101 should be rethought in favor of a strict interpretation of the *patentability* requirements of the patent law.

Perhaps the best argument in favor of a return to the statutory patentability requirements (versus the current Supreme Court patent-eligibility issues) is made in an *amicus* filing by several innovative pharmaceutical companies in the *Sequenom* case. *Sequenom, Inc. v. Ariosa Diagnostics, Inc.,* Supreme Court No. 15-1182, *Brief for Amici Curiae Eli Lilly and Company, Eisai Inc., Upsher-Smith Laboratories, Inc., Pfizer Inc., and Etiometry, Inc. in Support of Petitioner* (April 1, 2016).

The Court's analytical framework [focusing upon patent-eligibility under 35 USC § 101] is intended to operate as a surrogate for the broader policy question of whether a patent claim is so conceptual that rights under the patent might dominate or otherwise preempt access to a law or product of nature, a natural phenomenon, or an abstract idea. [footnote omitted] The Court has expressed concerns that the assertion of such a patent claim, by impairing access to basic tools of science and technology, could impede, rather than promote, progress in the useful arts. [footnote omitted]

Like many surrogate tests, it risks overreaching its policy objectives. This risk is magnified when the implicit exception is applied as a "threshold test." [footnote omitted] Not knowing if one or more of the remaining statutory patentability requirements would invalidate a patent claim, the tendency is to stretch the threshold test's application to assure a potentially problematic claim is invalidated lest such a claim might otherwise survive as valid under the explicit statutory requirements. Moreover, in applying such a nonstatutory limitation as a threshold consideration, it inherently operates without

considering whether or how the present, explicit statutory framework, taken as a whole, may operate to routinely invalidate conceptual patent claims.

Indeed, while the Court's jurisprudence assumes some overlap between the implicit exception and the statutory doctrines limiting patents, the Court has never considered whether the *proper interpretation* of the *current statutory* requirements, considered together rather than piecemeal, would fully address the policy considerations that caused the Court to mandate the non-statutory implicit exception.<sup>[11]</sup> As detailed below, the explicit statutory requirements now present in the Patent Act, when properly interpreted and applied, bar securing valid patents that might prevent access to a law or product of nature, natural phenomenon, or abstract idea. For these reasons, it is now essential as an exercise of judicial restraint for the Court to consider whether to abrogate the implicit exception in deference to the present explicit statutory scheme.

#### Sequenom case, Eli Lilly et al Amicus Brief at pp. 5-6/

Unfortunately, the Petitioner complicated its task by providing a *Question Presented* having nothing to do with this issue. The *amici* Petitioners address this shortcoming by proposing their *own* entirely different *Question Presented*.

"The Patent Act contains a set of statutory patentability requirements. In addition to these statutory requirements, the Court has imposed a nonstatutory "implicit exception" to patentability. This implicit exception was judicially imposed in part to assure that patents cannot be granted for concepts—or afford exclusive rights that may dominate or otherwise preempt access to concepts. *Concepts*, in this sense, refer to *laws* of nature, natural *phenomena*, or *ideas*, including abstract ideas. The implicit exception similarly bars patents directed or relating to *natural products* and entirely *mental processes*.

"The Court has applied the implicit exception as part of a "threshold test" for patentability that operates before other patentability requirements may be considered. The exception, however, does no more than duplicate the statute's effects when statutory provisions would also invalidate the same patent.

"As a threshold test, it has not taken account of the manner in which today's statutory requirements have evolved to fully address any policy justification for maintaining the exception. When other patent-limiting laws fully vindicate the policies that underlie the implicit exception, judicial restraint might demand outright abrogation of

<sup>&</sup>lt;sup>[11]</sup> "[T]he § 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." *Mayo* [*Collaborative Services* v. *Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1304 (2012)].

the exception.

"Given the current explicit statutory limitations on patenting in the Patent Act—and the proper interpretation of those limitations—should the Court's judicially imposed implicit exception to subject matter considered to be eligible for patenting be abrogated, such that patentability and patent validity are to be determined solely under such explicit statutory provisions?"

Whether the Court would treat this case exceptionally to rephrase the *Question Presented* in a grant of *certiorari* may make grant of the petition keyed to the new *Question Presented* problematic.

#### § 1[b][8][C] Search for an Independent View at the Patent Office

While it is difficult, to say the least, to have a grant of *certiorari* keyed to an *amicus* petition suggesting a different course of action than petitioner, to the extent that a new Administration faces the same *Mayo* problems that have existed before *Sequenom*, it would represent better public policy for the Patent Office to require that an Examiner exhaust all possibilities for examination under 35 USC §§ 102, 103, 112 *before* turning to a patent-eligibility analysis.

# § 1[c] Manufacturing and Electronics Industries



The largest users of the patent system, all from *outside* the pharmaceutical and chemical industries, are the big winners of the Leahy Smith America Invents Act. Such applicants now obtain an iron clad patent-defeating date against junior applicants without the possibility of a costly patent interference. As shown in the