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Will the US Emerge from the Subject Matter Eligibility Abyss?

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STAKEHOLDER DISSENSION LEADS TO PRACTITIONERS TRAPPED IN THE SECTION 101 QUAGMIRE

Hopes that at least one branch of the US government would address the confusion over subject matter eligibility under 35 USC. § 101 have recently been all but dashed.

In recent weeks, the US Supreme Court has denied certiorari on petitions for review of eight cases being appealed on § 101 grounds, including the case that practitioners were convinced could provide the Court with a platform to address the uncertainty it has created and perpetuated in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[1], *Association for Molecular Pathology v. Myriad Genetics, Inc.*[2], and *Alice Corporation Pty. Ltd. v. CLS Bank International*[3].

Indeed, even in the face of the Solicitor General's urging, the Court declined to review the Federal Circuit's decision in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*[4]:

> The Court instead should provide additional guidance in a case where the current confusion has a material effect on the outcome of the Section 101 analysis.
>
> For example, Mayo has had particularly significant practical effects with respect to medical-diagnostic methods. See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352-1353 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) ("*Since Mayo, we have held every single diagnostic claim in every case before us ineligible*."), petition for cert. pending, No. 19-430 (filed Oct. 1, 2019).
>
> In contrast to this case, where rehearing was denied without recorded dissent, the Federal Circuit's recent order denying rehearing en banc in *Athena* was accompanied by multiple separate opinions articulating different understandings of

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> *Mayo* and seeking clarification from this Court… Those various opinions provide substantial grounds for inferring that, if the Federal Circuit were not bound by the current Section 101 framework, that court might have reached different outcomes in *Athena* itself and in other diagnostic-method cases. Whether in *Athena* or in another such case, further guidance from this Court is amply warranted.[5]
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> Brief for the United States as Amicus Curiae in *Hikma Pharmaceuticals USA Inc., et al., v. Vanda Pharmaceuticals Inc*.[5]at 22-23; citations to dissents omitted.

CONGRESS ATTEMPTS TO CLEAN-UP SECTION 101 CONFUSION

Rather than follow the Solicitor General's suggestion, and to use an American sports analogy or two, it might appear that the Supreme Court decided to "punt", leaving it to Congress to "bat clean-up".

In June of 2019, the Senate Judiciary Committee Subcommittee on Intellectual Property held three hearings on "*The State of Patent Eligibility in America*", during which numerous witnesses testified regarding draft language proposed by the Subcommittee in order to clarify the metes and bounds of § 101.

The draft proposed deleting the term "new" from § 101, adding a section § 100(k)[6], and presenting "Additional Legislative Provisions":

The provisions of section 101 shall be construed in favor of eligibility.

No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.

The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.[7]

PROPOSED AMENDMENTS TO SECTION 112(F) TO APPEASE CERTAIN STAKEHOLDERS

However, as Congress is wont to do, they also proposed tacking on another amendment, not directly related to § 101, in an apparent attempt to appease those who might be opposed to clarifying § 101 – namely, those entities who would prefer to limit patent scope such that "the Progress of Science and useful arts" would **NOT** be promoted "*by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.*"[8] Specifically, the following amendment to § 112(f) was proposed:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Senators Thom Tillis and Chris Coons (Chairman and Ranking Member of the Senate Judiciary Subcommittee on Intellectual Property, respectively), in a statement dated June 24, 2019, referred to such a proposal as:

…reinforcing Section 112 of the Patent Act, which should operate to prevent inventors from claiming all possible solutions to a problem while also serving to protect inventors against those seeking to profit on trivial modifications.[9]

However, in a letter dated July 15, 2019 from FICPI International President, Julian Crump, to Senators Tillis and Coons, who had requested public comments on the proposed amendments, FICPI expressed concern regarding the amendment to § 112(f):

…the language of proposed Section 112(f) vaguely refers to limiting any element in a claim that is "expressed as a specified function without the recital of structure, material or acts in support thereof." This language does not clearly delineate the scope of "functional" language that would be construed as limited to the specific species disclosed in the specification and could lead to overly-broad application that would severely limit the scope of claims that were not intended to be so limited.

Unfortunately, despite what appeared to be a concerted effort by US Congress to legislatively address the chaos resulting from the *Mayo-Myriad-Alice* triumvirate, Senator Tillis, recently stated:

Given the reasonable concerns that have been expressed about the draft as well as the practical realities of the difficulty of passing legislation, absent stakeholder consensus I don't see a path forward for producing a bill—much less steering it to passage—in this Congress.[10]

Rumor has it that the amendment to § 112(f) was one on which the above-noted "entities" were not willing to compromise. As discussed in a recent article in Patent Docs:

Conspiratorial theories suggested that lobbyists from powerful and deep-pocketed parties had convinced the senators that it would not be in their best interests to continue their efforts. But Senator Tillis chalks up the difficulties to disagreement and stubborness [sic] amongst the stakeholders.[11]

Apparently, Senators Tillis and Coons still plan to engage in discussions to "*develop a consensus driven approach*". But Senator Tillis warns that "*[a]nything less than that is dead on arrival.*"[12]

USPTO ATTEMPTS TO CLARIFY APPLICATION OF SUPREME COURT PRECEDENT

While the USPTO's hands are effectively tied with respect to following the holdings in the *Mayo-Myriad-Alice* triumvirate, they continue a valiant effort to chart a course for stakeholders to follow in drafting subject matter-eligible claim language. Recently, the USPTO released its "*October 2019 Update: Subject Matter Eligibility*", new Examples 43-46, an Index of Examples and a Chart of Subject Matter Eligibility Court Decisions.[13]

The October 2019 Update seeks to "*clarif[y] issues with respect to the [January] 2019 PEG [Patent Eligibility Guidance], particularly the groupings of abstract ideas enumerated in the 2019 PEG and the evaluation of whether a judicial exception is integrated into a practical application*".[14]

While we await further action by Congress, and far less likely, action by the Supreme Court, practitioners unfortunately continue to be trapped in the § 101 abyss, while the US loses a competitive advantage as innovation moves to Europe and China, where the issue of subject matter eligibility is much more clearly defined and predictable.[15]

NEXT STEPS

- Consider getting involved with FICPI's Work and Study Committee 5 (CET5) on Biotechnology and Pharmaceuticals and/or CET6 on Software, High-Tech, and Computer Related Issues
- Get in touch with Sharon or consider joining the FICPI US National Section (navigate to USA)

[1] 566 US 66, 132 S. Ct. 1289, 101 USP.Q.2d 1962 (2012).
[2] 569 US 576, 133 S. Ct. 2107, 106 USP.Q.2d 1972 (2013).
[3] 573 US 208, 134 S. Ct. 2347, 110 USP.Q.2d 1976 (2014).
[4] 927 F.3d 1333, 1352-1353 (Fed. Cir. 2019).
[5] Brief for the United States as Amicus Curiae in *Hikma Pharmaceuticals USA Inc., et al., v. Vanda Pharmaceuticals Inc.*[5] at 22-23; citations to dissents omitted.
[6] (k) The term "useful" means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.
[7] https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26
[8] United States Constitution, Article I, Section 8, clause 8.
[9] https://www.tillis.senate.gov/2019/6/tillis-and-coons-what-we-learned-at-patent-reform-hearings
[10] https://ipo.org/index.php/exclusive-qa-with-sen-thom-tillis/
[11] https://www.patentdocs.org/patent_legislation/
[12] Id.
[13] https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility
[14] Id.
[15] See, Statements by Senator Tillis, David Kappos, Patrick Kilbride, Adam Mossoff at https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i

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This article was initially published by FICPI on the FICPI blog. You can view the original post here.