The State of Patent Eligibility in America: Part I

Testimony of:

Q. Todd Dickinson

Polsinelli, PC
Washington, DC

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1401 I St. NW
Washington, DC 20005
tdickinson@polsinelli.com

My name is Q. Todd Dickinson and I am Senior Partner with the Polsinelli law firm in Washington, DC.

I am the former Under Secretary of Commerce and Director of the U.S. Patent and Trademark Office ("USPTO") from 1999-2001, and held several other positions there. I have also served as the Corporate Vice President and Chief Intellectual Property Counsel of the General Electric Co., and the Executive Director of the American Intellectual Property Law Association. My understanding is that I have been invited here today to testify in my capacity as a former Director of the USPTO, and my comments are my own and not representing any clients or others affiliated with Polsinelli.

I come to this hearing, like I'm sure several of my colleagues on this panel do, with very serious concerns about where the U.S. patent system finds itself today. As I indicated, I do not come on behalf on any client; I have and have had clients on many sides of the question presented by this hearing. Rather, I am here as someone whose career's work has been focused on doing what's best for our patent system as a whole, both for stakeholders and the public. It is that background that gives rise to my concerns.

The primary question which we have been asked to address is the need to amend the Patent Act, 35 §101, concerning eligibility for a U.S. patent, and several other related sections. Based on my over 40 years' experience in intellectual property law and public policy, as well my belief in the inherent strength of the U.S. patent system if we do things right, I believe that the time has come to actively consider legislative solutions to questions of patent eligibility.

Several times in our history, public policy leaders in IP confronted challenges and weaknesses in our patent system and its effect on the innovation vitality of our country; shortly after World War II and at the end of the recessionary period in the late 1970's, for example. Blue ribbon commissions and study groups were appointed to study the system and make recommendations for improvements. But at the end of the day, it was up to the Congress to address these legislatively and the system was righted and improved.

Now we find ourselves in another period when the efficacy of our system is at risk, with public and stakeholder confidence in it at a low point. Since, the patent system is so critical to the economic well-being and the preservation of our traditional global leadership in innovation advancement, it is vital that we look again at where the challenges are coming from and what should be done to address them.

One specific challenge we face is coming from our Courts, particularly the Supreme Court, and its recent interpretation of §101 of the Patent Act which, until this recent series of cases, was thought to be the least critical and easiest to meet of the four basic statutory requirements to obtain a patent. Regarding the Supreme Court, and its views on the requirements for both patent eligibility in §101, and patentability, in Sections 102, 103, and 112 of the Patent Code, it is interesting to note several things.

First, as I will address in my brief recitation of the recent history of their patent jurisprudence, below, the Court has taken the opportunity to address §101, 102,

103, and 112 directly some 8 times in the last roughly 40 years. With only a single exception[1], in not one of these cases did the Court uphold the validity of the patent or patents in question, including the four dealing with the specific section under review in this hearing, §101. Moreover, in the roughly 6 years since the last time the Court addressed §101 in its *Alice* opinion, despite the well-known and widely articulated challenges in interpreting that case faced by the CAFC, the USPTO and patent owners alike, the Court has denied petitions for certiorari, and so refusing to address those challenges, some 42 times.

As will be discussed further below, all four of the most recent §101 have been criticized for various reasons, but primarily as articulating eligibility standards or analytic frameworks that are ambiguous and difficult to apply consistently (Bilski, Alice and Mayo) or which have led to inequitable results for valuable and health-improving technologies (Mayo and Myriad).

While there was fairly widespread criticism just after *Alice* came down, there was also a generalized belief then that the district courts, the CAFC and the USPTO would be able to interpret and clarify *Alice*. That hope has faded. We are now faced with not only calls for legislative reform from major neutral stakeholder organizations with members on all sides of the question, but now judges of the CAFC itself, both in their opinions and even in public speeches. They have repeatedly stated that they cannot figure out what the Supreme Court meant in these cases or that they have led to inequitable results, and that Congress needs to exercise its Constitutional duty to legislate in this area. As I indicated above, I join that in that call.

[1] *J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc*., 534 U.S. 124 (2001)., 534 U.S. 124 (2001). However, in *J.E.M.* the Court held that section 101 is a general and "dynamic provision designed to encompass new and unforeseen inventions." 534 U.S. at 135, 122 S.Ct. 593.

You will undoubtedly hear from organizations which prefer the status quo. Most of them will likely say that the Supreme Court's recent jurisprudence, particularly the *Alice/Mayo* framework, is a positive thing. The ambiguity, difficulty in interpretation, and challenges to consistent application by the USPTO and the courts, have led to a significant increase in patent invalidation, and a significant difficulty in getting patents in a variety of technologies through the USPTO. These entities apparently feel that this is a positive thing, in the sense that it gives them what several have referred to as "a new tool" to invalidate patents which they believe may interfere with business models. This is cynical and short-sighted.

Furthermore, to restrict the patent eligibility of a category of innovation because of purported effects, such as "preemption" of a field, is tautological and contrary to broad and good intellectual property policy. All patents, by the very nature preempt some portion of their field, and the individual determination of which ones might "preempt" and how broadly, especially at the USPTO examination level, is to attempt to pick technological winners and losers, which, particularly at early stages of a new technology, is inequitable, contrary to a key basis of the patent system that all technologies be treated equally, and something of a fool's errand.

To take an example, polymerise chain reaction (PCR) is one of the most important invention of the late 20th century, purportedly invented as the eventual Nobel Prize winner while driving up the Pacific Coast Highway during which it came to him and he stopped to write it down on a fast-food napkin. Did this ingenious and critically important new technology "preempt" its

technological field sufficient to warrant denying a patent and the chance to disclose, commercialize and license it? Who was capable of looking in their crystal ball and predict what the breadth of that field was or would become?

You may also hear that "loosening" the recent rules around patent eligibility will give renewed concern about patent assertion entities, the so-called "patent trolls", to obtain or rely on patents to intimidate small businesses and force inequitable and costly settlements. This is not to say that they weren't for a time a real problem – indeed they were. The reality of the experience, however, demonstrated that the actual litigation of these efforts were few and far between, given more than 2-3 million patents in effect at any given time. The most notorious of them, who sent out a great number of infringement notices, never actually filed a complaint until pushed by authorities, and then it was only one or two against major companies, and not mom and pop end users. As the FTC report on the topic makes clear, this represented a minority of actual likely litigants.

This distortion of the system was disappointing and rightly a cause of concern, However, at the end of the day, these were adequately dealt with by various forces other than changing the patent laws, such as state attorneys general, who brought consumer actions, and appropriately forced settlements with the genuine bad actors relying on often newly enacted state unfair competition laws to deal with this fairly contained actual problem.[2] Also, if problems specific to

[22] It should also be noted that the Director Iancu, the current Director of the USPTO has referred to this "troll" narrative as followes: "Remarkably, in what I believe amounts to Orwellian 'doublespeak,' those who've been advancing the patent troll narrative argue that they do so because they are actually pro-innovation. That by their highlighting, relentlessly, the dangers in the patent system, they actually encourage innovation. Right…"

the actual troll problems arise again and cannot be dealt with by actions already being used, we can consider other solutions, targeted more specifically at the problem, rather than using the expensive elephant gun of invalidation under §101.

You will likely also hear that this proposed legislation will inevitably lead to higher prices for drugs and diagnostic tests, presumably because it may become more difficult to invalidate patents of questionable quality. However, it seems equally possible, if the statute is drafted correctly, that it will actually lead to better, higher quality patents, since presumably the rules will be better known and easier to apply. This should result in improved drafting, more skilled and efficient examination and PTAB review, greater ability of the courts to differentiate the good from the bad, and increased ease of understanding of the metes and bounds by competitors and the public.

It is paradigmatic that most businesses highly value certainty, among other possible scenarios, primarily to facilitate their planning, budgeting and investment. This certainty of the rules, however, also benefits the public, who should value it, as well, allowing all to know what is in and what is out of the boundaries of patent eligibilty. Unfortunately, the current rules are unnecessarily ambiguous and uncertain, and this uncertainty ends up serving no one at the end of the day, least of all the system as a whole, long considered the global "gold standard" of patent systems.

I applaud the Subcommittee members, especially Chairman Tillis and Ranking Member Coons, and their very talented and dedicated staffs, as well as members of the related Committees in the House, for their commitment to

taking on this issue, and for quality of the work product which the Subcommittee has promulgated. While not yet complete, and certainly and appropriately open to continued discussion and debate, it represents a very good step forward, which I and others look forward to continuing to work with you on it.

Background

The question of eligibility has been present from the very first patent statutes. For example, the 1793 Patent Act stated that a patent may be granted to any person or persons who:

> "allege[s] that he or they have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter. . . .[3]

Over time, however, in their case law, the Supreme Court developed "exceptions" to patent eligibility, including, but variously worded, as "laws of nature", "naturally occurring phenomena" and "abstract ideas. A leading case of that era exemplifying this is *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), in which the Court interpreted the patent eligibility of Samuel Morse's code for use on the telegraph.

[3] Stat. 318, 319 § 1 (1793). The term "art" was eventually interpreted as "process" in 1952 Act legislative history. (See below).

This lasted generally until the 1952 Patent Act, usually cited as the most significant revision to the patent laws in our history. The 1952 Act, written by two of the most prominent patent experts of the day, Pasquale "Pat" Federico the Examiner-in-Chief of the USPTO, and Giles Sutherland Rich, the President of the New York Intellectual Property Law Association. Rich also went on to be the most famous and longest-serving judge dealing with patents, serving for 40 years on the Court of Appeals for the Federal Circuit ("CAFC") and its predecessor court.

Among other things, Federico is credited for providing the quotation said to underlie the scope of patentable subject matter under United States law when he testified before a House subcommittee in 1951. At that hearing, he stated that "under section 101 a person may have invented a machine or manufacture, which may include anything under the sun that is made by man," so long as it satisfies the other requirements of the patent statute.[4]

As Rich, later Judge Rich, wrote about the importance of the 1952 Act to more rigorously defining the legal concept of "invention", than the ones which various district and regional appellate courts had imposed up until that time:

> "These standardless terms and tests created wildly disparate approaches to determine sufficiency for 'invention," and that "judges did whatever they felt like doing according to whatever it was that gave the judge his feelings — out of the evidence coupled with his past mental conditioning — and then selected those precedents which supported his conclusions."[5]

[4] The phrase is believed to have been derived from Ecclesiastes, 1:2-9, 14.
[5] Giles S. Rich, "Principles of Patentability", 28 Geo. Wash. L.Rev. 393, 404 (1960).

The 1952 Act specifically sought to cure by this problem by introducing the new §103, for the first time imposing a patentability requirement of "non-obviousness". As CAFC Judge Lourie observed in his CAFC *en banc* opinion in *CLS Bank International. v. Alice Corp*[6]., in which he reviewed the history of the 1952 Act and the problems noted above by Judge Rich:

> "The 1952 Act focused its central purpose on correcting this systemic problem. 'One of the great technical weaknesses of the patent system' prior to 1952 was 'the lack of a definitive yardstick as to what is invention.' Victor L. Edwards, Cong. Research Serv., Efforts to Establish a Statutory Standard for Invention, at 2 (1958) (Study on Standard for Invention)….'The drafters of the present statute did their best to take out of the law the undefinable concept of `invention.' Whether lawyers will now take advantage of the terminology ... and stop talking nonsense is up to them.'[7]
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> "After deliberate effort, the 1952 Act replaced any need for an 'invention' or 'inventiveness' measure with an objective test for 'obviousness' in Section 103. See Dann v. Johnston, 425 U.S. 219, 225-26, 96 S.Ct. 1393, 47 L.Ed.2d 692 (1976)…Thus, the central thrust of the 1952 Act removed "unmeasurable" inquiries into "inventiveness" and instead supplied the nonobviousness requirement of Section 103.[8]

In the next decade, with the rise of such emerging technologies as the programmable computer and, more particularly it associated software, and biotechnology, in particular genomics such as genetically-modified organisms, the Court would turn to the issue of inventiveness, this time in the context of

[6] 717 F.3d 1269 (2013). This was the appellate opinion which led to the Supreme Court's own opinion in this case, discussed below.
[7] Principles of Patentability, 28 Geo. Wash. L.Rev. at 407.
[8] *CLS v. Alice Corp.* at 1296.

eligibility, despite the belief that §103 was meant to cure issues of what constituted an invention.

With regard to computer-related inventions, the Court issued a series of cases between 1972 and 1981 often called the “Patent Eligibility Trilogy. These began to be considered in the early years of software development. For example, Microsoft has just been founded in 1975, and IBM had begun to deal with the issue at around the same time. The primary issue, as framed in these cases at the time, concerned whether mathematical algorithms as used in computers or used by computers to direct processes such as manufacturing were “abstract ideas”. The evolution in these cases generally mirrored development and economic importance of software.

Gottschalk v. Benson, 409 U.S. 63 (1972) concerned a method for converting binary-coded decimal numerals into pure binary numerals on a general purpose digital computer. USPTO had rejected and CAFC reversed. USPTO appealed to Supreme Court, which reversed and held ineligible. The Court stated that the case concerned a process claim directed to a numerical algorithm, as such. In their view, it was not patent eligible because "the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself", and, therefore, would be allowing a patent on an abstract idea.

In *Parker v. Flook*, 437 U.S. 584 (1978), the question was whether an alarm limits process used in catalytic converters, which converters were generally known in the prior art, became patent eligible if it used a different algorithm from that in the art. Again, the USPTO had rejected, CCPA reversed and held the claims eligible under §101. And again, the Supreme Court reversed and held ineligible, the Court holding that the invention was patent eligible only if there is some other "inventive

concept in its application." The algorithm itself must be considered as if it were part of the prior art, and the claim must be considered as a whole.

Finally, in *Diamond v. Diehr*, 450 U.S. 175 (1981), the applicant claimed a process for curing rubber using which is computer-controlled and uses a specific algorithm to yield the desired specification of the rubber. Once again, the claims were rejected by the USPTO as ineligible, and were reversed by the CCPA finds them eligible. This time, however, the Supreme Court upheld patent eligibility, apparently recognizing the importance of protecting a now highly valuable technology..

The Court carefully avoided overruling *Gottschalk* and *Flook*, but criticized their methodology, in particular for not considering the claims as a whole, and only considering "new" elements. They also, sought to distinguish §101 eligibility from §§102/103 prior art patentabilty.[9]

In the biotechnology area, in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), decided the year before *Diehr*, the Court took up the question of the patent eligibility of genetically-modified living organisms, a much-debated issue at the time, in this case bacteria used for petroleum pollution remediation. As in software cases, the USPTO was reluctant to move forward and refused to grant patent, but the CCPA reversed.

[9] Section 101 "was never intended to be a `standard of patentability,' the standards, or conditions as the statute calls them, are in 102 and 103". *Id*, at 450 U.S. at 189-90. This is why I draw the distinction between eligibility and patentability in this testimony.

In this case, the Supreme Court agreed with the CCPA, and found the claims to be directed to a patent-eligible, in a strict statutory reading of §101. Writing for the Court, Chief Justice Burger articulated the now-famous maxim:

> "Congress ha[s] intended patentable subject matter to include anything under the sun that is made by man".

He also expressed the Court's view of the meaning of §101eligibility and its scope:

> "We have cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *United States v. Dubilier Condenser Corp,* 289 U.S. 178 (1933)….In choosing such expansive terms as "manufacture" and "composition of matter" modified by the comprehensive "any", **Congress plainly contemplated that the patent laws would be given wide scope**." (emphasis added).

During the "dot-com boom" of the mid-to-late 1990's the confluence of information technologies and new financial service innovations led to the USPTO issuing patents on so-called "Business Method Patents" or "BMP's". In the seminal case, *State Street Bank and Trust Company v. Signature Financial Group, Inc.,* 149 F.3d 1368 (Fed. Cir. 1998), the CAFC addressed the question of BMP and software patent eligibility.

The patent in question claimed a "hub and spoke" financial services process, in which the "spokes" were mutual funds that pool their assets in a central "hub". The USPTO had issued the relevant patent and this was appeal of an infringement action in which patent ineligibility was asserted as a defense.

In his opinion for a unanimous panel, Judge Giles Rich, who some 45 years earlier had helped right §101 in the 1952 Act, held that "software" is per se eligible, and that he finds no "business method exception" in §101. In doing so, he applies a test which came to be known as the "useful, tangible and concrete result" test to find eligibility. Notably, the Supreme Court did not take certiorari and let the opinion stand.[10]

After *Diehr* and *Chakrabarty*, the Supreme Court went quiet on §101, and accordingly, most stakeholders and patent professionals believed the state of patent eligibility articulated in those cases had generally settled the law in this area and could rely on it.

However, in the 2000's several things began to occur. First, there was a significant increase in the number of software and BMP patents – albeit generally matching the increased economic importance of software. Secondly, the economic importance of patents increases significantly, causing corporate patent strategies in particular, to assume a greater role in a company's overall strategic planning.

Additionally, in 2000, the National Academies of Science undertook an initiative which came to be known colloquially as the "Millennium Study", whose mission was to review and make recommendations, including possible statutory changes, in the U.S. patent system. This led ultimately, and after many revisions, to the Leahy-Smith America Invents Act of 2009.

[10] I was Director at the time, and in response the USPTO introduces Business Method Initiative (1999) to enhance the Office's search and examine, and thereby further strengthen, the quality of BMP's. This initiative included the so-called "second pair of eyes" or second level review of all BMP, and greatly enhanced examiner training and data base access in relevant classifications.

Also around this time, companies or groups which came to be known as "patent assertion entities" begin to assert their portfolios in certain ways, some highly criticized, and attracted attention of FTC and state attorneys general.

As one means to combat this, there was believed to have been funded an aggressive publicity campaign to promote idea that "patent trolls", i.e. patent assertion entities, no matter the assertion method, were asserting "bad patents" in negative ways and needed to be reined in. However, there are those who also came to believe that a collateral reason for this campaign may have been an attempt to keep smaller patent-holding entities from troubling larger ones on core software related technologies.

The Recent Supreme Court Jurisprudence and its Issues.

Traditionally, since *Chakrabarty/Diehr*, the CAFC had referred to §101, and the major stakeholders and practitioners believed it to be, a "coarse filter", which standard was easy to meet and under which applicants were imposed very few USPTO rejections. See, e.g. *Research Corporation Technologies, Inc. v. Microsoft Corp*[11].

However, by 2010, the Supreme Court decided to get back into §101 jurisprudence, and rendered four patent eligibility-related decisions between 2010 and 2014. These cases form the basis of the issues we are discussing today.

In *Bilski v. Kappos*, 561 U.S. 593 (2010), the Court considered the patent eligibility of a method for optimizing a fixed bill system for energy markets, as

[11] 627 F.3d 859, 869 (Fed.Cir.2010).

well as the CAFC's "machine or transformation" test, which they had substituted for the "useful, tangible or concrete result" test of *State Street.*

Unfortunately the Court was badly split and in its several opinions, reaching several somewhat contradictory conclusions. In his opinion for the Court, Justice Kennedy secured 5 votes for all sections but 2, which Justice Scalia opted out of, joining Justice Breyer's concurrence on one section. Kennedy reviewed the Court's opinions in *Gottshalk* and *Parker v. Flook,* and held that both cases refused to use the "machine or transformation test" as the only test of eligibility. However, he also rejected a categorical eligibility exclusion of business method patents, reasoning that the definition of "process" in § 100(b) includes the word "method," which appears to comprehend some forms of business method patents.

On the other hand, he held that this invention was ineligible as an "abstract idea" and stated that "this Court by no means desires to preclude the Federal Circuit's development of other limiting criteria that further the Patent Act's purposes and are not inconsistent with its text."

Finally, in his plurality opinion, which Justice Scalia did not join, he stated that strict adherence to only,

> "the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals… [but]… the Court today is not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection."

But he then went on to say that, despite his earlier comments on BMP's, they might not be eligible if they were on the idea that purely abstract ideas are not patentable, without defining in either opinion what he meant by "abstract".

Justice Breyer filed a concurring opinion, the second section of which also received 5 votes, Justice Scalia having joined this section, causing further confusion as to the Court's rules on eligibility. In that section, he stated that "transformation and reduction of an article to a different state or thing is the **clue** to the patentability [sic] of a process claim that does not include particular machines", and "while the machine-or-transformation test has always been a **'useful and important clue,' it has never been the 'sole test' for determining patentability** [sic]. (emphasis added.)

The Court next turned to life sciences technology eligibility, more specifically, medical diagnostic testing, a scientifically and financially important category of life science innovation. In the case of *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. 66 (2012), the patent claims were directed to a method of giving a drug to a patient, measuring metabolites of that drug, and knowing what the threshold for the efficacy of that drug, deciding whether to increase or decrease the dosage of the drug.

Prometheus was the exclusive licensee of these patents and sold diagnostic kits based on them. Mayo bought and used these kits until 2004, when it decided to offer its own diagnostic tests to its clients at the Mayo clinic and worldwide, without buying the kits from Prometheus, and so Prometheus sued for infringement and Mayo interposed a defense of ineligibility Reversing the CAFC, which had

held the claims eligible on remand in view of *Bilski*, the Court held unanimously that the claims were not patent eligible under §101.

The Court held that the claims encompassed an ineligible "natural law" and found the first two steps to be not "genuine applications of those laws[, but] rather ... drafting efforts designed to monopolize the correlations." The court said,

> "Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field. Such activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law."

The Court also articulated its belief that, when a process involves a natural law or abstract idea, it must also contain an "inventive concept," which they defined as "other elements or a combination of elements ... sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." Id. at 1294.

Perhaps acknowledging the controversy this opinion would engender in the life sciences community, the Court stated: "We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable."

However, perhaps inviting the review which you are undertaking today, he stated that "we must recognize the role of Congress in crafting more finely tailored rules where necessary...."

The next year, the Court confronted the controversial issue of the patent eligibility of genomic inventions, which had become significantly more important since the completion of the Human Genome Project a decade before. The USPTO had been issuing patents on these type innovations as "compositions of matter" under a very detailed set of utility guidelines and deposit requirements in place since the late 1990's, so long as the genomic inventions claimed compositions which had been isolated and purified from their natural state. Accordingly, many patentees and their licensees had come to rely on these patents as they developed and grew their businesses, especially again in the field of diagnostics.

In *Association for Molecular Pathology v. Myriad Genetics*, Inc., 569 U.S. 576 (2013), the Court considered the eligibility of isolated DNA sequences, methods to diagnose propensity to cancer by looking for mutated DNA sequences, and methods to identify drugs using isolated DNA sequence. Relying heavily on *Chakrabarty,* the CAFC had held that isolated DNA that does not exist alone in nature and were isolated and purified can be patented and that the drug screening claims were valid, but that Myriad's diagnostic claims were unpatentable, and again reiterated that opinion on remand from the Supreme Court in view of *Mayo*.

Again, the Supreme Court reversed the CAFC. Justice Thomas, in essence, seemed to be trying to "split the baby", basically holding that, despite almost two decades of practice to the contrary, "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but [so-called complementary DNA (cDNA)] is patent eligible because it is not naturally occurring." Tellingly, while Justice Scalia concurred in the result, he filed a concurrent opinion basically admitting that he basically did not understand

the science from his own knowledge, but relied on the teaching of various amicus briefs.

Several commentators faulted the science relied upon in the Court's opinion, as well as perhaps one of the public policy arguments, i.e. preemption, which may have affected that decision, noting that while it might result in greater access and lower prices for the particular diagnostic at issue, it also had the significant potential to reduce the incentive to discover and develop alternative or additional genetic diagnostic tests.

Finally, in *Alice Corp. v. CLS Bank International*, 573 U.S. 208, 134 S. Ct. 2347 (2014), the Court brings us to where we are today. In *Alice*, the claims at issue concerned a process for facilitating computer-implemented, electronic financial-trading service transactions in which trades between two parties seeking to exchange payments, are settled by a third party in ways that reduce "settlement risk", i.e. the risk that one party will perform while the other will not. It also contained so-called "Beauregard"[12] claims, i.e a tangible "article of manufacture", and a computer-readable medium, such as a computer disk or other data storage device, coupled with a computer program, i.e. software, and computer-systems claims.

The CAFC fractured badly in their *en banc* opinions below, various groupings of judges finding some claims patent eligible or not, depending primarily on what category of invention they were drawn to.[13] Significantly, Judge Moore, in her

[12] *In re Beauregard*, 53 F.3d 1583 (Fed. Cir.1995).
[13] The Chief Judge at the time, Randall Rader, has referred to the CAFC's inability to command a majority opinion in *Alice* as "the biggest failure of his career" https://www.reuters.com/article/us-usa-

dissent joined by 3 other judges (another judge, Judge Newman, would have held all claims patent eligible, yielding the 5-5 tie on the systems claims[14]), addressed the issue we address today:

> "I am concerned that the current interpretation of § 101, and in particular the abstract idea exception, is causing a free fall in the patent system. The Supreme Court has taken a number of our recent decisions and, in each instance, concluded that the claims at issue were not patent-eligible. See Bilski, Prometheus, Myriad (under consideration)….holding that [all claims] are all patent-ineligible under § 101. Holding that all of these claims are directed to no more than an abstract idea gives staggering breadth to what is meant to be a narrow judicial exception. And let's be clear: if all of these claims, including the system claims, are not patent-eligible, this case is the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents.[15]

Chief Judge Rader went so far as to include a section entitled "Reflections" in which he expressed his belief that the Supreme Court (and several of his colleagues) had, among other things, strayed for the plain meaning of §101 in it interpretation of "abstraction" and represented a retrenchment on what he viewed as the settled law of *Diehr* and *Chakrabarty*, decided some twenty years before.[16][17]

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judge-rader-insight/insight-rocker-judge-juggles-tech-policy-supreme-court-and-the-stones-idUSBRE9BA06D20131211

[14] In her dissent, albeit from a 5-5 split, Judge Newman stated: "I propose that the court return to the statute, and hold that when the subject matter is within the statutory classes in section 101, eligibility is established. This conforms with legislative intent. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980) ("In choosing such expansive terms as `manufacture' and `composition of matter,' modified by the comprehensive `any,' Congress plainly contemplated that the patent laws would be given wide scope.")." *Id*, at 1327.

[15] *Id* at 1313.

[16] *Id* at 1335.

[17] The fracturing of the CAFC and the varying opinions on the scope of §101 and the Supreme Court's exceptions are instructive for another reason: it highlights the debate we continue to have over the Supreme Courts holdings and analytical framework in this area. These CAFC judges see probably 100 patent cases a year. If they cannot reach consensus on the §101 scope, it only reinforces the need for Congressional intervention.

The Supreme Court upheld the plurality opinion of CAFC. In so doing, they set the course for the discussion we are having today.

Despite the *amici* almost begging the Court to set down a definitive rule, the Court in *Alice* basically declined. The basic holding of the Court was that adding a computer to an "abstract" idea was not patent eligible, a proposition on which few would disagree. Unfortunately, it did two additional things. First, it basically reduced it analysis of the invention to its most basic terms, the "gist" as it was sometime called, in this case an escrow performed on a computer. It then held that escrow was an abstract idea, in other words failing to consider the claims as a whole. In so doing, however, Justice Thomas declined to provide a working definition what the Court felt "abstract" meant:

> "In any event, we need not labor to delimit the precise contours of the 'abstract ideas' category in this case. It is enough to recognize that there is no meaningful distinction between the concept of risk hedging in Bilski and the concept of intermediated settlement at issue here. Both are squarely within the realm of 'abstract ideas' as we have used that term."[18]

Secondly, and more importantly for today's discussion, the Court purported to set up an analytical framework for divining "abstractness", relying particularly on their own decision in *Mayo*.

In the first step under *Mayo*, a court must determine whether the asserted patent claim contains an abstract idea, such as an algorithm, method of computation, or other general principle. If it does, that is the end of the analysis – the claim is not patent eligible. If it is not or does not contain an abstract idea,, the claim is

[18] *Alice*, 134 S. Ct. at 2357 (2014)

potentially patentable, subject to the other requirements of the patent code, and the court proceeds to the second step.

In the second step of the analysis, the court must determine whether the patent adds to the idea "something extra" that embodies an "inventive concept." ("We have described step two of this analysis 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.'").[19] If there is no addition of an inventive element to the underlying abstract idea, the court should find the claim ineligible under § 101 .

Criticism of the cases, in particular the so-called *Alice/Mayo* framework has been strong and on-going. The first criticism of *Alice* came very quickly, and focused on what it did not say, especially Justice Thomas's punt on the definition of "abstract", and his analytical framework. Among many critics of and commentators on the decision, the Washington Post probably said it the most succinctly:

> "[W]hile the court struck down what was universally said to be a bad patent, it didn't do much to say what kinds of software should be patentable. In other words, the court decided the most basic conflict in the case, but more or less declined to offer guidance for other, future cases."

Or as two well-known academics in this area, Prof. Robert Merges at Berkeley and Prof. John Duffy at UVA, neither usually seen as partisans on the topic said:

[19] 134 S. Ct. at 2355.

> "To say we did not get an answer is to miss the depth of the non-answer we did get." and "[T]he Supreme Court has been remarkably resistant to providing clear guidance in this area, and this case continues that trend."

Other criticisms have pointed out that it has been hard to apply consistently. The CAFC jurisprudence since *Alice* has reinforced that, as have a number of district courts who have considered the issue. To get a flavor of that, please see the following exemplary CAFC opinions: *Enfish*[20], *BASCOM*[21], *McRO*[22], *Thales*[23], and *Visual Memory*[24]. An excellent and very complete listing of some 64 cases decided since *Bilski* and their outcome, which also highlights the challenge in interpretation and eligibility, can be found here. https://www.bitlaw.com/patent/section-101-cases.html. Of those 64, in only 17 was eligibility upheld.

A second criticism the *Alice/*Mayo approach is that important and valuable technologies have been left unprotected, ultimately resulting in these technologies stunted. This is particularly true in the life sciences and biotechnology, which has been pointed out by the CAFC in several opinions.

In *Sequenom v. Ariosa*, the CAFC upheld the district court's holding of ineligibility under *Mayo*. Unfortunately, the technology in this case was a critically important new technology the invention of which, is the basic invention is the discovery of a fetal DNA marker in the amniotic fluid of a pregnant woman using PCR technology and a diagnostic method for using that discovery. The previous method involved inserting a needle into the fetus itself, with the resulting pain and possibility of miscarriage.

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[20] *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016)
[21] *BASCOM Global Internet v. AT&T Mobility*, 827 F. 3D 1341 (Fed. Cir. 2016)
[22] *McRO v. Bandai Namco, et al*. (Fed. Cir. 2016)
[23] *Thales Visionix, Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017)
[24] *Visual Memory v. NVIDIA Corp.*, 867 F.3D 1253 (Fed. Cir. 2017)

As Judge Linn said in his concurring opinion:

> "I join the court's opinion invalidating the claims of the '540 patent only because I am bound by the sweeping language of the test set out in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. ___, 132 S. Ct. 1289 (2012). In my view, the breadth of the second part of the test was unnecessary to the decision reached in Mayo. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."

He further criticized the actual analytical framework of the Supreme Court in *Mayo*:

> "In applying the second part of the test, the Supreme Court in Mayo discounted, seemingly without qualification, any "[p]ost-solution activity that is purely conventional or obvious," id. at 1299 (original alterations omitted). This was unnecessary in Mayo, because doctors were already performing in combination all of the claimed steps of administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels, id."

Many observers expected the Supreme Court to grant certiorari in this case, and revisit the effect of its Mayo decision; the CAFC opinions even seeming to tee that up. Once again, however, the Supreme Court declined.

In a similar recent case, *Athena Diagnostics v. Mayo*[25], the CAFC again held a valuable, new and non-obvious medical diagnostic for certain previously-un diagnosable myasthenia gravis to be ineligible. However, this time it engendered a vigorous dissent:

> "This court's decisions on the patent-ineligibility of diagnostic methods are not consistent, and my colleagues today enlarge the inconsistencies and

[25] No. 2017-2508, (Fed. Cir., February 6, 2019).

> exacerbate the judge made disincentives to development of new diagnostic methods, with no public benefit. I respectfully dissent. The claims are for a multi-step method of diagnosis, not a law of nature."

In response, the majority replied in a footnote:

> "The dissent states much that one can agree with from the standpoint of policy, and history, including that 'the public interest is poorly served by adding disincentive to the development of new diagnostic methods.' Dissent at 12. We would add further that, in our view, providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts."
>
> "But, whether or not we as individual judges might agree or not that these claims only recite a natural law, cf. Berkheimer v. HP Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring in the denial of rehearing en banc) (discussing traditional laws of nature such as 'Ohm's Law, Boyle's Law, [and] the equivalence of matter and energy'), the Supreme Court has effectively told us in Mayo that correlations between the presence of a biological material and a disease are laws of nature."

This jurisprudence has affected the CAFC in several negative ways. As seen in the cases discussed above, they illustrate the unfortunate result that the CAFC has ruled one way because of the Supreme Court cases, but stated the result was inequitable and should have held otherwise. As noted above, there are also sometimes inconsistent opinions. This has been particularly noted in the information technology and computer-related cases. It has also resulted in the related problem of apparent panel dependency, introducing additional significant uncertainty into the CAFC's own jurisprudence. It has resulted in open criticism of the Supreme Court, further aggravating relations between the Courts, with very little ability to resolve the differences.

Additionally, the inability of certain innovations and the confusing nature of the jurisprudence have caused innovation investment moving to other jurisdictions. It has been widely noted that the U.S. biotechnology industry was jump started by *Chakrabarty* has waned under the recent series of §101 cases. However, now it is believed that it is easier to get software and life sciences patents in Europe and China, where previously the U.S. was the leader in expansive patent protection.

Finally, it seems certain that the uncertainty bred by the muddled jurisprudence has ultimately resulted in lowered public confidence in the patent system itself. Several recent studies by the U.S. Chamber of Commerce have evaluated the U.S. patent system against those of other countries. While in the last year, the U.S. has bounced back into the top 5, for a number of years before that our system was ranked in the mid-teens, similarly to Hungary, and eligibility uncertainty was cited as a major negative factor. (As for this year's improvement, it's possible that the recent changes introduced by Director Iancu in dealing with this uncertainty at the USPTO may be responsible.)

The uncertainly has also had a telling effect on the USPTO. It is forced to constantly reinterpret varying jurisprudence with resulting uncertainty during examination. Moreover, as most examiners are not lawyers, it results in non-lawyers applying sophisticated and complex legal concepts and standards (§101 is a matter of law), with and additionally costly and time consuming re-training being required.

Several recent Directors have attempted to look at and potentially ameliorate the impact of this uncertainty on the USPTO. In the Obama Administration, Director

Lee convened several hearings on §101, covering both suggestions for substantive reform generally and then-current USPTO interpretation and implementation. Moreover, she initiated hearings and guidance specially directed to interpreting *Mayo/Myriad* in light of certain life sciences technologies.

To his great credit, current Director Iancu has pursued this even further, having begun to implement new directives for use by the USPTO and, by extension, the public, to actually address some of the concerns expressed.

First, in his so-called "Berkheimer Memorandum"[26], in which the Office was instructed on how to implement the holding in *Berkheimer v. HP, Inc.*,[27] As stated in the Memorandum the intent was to specifically "provide clarification as to the inquiry into whether an additional element (or combination of additional elements) represents well-understood, routine, conventional activity….[following]…the Federal Circuit [holding] that " [w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination."[28]

Even more to the point, the USPTO has issued specific §101 and §112 Guidance[29], representing a very positive and well-reasoned attempt to reconcile Supreme Court and CAFC jurisprudence in this area, particularly how to determine whether claims were in an excluded category and how to interpret what was meant by the phrase "directed to" in the *Alice/Mayo* framework. Additionally, Director Iancu made it

[26] https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF
[27] 881F.3d1360 (Fed. Cir. 2018).
[28] Id. at 1369.
[29] https://www.uspto.gov/about-us/news-updates/us-patent-and-trademark-office-announces-revised-guidance-determining-subject.

clear that this Guidance applies to the entire USPTO, i.e. Patent Office and PTAB, which hopefully will now conform to single standard.

Tellingly, the USPTO's recently-issued §101 Guidelines were premised on the current Director's concern that he found the ability of the Office to apply Alice/Mayo consistently was compromised. Upon issue, Direct Iancu stated in announcing the Guidance:

> "These guidance documents aim to improve the clarity, consistency, and predictability of actions across the USPTO," said Under Secretary of Commerce for Intellectual Property and Director of the USPTO Andrei Iancu. "The USPTO will provide training to examiners and administrative patent judges on both documents to ensure that guidance is being properly administered."

The "2019 Revised Patent Subject Matter Eligibility Guidance" made two primary changes to how patent examiners apply the first step of the U.S. Supreme Court's Alice/Mayo test, which determines whether a claim is "directed to" a judicial exception.

The challenge the USPTO has and has had is clearly illustrated by his detailing of how they are to be applied.

To have some 10,000 examiners and 250 Administrative Patent Judges trained on this examination process, applying a legal standard effectively when the vast majority of examiners are not attorneys, and to do it consistently across all technologies is, to put it mildly, a very ambitious undertaking.

However, while an excellent step in the right direction of providing clarification and direction, this Guidance obviously has its limitations. Specifically, the USPTO is still interpreting a flawed and confusing jurisprudence and analytic frameworks. They are also hampered somewhat by their continued lack of substantive rule-making authority in this area.

Need for legislative action

Why is there a need for legislation right now? It should be remembered, that in light of *Alice*, there was a substantial increase in patent invalidation and a strongly heightened difficulty of getting applications in relevant classifications allowed. One study found that there were examiners and classifications which did not allow a single application over a two-year period because of *Alice.*

All of this initially led to a fairly wide-spread belief that clarity and relief was needed, but that the best way to achieve was waiting to see how the courts, and the CAFC in particular, would handle *Alice*, in the hope that they would bring this needed lucidity.

Fairly recently, however, it became clearer that the judicial route was not likely to yield a consistent result nor Supreme Court relief. As noted above, CAFC judges themselves criticized the current situation and stated that Congressional intervention was needed. Again, too, as noted above, the Supreme Court has had

some 42 certiorari opportunities itself since *Alice* was decided and has declined to take any of those cases.[30]

There accordingly then developed a general agreement among major stakeholders and opinion leaders that the best way to achieve §101 reform would be legislatively, which in many ways, brings us to today.

There have been a number of developments along these lines recently:

- As you will no doubt hear from them, several major stakeholder organizations, i.e. AIPLA, IPO, and ABA IPL Section prepared draft legislation, and in the IPO and AIPLA's case, a joint proposal was eventually adopted.

- Several prominent members of Congress, e.g. the Subcommittee's Ranking Member, and Rep. Stivers of Ohio, indicated publically that they were open to the idea of legislative reform, albeit urging that there be general stakeholder consensus on a single version.

- There was a significant increase in conferences, speeches, resolutions, other public fora discussing the challenges in *Alice* and §101 generally.

- The reconstitution of the Intellectual Property Subcommittee in the 116th Congress, the agenda of which was indicated that consideration of §101 reform would be a priority of the Subcommittee.

[30] However, it should be noted that they have recently asked for the Government's views in two cases, the *Berheimer* case noted above, and in the case now-titled, *Hikma v. Vanda*, originally cited as *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd*, 887 F.3d 1117. It seems possible that the effort undertaken by the Congress may be influencing the Supreme Court to revisit the issues raised here, which is a positive reason to continue to review the issue and propose legislative reforms .

- Finally, the convening of the four §101 Roundtables seeking stakeholder and IP leader input on §101 reform legislation and what it might look like, including the recent draft of potential legislation.

Reactions to the Current Draft

You have asked for our reactions and input, even at a granular level, to the current draft. Accordingly, I would note the following.

It is an excellent initial draft for its simplicity, structural reliance on the current statute, clarity, and success in achieving and reconciling a variety of sometimes competing goals or concerns. Specific positive developments include:

- A reversal of previous plan to have a "list" of various exclusions.
- The declared goal of elimination of the Supreme Court's exclusion categories.
- Clear abrogation on all cases "establishing or interpreting" those exceptions.
- No apparent reliance on or use of pre-emption as a grounds for exclusion or invalidation under §101.
- Greater emphasis on "usefulness" in the §101 analysis.
- Elimination of "new" in the current §101.
- The rule of interpretation requiring that the provisions of §101 "shall be construed in favor of eligibility".

There are a few questions, concerns or and suggestions for amendment or clarification that I would like to raise:

- The proposed revised §100 definition of "utility" uses the word "practical" in "specific and practical utility". One question is whether "practical" implies the invention has to meet some undefined standard of practicality or even working. Will it simply be sufficient to have alleged what the utility is and of what practicality, or will some demonstration be needed? As a possible amendment consider using "substantial" from the Supreme Court's *Brenner* or language from the USPTO "Utility Guidelines".[31]

- At the moment, the only technologies which are traditionally determined not to meet the current usefulness standard are those which are believed to violate physical laws, such as perpetual motion machines and inventions resulting in something exceeding the speed of light in practice. Will that still be considered roughly the same standard?

- In the same §101 definition of "useful", the phrase "in any field of technology" is proposed. The meaning of this term has varied over time and in various contexts. For example, as the CAFC has noted the PTAB's definition of "technology" for it CBM rules is tautological and not workable. Also, in Europe, there is a long-standing concept in their patent law of "technological effect". It would be important to clarify the metes and bounds of this important word, perhaps in the legislative history, if not the statute.

- Regarding a specific issue on the question of "technology", even Justice Kennedy allowed in *Bilski* that "business methods" were not per se ineligible, although he did urge the CAFC to apply a strict "abstract" test to them. He also acknowledged that the term is also used elsewhere in the

[31] https://www.uspto.gov/web/offices/pac/mpep/s2107.html.

statute. If "abstract" is no longer being applied, where is the boundary with regard to BMP's, especially given their continuing growth in importance to financial services organizations. One possible approach would be to make clear that "technology" should be broadly interpreted and relate it the requirement for construing in favor of eligibility.

- With regard to "human intervention", there may come a time with advanced artificial intelligence that those processes may result in innovation that would otherwise meet the novelty/non-obviousness standard. Will the "human intervention" requirement now in §101 via §100, result in these inventions be patent eligible, or would the fact that AI is a function or result of human intervention be sufficient? One suggestion might again be clarification in the legislative history and reliance on the broad construction requirement again.

- In the "Additional Legislative Provisions" section, the phrase "all cases establishing or interpreting those exceptions are hereby abrogated. Several questions arise:

    - Use of the word "interpreting" the previous use of the exceptions is perhaps too broad. It could conceivably take in any cases where they are simply mentioned or references, including, for example *Graham v. John Deere.* An alternative phrase which might work better is "relying on" in place of "interpreting." That would narrow and clarify that only it applies only to those cases that have used the exceptions to invalidate patents or disallow patent applications.

- Does this mean to it literally apply to **all** cases? Does that include the CAFC, the PTAB, the ITC, the district courts, the Court of Federal Claims, etc. If that's what is meant, fine, but some additional consideration should be given to what might be the unintended consequences of that interpretation.

- Regarding the breadth of "abrogated", do we have to articulate some exceptions, especially relating to aspects of patent prosecution to which this relates but is somewhat ancillary, such as obviousness-type double patenting, and certain interpretations of "utility"?

- This question, among others, also necessarily raised the question of retroactivity. I understand from the last Roundtable, that the staff is still considering the retroactive effect of the implementation of the new statute, and appreciate the arguments on either side. Perhaps a compromise might be to have it apply to all patent applications currently pending at the USPTO and all litigation for which there has not been a final, non-appealable determination, either in the federal courts, the PTAB, or the ITC.

- There has been concern voiced in the proposed revisions to §112 whether it affects certain technologies more than others. While the concerns of the high technology sector regarding over broad interpretations under current "means plus function" jurisprudence warrants attention, certain life sciences technologies may be more negatively affected due to the nature of their research and how its results are expressed in the patent application specification and examples, e.g. antibodies and certain diagnostics.

- Does it also mean that all method claims, for example in methods of treatment, are to be narrowed to just the text of the specification, the examples and their equivalents, especially considering that most stakeholders generally believe the doctrine of equivalents jurisprudence is currently overly narrow. Clarification would be helpful, perhaps including additional language.

- Regarding the first Additional Provision, that, as a matter of applied statutory interpretation, §101 shall be construed in favor of eligibility is a welcome addition. Others have suggested that how it is expressed or implemented may need to be discussed. Is it considered to be a matter of the burden of proof or a applying the presumption of validity to the determination?

- Finally, in the last paragraph under Additional Legislative Provisions, it is very good to include, as you suggest, a provision that specifically points out that the issue of §101 eligibility is separate and distinct from issues of patentability, as specified in the Patent Act §§102, 103 and 112.

Conclusion.

In conclusion, I would like to reiterate my general support for this positive proposal that should go far in clarifying and resolving several major issues in the current Patent Act, particularly the interpretation and use of §101, and the great assistance this should give the USPTO in its work. My congratulations to the the Subcommittee, and especially the staff, for all their hard work to this point and

their cogent work product. Like others, I look forward to working with the Subcommittee as this project moves forward.

Q. Todd Dickinson
June 4, 2019