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Diagnostics patent eligibility: a turning point approaches

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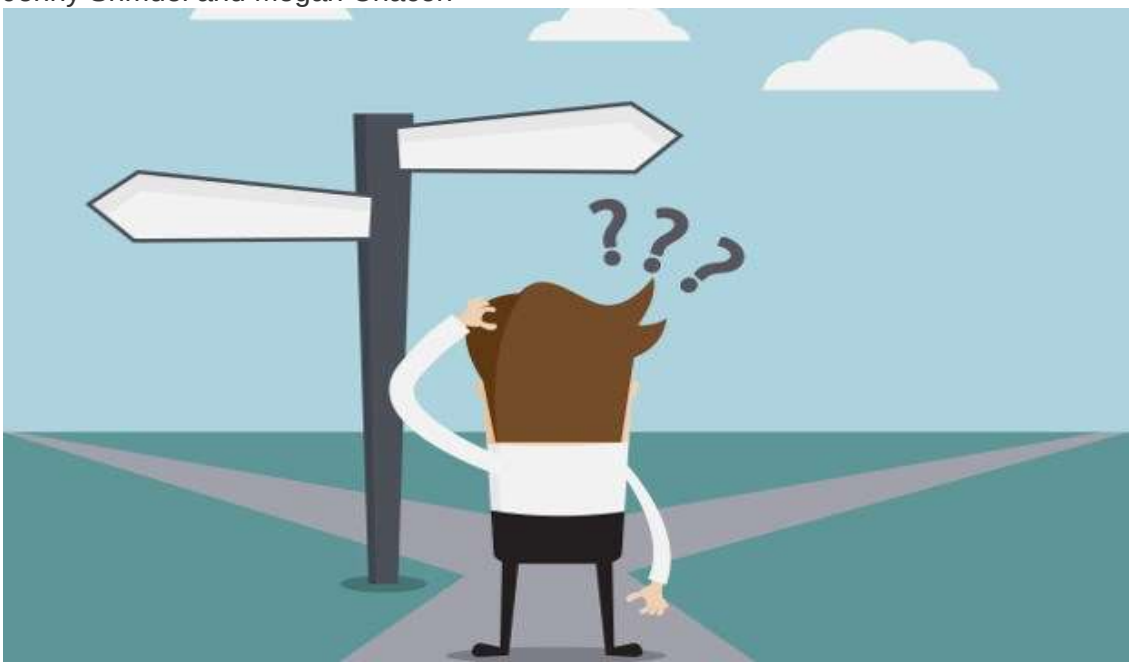

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As reflected in numerous recent court opinions, the broad Supreme Court rulings of Mayo, Myriad and Alice have drastically changed the landscape of patent eligibility in diagnostics. Jenny Shmuel and Megan Chacon of Fish & Richardson review the situation and discuss some future scenarios.

The patent eligibility landscape under 35 USC §101 has shifted in the past few years, with the courts issuing a series of decisions which threaten to undermine a system designed to encourage and reward innovation and development. The application of this law in one particular area—screening and diagnostic testing during and after pregnancy—highlights the unprecedented difficulty faced by those seeking patent protection in the life sciences arena and points to a potential turning point in the law.

Where we have come from

More than 35 years ago, the Supreme Court in Diamond v Chakrabarty (1980) held that a live, human made microorganism was patent-eligible subject matter, setting the tone for the next 30 years for the liberal grant of a multitude of life sciences related patents. However, the Supreme Court's recent rulings on patent eligibility have moved in a very different direction.

In 2012, the Supreme Court's decision in Mayo v Prometheus began to blur the boundaries of what patent-eligible subject matter means. The court held that claims to methods of administering drugs to treat gastrointestinal autoimmune diseases did not meet the patenteligible subject matter standards of §101. In coming to this conclusion, the court outlined a twostep inquiry that provided more regimented guidance than predecessor cases such as Chakrabarty.

Under the Mayo test, one must first determine whether claims are directed to a patent ineligible concept, i.e., laws of nature, natural phenomena, or abstract ideas. If so, one must then search for the "inventive concept" by determining whether additional elements "transform the nature of the claim" into a patent-eligible application. This framework recalibrated the starting point for the analysis of patent-eligible subject matter, but with little guidance from the court on how the test should be applied.

Soon after Mayo, the Supreme Court revisited §101 in Association for Molecular Pathology v Myriad Genetics. The claims at issue were directed to isolated DNA sequences associated with predisposition to breast and ovarian cancers and to diagnostic methods of identifying mutations in those DNA sequences. The court found that the isolated DNA involving a naturally occurring segment of DNA precluded patent eligibility, but held that synthetically created DNA —known as complementary DNA (cDNA)—was not naturally occurring and therefore was patent-eligible.

The Supreme Court did not disturb the ruling by the US Court of Appeals for the Federal Circuit that the diagnostic methods were patent ineligible under §101. Notably, the Myriad court was clear that "ground breaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry".

The Supreme Court addressed patent-eligible subject matter again in 2014 in Alice Corp v CLS Bank. The Alice court revisited the Mayo two-step framework in determining that patent claims directed towards a scheme for using a third party to mitigate settlement risk were drawn to a patent ineligible abstract idea. As in Mayo, the Alice court did little to expand on what it truly means to be patent-eligible, yet it reinforced the application of the arguably amorphous two-part framework for patent eligibility.

The Supreme Court's rulings have had a drastic effect: in the year after Alice, 12 of the 13 federal circuit decisions involving §101 challenges and 64 of the 93 district court cases involving such challenges resulted in invalidity rulings. The practical ramifications of these decisions can be illustrated by looking at the treatment of patents in a particular field, namely: screening and diagnostic testing during and after pregnancy. In each case below, the importance and value of the testing is acknowledged, but nonetheless the claims were found to cover patent ineligible subject matter.

Shortly after the Mayo decision, the federal circuit decided PerkinElmer v Intema, a case concerning the validity of a patent disclosing screening methods to estimate the risk of foetal Down's syndrome. The court acknowledged the importance of these non-invasive tests, stating that although alternative invasive testing can definitively determine whether a foetus has Down's syndrome, "doctors seek to avoid them if possible" because they "carry a significant risk of miscarriage".

In 2011, the district court ruled that the claims-at-issue covered patent-eligible subject matter. But by the time the federal circuit considered PerkinElmer, the Mayo case had been decided. The federal circuit invalidated the claims in PerkinElmer under §101, concluding that the claims simply recited "mental processes and natural laws" along with "conventional steps, specified at a high level of generality".

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Relying on PerkinElmer and the watershed cases discussed above, the US Patent and Trademark Office has denied patent claims from issuing in the first instance. For example, the Patent Trial and Appeal Board (PTAB) held that a claim to a method of testing and optimising breastmilk production was directed to a patent ineligible "law of nature" or "abstract idea"—in particular, "the relationship between the volume of milk expressed by a woman in a pumping session and the time interval between pumping sessions, in order to identify optimal time intervals for pumping sessions to maximise intervals and milk production".

The denial of this claim was juxtaposed with the PTAB's acknowledgement of the value of the testing; the PTAB cited portions of the application emphasising that the claimed method "would greatly enhance mothers' chances of having successful lactation", especially mothers who deliver prematurely. Where we are now

The attack on patent eligible subject matter—and the backlash—has recently come to a head in Ariosa Diagnostics v Sequenom. On June 12, 2015, the federal circuit affirmed summary judgment of invalidity under §101 of claims directed to non-invasive prenatal testing using cellfree foetal DNA (cffDNA) found in a part of blood samples from pregnant women that were previously discarded as waste. This non-invasive testing can detect genetic defects and, as

the court admitted, “avoids the risks of widely used techniques that took samples from the foetus or placenta”.

The claims were, nonetheless, invalid because the methods begin and end with a “natural phenomenon”—paternally inherited cffDNA—and amount to no more than “a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA”. Judge Linn, concurring, joined the court’s opinion “only because he was bound by the sweeping language of the test set out in Mayo”, but felt that the second step of the Mayo test (discounting any “post solution activity that is purely convention or obvious”) was unnecessary and incorrect, and the cffDNA patent at issue was a “meritorious invention” deserving of patent protection.

In December 2015, the federal circuit denied Sequenom’s petition for rehearing en banc. Of the three opinions issued, however, all unequivocally expressed that patentability of the cffDNA invention should not be barred under §101. Judge Lourie, joined by Judge Moore, concurred in the denial of rehearing based on Mayo. However, in their opinion, the claims were not drawn to a natural phenomenon—they were a use—and were not an abstract idea because actual physical steps were performed.

Judge Dyk likewise concurred in the denial of rehearing based on Mayo, emphasising the important role that §101 plays in the patent system, but “sharing the concerns of some of my colleagues that a too restrictive test for patent eligibility … with respect to laws of nature (reflected in some of the language of Mayo) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences”.

Judge Newman dissented, believing that Mayo and Myriad were distinguishable because, unlike in those previous cases, here “the claimed method was not previously known, nor the diagnostic knowledge and benefit implemented by the method”.

Where we are going

Lourie, in his concurring opinion denying rehearing en banc in Ariosa, stated that “it is … said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern”. As reflected in the numerous Ariosa opinions, the broad Supreme Court rulings of Mayo, Myriad and Alice have resulted in an unprecedented crisis in patent law, drastically changing the patent eligible subject matter landscape and threatening to undermine a system designed to foster innovation and development.

As courts continue struggling to apply the Supreme Court’s two-part framework and as the effects of this framework become more apparent, it is likely that the pendulum will swing back to some middle ground.

Although it is too early to know what that will look like, in Ariosa the federal circuit judges offered some possible alternatives. Maybe, as suggested by Linn, the second step of the Mayo test should be refined such that when “conventional steps” are applied in new ways (e.g., to newly identified compounds such as cffDNA), claims are drawn to patent eligible subject matter.

Maybe, as suggested by Dyk, the inventive concept should be allowed to spring from discovering something new in nature (e.g., a new “natural relationship or property”), as long as the claims are sufficiently narrow such that they do not pre-empt the entire field. Or maybe another option should be employed.

But with so many important advances depending on patent protection, such as pregnancy related diagnostics ensuring the health and wellbeing of the next generation, it is unlikely that the status quo will be maintained.

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