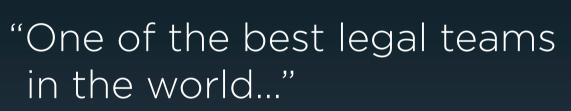


Life Sciences 2017 Key issues for senior

Key issues for senior life sciences executives

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Patent eligibility and life sciences patents

By Leora Ben-Ami and Thomas Fleming, Kirkland & Ellis LLP

In the few years since the Supreme Court turned to the issue of patent eligibility with its decisions in *Mayo Collaborative Servs v Prometheus Labs, Inc* (132 S Ct 1289 (2012)) and *Alice Corp Pty Ltd v CLS Bank Int'l* (134 S Ct 2347 (2014)), numerous biotech and diagnostic patents have been found to be ineligible under the threshold patent statute (35 USC Section 101). Section 101 of the patent statutes defines the conditions for patent-eligible subject matter. Historically not a primary focus for patent applicants in the life sciences area, it is now a central issue.

Section 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor". However, a judicially created prohibition in patent law reads into Section 101: the prohibition on attempting to patent laws of nature, natural phenomena or abstract ideas.

The Supreme Court has said that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry" (Ass'n for Molecular Pathology v Myriad Genetics, Inc, 133 S Ct 2107, 2117 (2013)). Courts have seized on this language and used it to invalidate patents directed to a wide swathe of important scientific discoveries. In essence, the courts recognise that scientific discoveries are important and should be used to advance medical treatments and further innovations, but that does not necessarily dictate that they be entitled to a patent. The concern is that once patented, such new discoveries of natural phenomena broadly claimed are no longer freely available to the public (what the courts refer to as 'pre-emption').

The Supreme Court did caution against the

exception enveloping the rule, saying that "too broad an interpretation of this exclusionary principle could eviscerate patent law... all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas" (*Mayo*, 132 S Ct at 1293).

Thus, while abstract ideas, physical phenomena and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena and laws of nature to perform a real-world function may well be (*Alice Corp* at 2354 ("an invention is not rendered ineligible for patent simply because it involves an abstract concept")). A claim that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle or phenomenon itself. This later step is where many patents have fallen short.

Because questions about patentability under Section 101 are seen as threshold issues, many courts are addressing challenges under Section 101 at an early stage, before claim construction and at times on a pre-answer motion. Litigants must be prepared to face such a challenge in the first instance.

How is patent eligibility tested?

In *Alice* the court employed a two-step test to determine whether a patent is directed to ineligible subject matter. First, one considers whether the claims at issue are directed to a patent-ineligible concept, such as a natural process or law of nature. If so, one evaluates whether the claim's elements – considered both individually and as an ordered combination – transform the nature of the claim into a patent-eligible application. This second step is called the 'inventive concept' – an improvement

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or tangible feature that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself" (*Mayo*, 132 S Ct at 1294).

In *CellzDirect* the Federal Circuit stated the test as follows: "Under step two, claims that... also 'improve an existing technological process,' are sufficient to 'transform[] the process into an inventive application' of the patent ineligible concept" (*Rapid Litig Mgmt Ltd v CellzDirect, Inc*, 827 F3d 1042, 1050 (Fed Cir 2016) (citations omitted)).

It is worth considering how the courts have applied the evolving standard for patent ineligibility in the life sciences. Practitioners should take note of these precedents in drafting new claims and considering whether previously issued patents are at risk.

Can DNA be patented?

Before 2013, most patent attorneys would probably have said that claims directed to isolating and identifying, cloning or synthesising various genes and DNA sequences were safe ground for patents. That seemed to change with the Supreme Court's decision in Myriad. The patents in Myriad were directed to the detection and isolation of the precise location and sequence of the BRCA1 and BRCA2 genes, mutations which were understood to cause cancer. The patents also contained claims for the means to synthetically create BRCA cDNA. The court held that naturally occurring DNA sequences claimed in that case, such as those encoding the BRCA 1 and 2 genes, even if synthetically made, were products of nature and not patentable. Applying the second step of the test under Section 101, the court also found that isolating a DNA sequence from nature – even synthesising that sequence - was not enough to make that discovery patentable. The court stated that Myriad did not create or alter these genes or the sequences; it merely located and isolated them. Even though it required "extensive effort", the processes for isolating DNA were well developed

and widely used (*Myriad*, 133 S Ct at 2118-19). In other words, the claims merely described a product of nature and the other steps relating to isolation and sequencing were not inventive concepts. The Federal Circuit has made clear that "patenteligibility does not turn on ease of execution or obviousness of application. Those are questions that are examined under separate provisions of the Patent Act" (*CellzDirect*, 827 F3d at 1052, citing *Mayo* at 1304). The focus under a Section 101 analysis is whether the process steps purporting to be the inventive concept are so well known as to be routine, so that when taken as a whole they render the claim obvious.

By contrast, the court held that the claims to cDNA were patent eligible, since cDNA does not exist in nature and, when made, is something new (*Myriad*, 133 S Ct at 2119).

In a follow-on case (In re BRCA-1 and BRCA-2 Based Hereditary Cancer Test Patient Litig, 774 F3d 755 (Fed Cir 2014)), the question evolved to whether composition claims to DNA primer sequences were patentable. Here the Federal Circuit found that claims to primer sequences were directed to products of nature, as the primers contained the identical nucleotides sequence to a portion of the gene (here the BRCA gene) to which they were created to bind. The court was not persuaded by the fact that primers are singlestranded DNA that do not exist in nature. The claims in In re BRCA-1 also required amplifying a BRCA gene and sequencing and detecting the amplified nucleic acids (id at 764). The court in Myriad already found that the steps of amplification and sequencing were routine and thus unpatentable, and that the claims lacked an inventive concept because separating DNA from its natural environment - even separating it into single strands, such as isolating a segment of DNA - was "not an act of invention" (Myriad, 133 S Ct at 2117). The court also rejected arguments relating to the structural differences between genomic DNA and primers, finding that they have the same structure (In re BRCA-1, 774 F3d at 761).

The claims in *Myriad* and *In re BRCA-1* were composition claims. Biotech patents often also contain method claims. The analysis of method claims under Section 101 is not different from composition claims, but it invokes a different focus. With method claims, the courts assess whether the method or process adds something new and useful over the art – that is, "additional features" to the mere discovery of the underlying human biology (*Mayo*, 132 S Ct at 1297).

The patents in *Mayo* claimed a method to measure metabolites in the bloodstream to calibrate the proper dosage of thiopurine drugs for treating autoimmune diseases (*Mayo*, 132 S Ct at 1295). The court found that:

- metabolism of the compound was a natural process;
- the methods to determine metabolite levels were "well known in the art"; and
- the further methodology added "nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients" (*id* at 1298).

Of note was the finding in *Mayo* that the additional elements of the claims lacked inventive concept, as the steps of monitoring the metabolite levels and adjusting dosages were already in practice by physicians in treating patients before the patent was filed. Thus, the court held that these claims, employing existing and well-known practices, did not claim more than the natural process, and that determining how a drug works in the body by measuring its response was not patentable (*id* at 1305).

The inventors in *Ariosa Diagnostics, Inc v* Sequenom, Inc (788 F3d 1371 (Fed Cir 2015)) discovered that paternally inherited cell-free foetal DNA (cffDNA) was present in the mother's serum or plasma. They developed and claimed a non-invasive prenatal test method for identifying potential birth defects using that cffDNA. The claimed methods used the cffDNA, including amplifying the cffDNA contained in a sample of serum or plasma by methods such as polymerase chain reaction (PCR) and detecting the paternally inherited cffDNA. The court first found it "undisputed" that the existence of the cffDNA was a natural phenomenon. Notably, prior to this invention, no scientist had used the maternal serum or plasma to detect paternal cffDNA. However, in looking for an inventive concept, the Federal Circuit determined - as it did in Mayo - that "[u]sing methods like PCR to amplify and detect cffDNA was well-understood, routine and conventional activity", and that the method amounted to "a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA". It therefore ruled the claims unpatentable (id at 1377). Particularly interesting was Judge Linn's concurrence (id at 1380). Linn concurred in finding the claims invalid because he felt constrained to do so given the "sweeping language" of the test set out by the Supreme Court in Mayo. Linn observed that in Mayo, the process steps in the claims were conventional techniques that doctors were already practising at the time of patenting: adjusting dosages based on metabolite levels. By not limiting Mayo to those facts, Linn felt that the test of using broadly "conventional and routine" methods without a correlation to what was done in the prior art went too far. He stated that even though amplification and detection techniques for analysing DNA sequences were known, since no one before the Ariosa inventors "was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers", the process was deserving of a patent (*id* at 1381). He saw the widely acknowledged claimed method in Ariosa as new and completely different from the commonly practised techniques at issue in Mayo.

The Federal Circuit's decision in *Genetic Techs Ltd v Merial LLC* (818 F3d 1369 (Fed Cir 2016)) addressed again the situation where the inventors discovered a previously unknown "fact about

"In assessing method claims under a Section 101 analysis, courts focus on the product or result of the method or process claimed Claims are not patent eligible 'when they [amount] to nothing more than observing or identifying the ineligible concept itself'" human biology" (Genetic Techs at 1376). In this instance it was the identifiable linkage between the coding region and non-coding region of certain genes (termed 'linkage disequilibrium'). The patent claimed methods of locating and detecting certain genomic genes by amplifying and analysing the non-coding regions for the genes of interest. The court found that linkage equilibrium is a natural law/phenomenon. The claims also required the amplification of genomic DNA with a primer pair and analysis of the amplified DNA to detect the coding region allele. The court again held that the claim "involves no creation or alteration of DNA sequences, and does not purport to identify novel detection techniques", but rather only the application of prior art techniques to determine "information" about the coding sequences (id). The

court never addressed that the application of those known techniques using the claimed primers had never been done before. The court found that the element of the claim that required the "detection" of the allele was essentially a mental process step calling for a routine comparison of sequences, and one that could be performed in the mind by routine techniques. One issue with these claims that troubled the court was their breadth; they applied to a comparison of any non-coding region to ascertain the locus of any coding region (*id* at 1374-75).

The cumulative effect of the decisions in *Myriad*, *In re BRCA-1* and *Ariosa* has been to establish a strong precedential foundation for courts to follow when assessing life sciences patent claims. Most recently, the court in *Roche Molecular*





Leora Ben-Ami, a seasoned trial lawyer, is an IP partner in the New York office of Kirkland & Ellis LLP. Her practice generally focuses on biotechnology, medical devices, pharmaceuticals and chemistry. Her experience is wide ranging, from cases involving recombinant DNA technology to personalised medicine to plant biology, from angioplasty catheters to laser devices, from medicinal chemistry to polymorphs, and from polymer chemistry to pesticides. She has tried numerous patent cases to both juries and judges in the federal courts, as well as before the US International Trade Commission. Ms Ben-Ami has also argued before the US Court of Appeals for the Federal Circuit. She has published widely on IP issues and has been recognised by numerous legal publications and directories.



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Thomas Fleming is an IP partner in the New York office of Kirkland & Ellis LLP. He is a veteran trial lawyer with extensive experience in complex commercial litigation, IP litigation and patent litigation. He has co-chaired numerous jury patent trials in the areas of biotechnology, pharmaceuticals and wireless technology, and has been lead counsel in patent and trade secret litigation matters in the areas of chemical products, medical and software devices. He has argued numerous appeals, including before the Federal Circuit. He advises Fortune 100 companies on IP aspects of international merger and acquisition matters, licensing and deal-related matters. *Systems, Inc v Cepheid* (Dkt 131, CA No 3:14-CV-03228 (ND Cal January 18 2017)) found that claims to primers containing identical nucleotide sequences to a naturally occurring bacterial gene (MTB) were not patentable. The method claims in *Roche* employed primers with signature nucleotides known to exist in the MTB gene, and then amplification and detection by PCR of the object sequence to determine the presence of the MTB gene. The court, following *Myriad* and *In re BRCA-1*, found these steps conventional and routine and held the claims invalid.

The identification of a new and useful process led the court in Rapid Litig Mgmt Ltd v *CellzDirect, Inc* (827 F3d 1042 (Fed Cir 2016)) to find the claimed methods patent eligible. The claims were to a method for creating a pool of cryopreserved hepatocytes (liver cells) by employing multiple freezing and thawing steps previously thought not to be possible, along with other steps. Here the Federal Circuit found that the claimed invention was not drawn to a natural process or phenomenon - so that it did not satisfy the first step in the *Alice* test, essentially finding that the claims were directed to patent eligible material. However, the court went on to note that even if the first step had been met, the claims added novel and improved processes over the art for creating and preserving pooled hepatocytes for future use. The court found that the claimed methods were improved over prior art methods, as the process of preserving hepatocytes by repeating the well-known steps was "itself far from routine and conventional" (*CellzDirect*, 827 F3d at 1051).

In assessing method claims under a Section 101 analysis, courts focus on the product or result of the method or process claimed. Claims are not patent eligible "when they [amount] to nothing more than observing or identifying the ineligible concept itself" (*CellzDirect*, 827 F3d at 1048). If all that the claims provide are conventional and routine steps for observing, identifying, assessing, comparing or detecting the natural product or law of nature, the courts tend not to find the requisite inventive concept, thus rendering the claims unpatentable.

The US Patent and Trademark Office recently published multiple guidelines instructing examiners that claims involving natural products must be "significantly" or "markedly" different from the natural products to be patent eligible (US Patent and Trademark Office May 2016 Update: Subject Matter Eligibility Examples: Life Sciences). **Iam**

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