

Is there a legislative fix for biotech patents?

Section 101 under the US Patent Act is in urgent need of clarification, say **Matthew Kreeger** and **Christopher Jamieson Kendall**



By some accounts, we have entered a golden age for innovation in personalised medicine. Through scientific advancements in the study of genetic coding and molecular analysis, it is now possible to screen an individual for certain diseases and to tailor therapies for maximum effectiveness.

But continued innovation in personalised medicine is threatened by the US' patent system, which has increasingly found biotech inventions ineligible for patent protection. Confronted by a string of Supreme Court of the US (SCOTUS) rulings in recent years over patent eligibility, the Federal Circuit and other lower courts have invalidated biotech-related patents at an alarming rate and sent mixed signals about what can be patented.

The rulings have provided ammunition to advocates for patent reform, especially those from pharmaceutical and biotech companies who fear that such rulings are gutting incentives for important new investments. Historically, legislative reform has long proved elusive, in part because of the divergent interests between the technology and pharmaceutical sectors. But there is increasing momentum on the side of patent-reform advocates. Recognising the turmoil created by recent court decisions, the US Patent and Trademark Office (USPTO) has recently sought input on patent-subject matter eligibility. And in remarks made in November 2016, USPTO director Michelle Lee predicted that targeted patent reform would continue to be discussed in Congress, including possible changes to Section 101 under the Patent Act of 1952. The section is in urgent need of clarification.

Section 101

For decades, Section 101 has acted as a "coarse filter" to determine whether an invention is eligible for patent protection. The statute opens the door to anyone who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." But SCOTUS has also long recognised three narrow exceptions to patent eligibility: laws of nature, physical phenomena, and abstract ideas.

In a series of decisions analysing Section 101 within the last seven years, SCOTUS has sought to parse the meaning of those exceptions. The result has been more confusion and more patents found ineligible than ever before.

For the biotech industry, the troubling line of decisions began in 2012 with *Mayo Collaborative Services v Prometheus Laboratories*. In that case, SCOTUS invalidated claims related to a process for testing the relationship between drugs to treat autoimmune diseases and metabolites. The inventors claimed to have found a way to identify correlations between metabolite levels and the likely harm or ineffectiveness of drugs with precision. But the court found that the discovery was rooted in laws of nature and that the rest of the claims "[amount] to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients".

SCOTUS reaffirmed its approach to patent eligibility in its 2014 *Alice Corp v CLS Bank International* verdict, which addressed method claims for exchanging financial instruments. What emerged from those two cases was a two-step test for determining patent-subject matter eligibility. As interpreted by the Federal Circuit Court of Appeals, the test requires a court to see "whether the claims at issue are directed to a patent ineligible concept". If the answer is no, the inquiry is over. If the answer is yes, then the court considers "the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements 'transform the nature of the claim' into a patent-eligible application."

Mayo/Alice application

These rulings have been devastating for many biotech companies. Their inventions, which in many cases form the core of their businesses, often rely on recently discovered correlations between genes and cell-signaling pathways.

But as a result of *Mayo/Alice*, those discoveries are now under threat. Courts have been invited to define "natural law" or "natural phenomenon" so broadly that the claims of the invention are almost always directed to an ineligible concept under the first step of the *Mayo/Alice* test. In cases concerning discoveries at the cellular level, the Federal Circuit has found claims to be directed to a patent-ineligible concept "when they amounted to nothing more than observing or identifying the ineligible concept itself".

In a 2015 *Ariosa Diagnostics, Inc v Sequenom, Inc* decision, for example, the Federal Circuit rejected patent claims related to a method for detecting paternally inherited cell-free fetal DNA in the blood or

serum of a pregnant female. It noted that the method “begins and ends with a natural phenomenon” – cell-free fetal DNA – and therefore the “claims are directed to matter that is naturally occurring”.

Patents that focus on comparing sequences at the nucleotide level have also been found to be directed to an ineligible concept – an abstract mental process. For example, in its 2014 decision *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, the Federal Circuit found that claims comparing DNA sequences in order to detect alterations an abstract idea that cannot be patented.

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Pushback

To be sure, not all biotech-related patent claims have been found by courts to be directed to an ineligible concept under the first step of the *Mayo/Alice* test. In *Rapid Litig Mgmt Ltd v CellzDirect, Inc*, the claims at issue recited a “method of producing a desired preparation of multi-cryopreserved hepatocytes”. The Federal Circuit, in its 2016 decision, reasoned that the claimed methods were “not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles”. Instead, the claims were directed to “a new and useful method of preserving hepatocyte cells”.

The Federal Circuit was apparently seeking to find a rationale for finding some biotech patents eligible under the first step of the *Mayo/Alice* test. But the ruling illustrates the struggle courts face in distinguishing between claims that use or rely on a natural law to achieve the invention versus claims that are “directed to” a natural law.

Recent district court cases demonstrate the fine parsing required. In *Vanda Pharm Inc v Roxane Labs, Inc*, for example, the majority of the asserted claims were related to methods of treatment for patients suffering from schizophrenia by administering iloperidone. But the district court found they “depend upon laws of nature”, specifically the relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation (emphasis added).

In *Athena Diagnostics, Inc v Mayo Collaborative Servs*, the district court considered method claims for diagnosing a chronic autoimmune disorder using a non-naturally occurring protein called I25I-MuSK. Despite the use of a man-made protein, the court found the claims do not transform the subject matter of the patent. “The focus of the claims of the invention is the interaction of the I25I-MuSK and the bodily fluid, an interaction which is naturally occurring,” the court wrote.

Mayo/Alice: step two

The second step in the *Mayo/Alice* test – which asks courts to judge “inventiveness” – has been no less problematic for biotech companies. Courts have offered no clear guidance on how to assess whether the elements taken individually and in combination do not amount to a claim that, as a whole is “significantly more” than natural law. In

practice, courts that have found the first step of the *Mayo/Alice* test satisfied have generally found the claims ineligible for patent.

In *Ariosa Diagnostics*, the Federal Circuit found that “because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.” Other courts have similarly found that steps in biotech-related patent claims were “well-understood, routine or conventional”.

In a rare win for a biotech patentee, a district court in *Ameritox Ltd v Millennium Health, LLC* recently found eligible a patent covering a urine-screening method for determining whether a patient was adhering to a prescribed treatment plan. The court ruled that the combination of steps produced a new and useful result when “examined as an ordered combination,” noting that “if inventors engage in activities that run counter to scientific thought, those activities can hardly be considered conventional under § 101.”

Legislative fix needed

Court rulings over the last five years have exposed the lack of certainty in the country’s patent system, which is critical for new emerging industries to thrive. Because of the large investments required to bring new innovations to market, biotech firms especially must have confidence in what can and cannot be patented.

At the same time, the system has shown a lack of adaptability. It has proven incapable of accommodating innovative applications of natural laws like correlations and cellular phenomena in rapidly developing areas of diagnosis and treatment, as well as nascent or emerging subfields of biotechnology that are not yet well defined or understood.

Because many of the system’s current problems have come from judicial decisions, a legislative fix could be the best solution. The Intellectual Property Owners Association recently proposed a narrow statute that would effectively overrule *Mayo*, providing that “[a] claimed invention is ineligible under [Section 101] if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind.”

Another possible approach would be to look to other jurisdictions. In Europe, for example, certain categories of subject are explicitly included for patent protection, while other enumerated categories are excluded. “Biotechnological inventions” are explicitly permitted if they concern “(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature; (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety; (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.” Similar language could readily be folded into the US patent system.

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