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How Mayo, Myriad And Alice May Impact Patent Valuations

Law360, New York (March 04, 2015, 8:48 AM ET) --

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Patentable subject matter is broadly defined as "any new and useful process, machine, manufacture, or composition of matter" (see 35 U.S.C. § 101). There are, however, certain exceptions to this broad definition of patentable subject matter. The key exceptions include laws of nature, natural phenomena, naturally occurring products and abstract ideas.

As technology, and biotechnology in particular, has continued to evolve at a rapid pace the courts have repeatedly had to explore and decide upon the boundaries of patent-eligible subject matter. These decisions impact many different industries but the greatest impact will arguably be in the life sciences sector.

This article first provides an overview of recent high-profile court cases that have addressed the issue of patentable subject matter. The second section describes how these decisions are changing patent examination at the U.S. Patent and Trademark Office. The final section discusses how the changing scope of patent-eligible subject matter may impact intellectual property valuations and transactions in the life sciences field.

Mayo, Myriad and Alice

Over the past few years, there have been three key Supreme Court decisions that have been of significant importance to the issue of patent-eligible subject matter. These include the 2012 decision in Mayo v. Prometheus, the 2013 decision in Association for Molecular Pathology v. Myriad Genetics Inc. and the 2014 decision in Alice Corp. Pty. Ltd. v. CLS Bank International.

The patented technology at issue in Mayo was a personalized medical test for determining the optimal dose of a drug. The patent claims involved administering the drug to a patient and measuring the level of a particular metabolite in the patient's blood. The measured metabolite levels, when compared to the optimal metabolite range, indicate whether to increase or decrease the drug dose. In Mayo, the Supreme Court unanimously ruled that this method was not eligible for patent protection since the correlation between drug dose and metabolite levels was a law of nature and the additional claimed steps were considered to be simply the routine activities of researchers.

The patented technology at issue in Myriad was a genetic test for two cancer-associated genes. The

patents claimed segments of genomic DNA as well as complementary DNA (cDNA). In Myriad, the Supreme Court unanimously ruled that naturally occurring DNA segments are products of nature even when isolated from an organism's genome and are therefore patent-ineligible subject matter. In contrast, the Court found that cDNA (DNA which is synthesized using RNA as the template) is patentable because it is not naturally occurring.

Alice is different from Mayo and Myriad in that the patented technology at issue was a computer-implemented business method rather than a life sciences technology. The patents in this case claimed a method for exchanging financial obligations, a computer used to perform the method and software designed to cause the computer to perform the method. In Alice, the Supreme Court unanimously ruled that the technology was not eligible for patent protection since it was simply an abstract idea implemented using a generic computer system and software.

While the relevance of Alice to the life sciences may not be immediately apparent, it was recently cited in a Federal Circuit case in which additional Myriad genetic testing patents were invalidated. These patents claimed primers derived from genomic DNA as well as methods for comparing a patient's DNA sequence for a particular gene to the normally occurring, nonmutated sequence. The court cited Myriad in its finding that primers were isolated, naturally occurring DNA segments and therefore patent-ineligible subject matter. It then relied on Alice in its finding that the method claims were patent-ineligible since the court considered the comparison of a patient's DNA to a reference sequence to be an abstract mental step.

Impact on the USPTO

The USPTO issued three separate guidance memos on the issue of patent-eligible subject matter to its patent examiners in 2014. The first memo was issued to help guide examination of claims directed to natural phenomena/products in view of Mayo and Myriad. After Alice, a second memo was issued to help guide examination of claims involving abstract ideas. Finally, after receiving substantial feedback from the life sciences community on its first 2014 memo, the USPTO issued a third guidance memo dealing with natural phenomena/products. The USPTO has indicated that this most recent guidance memo will be updated further in view of developments in the case law and in response to public feedback.

These multiple memos suggest that the USPTO is still trying to clearly define the boundaries of patent-eligible subject matter for its examiners. Given this uncertainty at the USPTO, one would expect a similar or potentially even greater level of uncertainty amongst the various participants in the life sciences sector (biotech and pharmaceutical companies, universities, start-ups, investors, IP attorneys, etc.). There are numerous ways in which uncertainty around intellectual property assets can financially impact a company or industry. Two of the more immediate issues are discussed in the final section below.

Potential Impact on IP Valuations and Transactions

The full impact of the shifting scope of patentable subject matter will ultimately depend on how the courts and the USPTO interpret and apply Mayo, Myriad and Alice. While these rulings most immediately affect personalized medical tests and genetic tests like those at issue in Mayo and Myriad, there is concern within the life science sector that other technologies may now be viewed as patent-ineligible as well. For example, how will these cases apply to patents on naturally derived antibiotics, naturally derived therapeutic compounds or any number of other diagnostic tests?

Some patents may clearly be identified by a patent holder's IP counsel as being invalid in light of Mayo,

Myriad or Alice, but many of these patents are likely to fall in a gray area. Given the absence of a bright-line rule that patent holders can use to identify patent-ineligible subject matter and the fact that even the USPTO's rules for identifying such subject matter are still being shaped, there is increased risk associated with issued patents and pending applications claiming these kinds of inventions. The real-world impact of this increased risk is still unknown, but it could have immediate consequences for patent valuations and transactions.

Patent valuations are performed for a variety of reasons including but not limited to, evaluating potential acquisitions, sales or licenses, supporting negotiations in IP-related transactions, prioritizing products in clinical development and informing investment decisions. Regardless of the purpose, in all such valuations the goal is ultimately to quantify the present value of the future benefits that may be derived from the IP assets in question. Forecasting future benefits (e.g., cash flow, cost savings, etc.) requires the valuator to account for the level of risk or uncertainty associated with receiving those benefits.

So, for example, if a genomics company's IP counsel identifies a group of its patents that suddenly have greater invalidity risk due to potentially patent-ineligible subject matter, the risk-adjusted present value of those patents would be reduced (assuming all other factors remain constant). The results of any change in value will of course be dependent upon a range of other factors including but not limited to the strategic importance and intended use of the IP assets, the magnitude of the change, and the risk-adjusted value of the opportunity.

If the risk-adjusted value of certain patents changes, a wide range of transaction types involving those assets could be impacted. These patent transactions may take many forms including in-licenses, out-licenses, cross-licenses, purchases or sales. Equally important are the other transactions that are often driven in large part by patent value. For example, the amount paid to acquire a diagnostic company or the size of an investment in a fledgling biotechnology company may depend heavily on the results of due diligence focused on the strength, scope and enforceability of the target company's patent portfolio. This due diligence is particularly important in the life science sector due to the enormous amount of time and money required to obtain regulatory approval for new drugs and medical tests and the fact that many biotech start-ups are built around a single patented technology.

Will value changes resulting from increased invalidity risk reduce patent transaction activity or investments? The answer to this question will depend on the numerous factors impacting patent value, the number of patents currently directed toward potentially ineligible subject matter, future decisions of the courts and the USPTO and the direction of new biotechnology development. What is clear, however, is that greater clarity on the issue of patentable subject matter should lead to greater confidence in the long-term financial projections required for making critical transaction decisions in the life sciences sector.

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