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Biotech: Guidance changes US patentability and its impact in Mexico

How relevant is the US Patent and Trademark Office's Eligibility Guidance released in response to the Supreme Court's rulings in *Myriad* and *Mayo* for PCT applicants? Alejandro Luna Fandino and Erwin Cruz, Olivares, Mexico investigate.

Substantial changes to biotechnology patent practices have recently occurred in the US. The changes should certainly have caused patent applicants to adjust their strategies for achieving patent protection, and particularly, to achieve patent eligibility for their innovations. Strategies for Patent Cooperation Treaty (PCT) patent applicants whose first filing is not at the US Patent and Trademark Office (USPTO) should certainly deal with not only the complex task of getting commercially meaningful and enforceable US patents, but also with how not to exclude valuable subject matter that is patent eligible in other jurisdictions, such as in Europe and Mexico. This article provides an overview of the changes and some points to bear in mind when developing patent strategies.

Résumés

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The guidance

The USPTO issued on March 4, 2014, Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, and Natural Products[1] for its patent examiners to help them assess claims reciting or involving laws of nature, natural phenomena, and natural products. The Guidance was released in view of the recent US Supreme Court decisions over the statutory provision for patent eligibility, 35 U.S.C. § 101. These decisions are, particularly, the *Myriad*[2] and *Mayo*[3] rulings.

Whilst *Myriad* relates to compound claims and ineligibility of products of nature, *Mayo* relates to method claims and ineligibility of laws of nature. In *Myriad,* the Supreme Court ruled that a naturally occurring DNA segment is 'not patent eligible merely because it has been isolated'. The Court reasoned that, according to the *Chakrabarty*[4] ruling, claimed subject matter should be markedly different form products of nature. Therefore, while isolated DNA is not patent eligible in view of its identical structure with natural occurring DNA, complementary DNA (cDNA) is eligible for protection by virtue of its non-naturally occurring and structural difference.

In *Mayo,* the Supreme Court reasoned that, in order to be patent eligible, method claims should add 'significantly more than simply describe' natural relations, such as administering a known drug for a known condition according to the relation between them. The Court conceded that administering a drug implies human intervention; however, the Court considered that the method under analysis was 'purely conventional or obvious'.

In the Forum[5] of May 9, 2014, hosted by the USPTO for receiving public feedback on this issue, the Office provided an overview of the Eligibility Guidance[6]. The USPTO's interpretation is basically that there are two pathways for patent eligibility analysis: the 'markedly different' *Chakrabarty (Myriad)* pathway, and the 'significantly more' *Mayo* pathway. The patent subject matter should be, therefore, 'significantly different' (a mixed formed from 'markedly different' and 'significantly more' phrases), in order to be patent eligible.

The impact

The new UPSTO position has already had impacts for applicants seeking patent protection. The 2014 Bloomberg BNA study[7] reports that, from 1000 patent applications with related biotechnologies filed between April 2011 and March 2014, 40% have been rejected based on the USPTO's interpretation of the rulings. Although there is an overlap, *Myriad* was the base for rejection in 23% of cases, and *Mayo* was the base for rejection in 35% of cases. These claim rejection rates are notably higher than those of previous years[8].

The USPTO's new position has been widely criticized by stakeholders, such as the Biotechnology Industry Organization[9] (BIO), the American Intellectual Property Law Association, and the American Bar Association[10]. The plausible critics have gone from qualifying the Guidance as an unduly large expansion of the patentability-exclusion to products that were not subject matter of the Court decisions, to oppositions of importing patentability standards into a patent-eligibility analysis.

It has been pointed out that the *Myriad* ruling limited itself to DNA, while the Guidance broadened the scope of this ruling to non-related products, such as antibiotics, pharmaceutical compositions, industrial enzymes, and methods of treatment using medicinal molecules. Moreover, it has been argued that the 'significantly different' approach is inappropriate, as nowhere did the Supreme Court hold that patent eligible products must be both significantly more and markedly different. BIO pointed out, however, that there is no a unified reading of Supreme Court case law 'that is fully coherent, free of internal tension, and that operates harmonically with the other requirements of patentability'.

It was observed that further dialogue is required to achieve the best interpretation and outcome. As a result of several and diverse comments, the USPTO requested the public to submit written comments to their Guidance before July 31, 2014.

Example and feedback

At the 2014 BIO International Conference, the USPTO provided a sample of claims[11] that would meet the patent eligibility criteria, within the proper context. The example relates to a hypothetical naturally occurring antibiotic, antibiotic L, produced by particular bacterial species. This antibiotic, however, is not naturally occurring in humans or mice. The first two claims cover 90% rather than 100% of the sequence of an isolated DNA or a polypeptide. The third claim adds to the sequence a fluorescent label attached to the nucleic acid. While the fourth claim is for a chimeric or humanized antibody, the seventh claim is for a human or fully human antibody. The fifth claim is for a purified version and the sixth is for the antibody expressed by recombinant yeast.

More than 20 public comments[12] to the Guidelines and the sample of claims have been submitted to the USPTO before the deadline. Some commentators have observed that 'marked difference' should be considered as a difference in function rather than a difference in structure, and that real examples should be used rather than hypothetical ones. Furthermore, there have been several concerns about the enforceability and commercial value of patent claims similar to those elaborated by the USPTO.

Other jurisdictions

Whilst it is not yet certain what changes will be made by the USPTO to its Guidance and practices, PCT applicants' strategies should deal with both getting meaningful US patents and preserving valuable patentable subject matter in other jurisdictions.

This is the case with, for example, DNA sequences claims. Notwithstanding its identical structure with a sequence in nature, an isolated sequence or a partial sequence of a gene, as long as it has a specific function, is patent eligible within member states of the European Patent Convention (EPC) and the European Union, as well as in Mexico[13].

This is relevant for PCT applicants whose priority or subsequent filing is in the US. On the one hand, in cases where an applicant has filed its application first in the US claiming less than the whole corresponding sequences (90% as in the USPTO example), the applicant would face important obstacles to claim the complete sequences in other jurisdictions, such as in Europe or in Mexico. Whilst the Mexican application should not pretend additional rights than those claimed in the application filed abroad, pursuant to Article 41(II) of the Mexican IP Law, the European application should claim the same invention, according to Article 87(1) of the EPC.

In contrast to the Mexican Patent Office (IMPI), the European Patent Office (EPO) has clarified in its Guidelines for Examination that it will be the same invention 'only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole' (F-VI, 1.33). On the other hand, applications for the US where the priority is from Europe or Mexico, may face claim rejection, as isolated DNA is no longer patent eligible. They would be requested to show why their claimed subject matter is markedly different from that naturally occurring.

On this grounds, analyzing and adjusting claimed wording and first filing practices, among other practices, are key for PCT applicants to avoid losing protection and/or enforceability of valuable intangible assets. There are several factors that would help the USPTO to achieve the best outcome to promote innovation and to provide legal certainty to stakeholders. Meanwhile, adaptive patent strategies are essential for PCT biotechnology patent applicants.

[1] http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf
[2] *Association for Molecular Pathology v Myriad Genetics, Inc.*, 569 U.S. _, 133 S. Ct. 2107, (2013): http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf
[3] *Mayo Collaborative Services v Prometheus Laboratories, Inc.,* 566 U.S. _, 132 S. Ct. 1289, (2012): http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf
[4] http://www.uspto.gov/cgi-bin/exitconf/internet_exitconf.pl?target=bulk.resource.org/courts.gov/c/US/447/447.US.303.79-136.html
[5] http://www.uspto.gov/patents/announce/forum-agenda_20140509.pdf
[6] http://www.uspto.gov/patents/announce/may9forum_uspto.pdf
[7] http://www.bna.com/BIO_2014_PR/
[8] M. McFarlane *et al*, 'Stopped at the Threshold: The Practical Implications of the Supreme Court's Mayo and Myriad Decisions on Biotechnology Patent Practices' *Bloomberg BNA*, 2014.
[9] http://www.uspto.gov/patents/announce/may9forum_bio.pdf
[10] http://www.uspto.gov/patents/announce/may9forum_aba-ipl.pdf
[11] http://www.uspto.gov/patents/announce/bio_sample_claims_2014-06-25.pdf
[12] http://www.uspto.gov/patents/law/comments/myriad_mayo_guidance_comments.jsp
[13] Articles 5.1 and 5.2 of the Biotechnology Directive 98/44/EC, rule 29 of the Implementing Regulations of the EPC, Articles 15, 12(IV) and 16 of the Mexican IP Law.