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AND THE WINNER IS……?

Since the publication of the most recent Myriad/Mayo Guidance in March, 2014 [1], and its widespread negative reception by both the Biotech and IP communities, USPTO spokespersons have encouraged and engaged in extensive public discourse on the subject of Patent Eligibility (101) in light of the recent Supreme Court decisions in Mayo (Mayo Collaborative Services v. Prometheus Laboratories, Inc, 2013 [2]) and Myriad (Association for Molecular Pathology v. Myriad Genetics, Inc, 2012 [3]). Recent statements by Ms. June Cohan, Legal Advisor with the USPTO's Office of Patent Legal Administration have created an expectation that some of the criticism of the USPTO's interpretation of the Mayo/Myriad decisions has been considered, and that a significant revision of the Guidance is underway and soon to be announced.

Background

In the Mayo decision, the Supreme Court ruled that: "(1) a newly discovered law of nature is itself unpatentable and (2) the application of that newly discovered law is also normally unpatentable if the application merely relies upon elements already known in the art." This ruling calls into question the patent eligibility of many types of method claims, and particularly diagnostic methods. In the Myriad decision, the Supreme Court tried to distinguish between scientific discovery and invention: "Groundbreaking, innovative or even brilliant discovery does not by itself satisfy the 101 inquiry" and, in a reversal of previous practice, ruled that a naturally occurring gene or DNA sequence does not become patent eligible by its isolation from the genomic context: "It [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." The USPTO's implementation of these landmark decisions, born in controversy, has become a controversy in itself.

Guidelines

In March, 2012, the USPTO issued preliminary guidelines for determining Patent Eligibility for Patent Examiners [4] and, in July 2012, issued the first Interim Guidance on Process Claims [5], holding that in order to be patent eligible under 35 USC 101, "A claim that focuses on a law of nature, a natural phenomenon, or naturally occurring correlation (principle)…" must include "more than that natural principle and general instructions to apply it." A sharp increase in the frequency of rejections of method claims under 101 was evident immediately thereafter, and has continued since. Particularly affected are diagnostic method claims.

In March 2014, in the wake of the Myriad decision, the USPTO issued updated Guidance for Determining Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena and Natural Products [6]. The March 2014 Guidance added "Natural Products" (and "abstract

[1] Myriad/Mayo Guidance (USPTO website, 4.3.2014)
[2] Supreme Court decisions in Mayo (Supreme Court of the United States, 20.3.2012)
[3] Supreme Court decisions in Myriad (Supreme Court of the United States, 13.6.2013)
[4] USPTO preliminary guidelines on Examination Procedure (USPTO website, 21.3.2012)
[5] Interim Guidance on Process Claims (USPTO website, 3.7.2012)
[6] Updated Guidance for Determining Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena and Natural Products (USPTO website, 4.3.2014)

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ideas") to the list of "judicial exceptions" to patent eligibility, and established two overarching criteria for evaluating claims under 101: presence of any product which is not "significantly different" from *any* naturally occurring product (not only nucleic acids), "significantly different" being defined as "markedly different in structure" or including, in addition to the natural product "an element or step which is other than well-understood, purely conventional and/or routine". Regrettably, the Guidance has illustrated the use of the new criteria with examples of obvious eligibility (e.g. method employing a novel Ab) or obvious ineligibility (method using a wild-type BRCA2 sequence), avoiding the more common but poorly defined area of questionable eligibility. This approach has now been interpreted in the Patent Office as rendering both composition and method claims which recite any naturally occurring products subject to rejection on the basis of patent ineligibility under 101, regardless of any functional differences that may exist between the naturally occurring and claimed product. Inventors and Patent Attorneys are already contending with a marked increase in 101 rejections. By way of illustration, we (at Ehrlich and Fenster, Ltd.) have recently received 101 rejections for kits deemed novel but comprising naturally occurring products and for diagnostic methods employing novel combinations of markers.

Practical and Legal Considerations

The Biotech and IP communities have criticized the Guidance as being unfaithful to basic principles of Patent Law, going beyond the Supreme Court's intent in the Mayo/Myriad decisions, dangerously restrictive to drug development and having a "chilling effect" on innovation in general. In particular, they claim that the Court's recent decisions were narrow and did not address patent eligibility of natural products, and that the Court had even cautioned against an expansive reading of the decision. Further criticism of the Guidance holds that it creates an analysis in which the claim is not examined as a whole, violates international trade agreements and undermines global patent harmonization efforts. Other critics have pointed out that nearly every pharmaceutical composition currently in use includes at least one naturally occurring product (as active ingredient or otherwise), pointing to the irrationality of the Guidance's focus on structural differences (to the exclusion of functional differences) as a means of satisfying the significantly different standard. Criticism has even been heard from USPTO Patent Examiners, complaining of the 101 criteria as an obstacle to fair and judicious examination of inventions.

USPTO Reconsiders

In response to mounting criticism, and following many rounds of the public forum for discussion of the Mayo/Myriad Guidance, the USPTO s Legal Advisor, Ms. Cohan, has promised revised Guidance, originally slated for October 2014 but now delayed for unclear reasons. Speaking at recent meetings of BIO (Biotechnology Industry Organization), Ms. Cohan addressed four issues: the breadth of the Guidance, the patent eligibility of discoveries, the impact of examining claims that are directed to a judicial exception rather than those that merely recite or involve a judicial exception, and the Guidance's "significantly different" standard. Ms. Cohan defended the USPTO s interpretation of legal underpinnings of the Mayo/Myriad decisions, reminding listeners that, despite the express language of 35 U.S.C. § 101 that "[w]hoever invents *or discovers* any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor. . ." the Supreme Court had consistently held that "a mere discovery of nature's handiwork" is not patent eligible. However, Ms. Cohan conceded that the distinction between patent eligible and patent ineligible discoveries can be somewhat confusing.

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On the critical issue of the difference between claims *directed* to a judicial exception and those that merely *recite or involve* a judicial exception, Ms. Cohan indicated that the revised Guidance would focus on the (allegedly) narrower category of claims that are *directed* to a judicial exception.

Finally, addressing the "significantly different" standard, which "brings together the outcomes of both *Myriad* and *Mayo*" by merging the "marked difference" standard of *Chakrabarty*, which was applied in *Myriad*, with the "significantly more" standard of *Mayo*, which was applied in *Alice Corp.*, Ms. Cohan argued that the Office did not intend to merge the two standards, and announced (once again) that the phrase "significantly different" would not appear in the revised Guidance, and that the Office would be "sticking closer to the cases." Further, Ms. Cohan indicated that the revised Guidance would allow applicants to demonstrate that the claimed subject matter is "markedly different" from a natural product by showing differences in function or utility. Ms. Cohan also noted that the complex, twelve-factor test of the original Guidance would not appear in the revised Guidance. While not yet a cause for celebration, many expect the new Guidance to streamline ongoing prosecutions and provide renewed interest in Biotech innovation and development.

Of relevance is the different approach to the issues of patent eligibility of natural products taken in European Patent Law. Article (3)(1) of EP Directive 98/44 EC [7], issued in 1998(!) clearly states that inventions shall be patentable "even if they concern a product consisting of or containing biological material or a process by means of which the biological material is produced"; and Article (3)(2) further confirms that: "Biological material which is isolated from its natural environment…may be the subject of an invention even if it previously occurred in nature". Thus, in European practice, identity of a product with a natural product is not a barrier to patentability as long as an application describes the industrial applicability of the claimed subject matter. This borne out in the fact that the Mayo and Myriad European National Phase applications have not encountered anything like the challenge to patent eligibility that their corresponding US applications experienced.

While revised Guidance may alleviate some of the uncertainty surrounding current USPTO practice regarding patent eligibility, and aid in heightening interest in patenting in the field of Biotechnology, drawing on the experience with the KSR guidelines for determining obviousness [8], it seems that the Industry will have to wait for sufficient case law to accumulate before a clear and coherent, well reasoned interpretation of the Supreme Court's decisions in Mayo/Myriad becomes available for Examiners, Industry and IP practitioners alike. The professional advice of experienced Patent Attorneys can be particularly valuable for their clients in managing their patent portfolios and strategizing prosecution to minimize limits on scope of protection during such periods of legal uncertainty. Ehrlich & Fenster, Ltd. invites interested parties to find out more about Mayo/Myriad in person.

Thanks to Daniel Zuhn, Kevin Noonan and Andrew Williams at PatentDocs Blog for keeping us current on this and other Biotech issues.

[7] Directive 98/44/EC of the European Parliament and of the Council (Official Journal L 213, 30.07.1998 P. 13-21)

[8] Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex (GPO, Federal Register / Vol. 75, No. 169, 1.9.2010)

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