Burdens of Section 101 following *Myriad*

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The Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics Inc., 2013 DJDAR 7484 (2013),* held that Myriad's claims directed to "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated." In addition, the court held that "cDNA is patent eligible because it is not naturally occurring."

Left largely unaddressed by this decision was who bears the initial burden during the patent examination process of showing that a claimed invention is in fact naturally occurring as well as what evidence is needed to meet that burden.

Shortly after *Myriad*, the U.S. Patent and Trademark Office (USPTO) issued a memorandum on June 13 instructing patent examiners to reject composition claims drawn solely to naturally occurring nucleic acids or fragments thereof. Unfortunately, the memorandum failed to address which party (patent applicant or patent examiner) bears the initial burden of demonstrating that the claimed invention is naturally occurring (or not) and what sort of evidence would need to be presented, if any, to make that showing. No additional *Myriad*-related guidance has been issued by the USPTO to-date.

The examination guidelines of the Manuel for Patent Examining Procedure (MPEP) for Section 101 provide some additional insight in Section 2106: "USPTO personnel should review the totality of the evidence (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter. USPTO personnel must weigh the determinations made above to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole either falls outside of one of the enumerated statutory classes or within one of the exceptions to statutory subject matter. 'The examiner bears the initial burden... of presenting a prima facie case of unpatentability.' *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the record as a whole suggests that it is more likely than not that the claimed invention would be considered a practical application of an abstract idea, physical phenomenon, or law of nature, then USPTO personnel should not reject the claim."

This section of the MPEP states that the initial burden of presenting a *prima facie* case of unpatentability under Section 101 falls on the patent examiner based on Federal Circuit precedent from 1992. However, the guidance offered by this section of the MPEP fails to clearly consider what sort of evidence, beyond the "totality of the evidence," is needed for the patent examiner to make such a *prima facie* case, and in particular what evidence is needed to make a *prima facie* case against a composition claim.

A patent ineligible composition claim drawn solely to a naturally occurring product would necessarily be directed to something that must physically exist in nature. As a result, assuming that the naturally occurring product has been reported at some point in time in the literature, the evidence needed to demonstrate that a claimed composition is directed to a naturally occurring product should be ascertainable and identifiable within the art, both the prior art and non-prior art. So, while it can be challenging to determine whether a particular method claim may or may not be directed to an abstract idea; it should not be unduly challenging to determine whether the subject matter of a composition claim physically exists in nature. The evidence necessary to make such a determination, and thus a *prima facie* case, should be ascertainable by a patent examiner, e.g., via routine database searching. Though such searching should be more broadly conducted by the patent examiner to also include literature that would not qualify as prior art under Section 102 or Section 103 since the scope of Section 101 is not limited by application filing or invention dates.

The more challenging inquiry is what to do in the event that a claimed composition might be naturally occurring but no significant evidence can be found in the literature to make the needed determination for patent eligibility purposes under Section 101. In this regard, the Supreme Court provided guidance for a similar situation in Footnote 8 of *Myriad*, stating: "The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable." This indicates that the correct path for a patent examiner to take when faced with a situation involving a claimed composition that *might* exist in nature is to allow that claim to pass Section 101 scrutiny. Not only can a *prima facie* case not be made by a patent examiner in the absence of evidence showing the existence of a claimed composition in nature, but the Supreme Court has instructed that the possibility that it might exist in nature is also not enough.

Thus, when a composition claim is presented by a patent applicant the Section 101 inquiry should proceed with the initial burden falling on the patent examiner to determine whether the claimed composition is naturally occurring or not. If evidence can be ascertained (e.g., via database searching similar to the searching normally conducted for examination under Section 102 or Section 103) that the claimed composition is naturally occurring then the claim should likely be rejected under Section 101 as ineligible for patenting in the U.S. However, if no significant evidence can be found by the patent examiner that the claimed composition exists in nature then the claim should pass Section 101 scrutiny even if the claimed composition might exist in nature.

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