EXAMINING PUBLIC POLICY IMPLICATIONS OF GENE PATENTING POST-MYRIAD v AMP

PACEOMICS

Event

SCOTUS rulings in in the *Association of Molecular Pathologists (AMP) v. Myriad Genetics* and *Mayo v. Prometheus* that help define what can be patented in the genetic and diagnostics field were eagerly awaited by personalized medicine stakeholders including policy-makers, academics, industry, clinicians and patient groups. Stakeholders are now considering the broader implications of these decisions.

Significance

Patents are a key asset in attracting and protecting investment for the biotechnology industry, however they may also lead to reduced public access to the products of such innovation, particularly in the case of patents on human genes[1]. SCOTUS rulings in these two cases have been criticized for increasing uncertainty, but also praised for ensuring that follow-on innovation can proceed without roadblocks.

Analysis

In the two decisions, SCOTUS held both that methods comprising the measurement and analysis of natural molecules in a person's body and isolated genes or parts of genes (gDNA) cannot be patented.

Gene patents seem to have limited value for bringing new diagnostics to patient care. Although empirical data is limited, they indicate that gene patents are not required to commercialize simple genetic tests. Further, the absence of patent exclusivity allowed many different providers to develop and offer tests, enabling robust methods to ensure quality and drive further innovation. The effect of gene patents on follow-on innovation has been a key policy concern, particularly the ability to do clinical whole genome sequencing without fear of infringement liability. The *AMP v. Myriad* ruling seems to have placed this kind of testing squarely in the clear. Thus, the SCOTUS decisions seem to provide more patient access and openness to innovation, yet lack of clarity and inconsistency may undermine these goals. In particular, *AMP v. Myriad's* cDNA/gDNA distinction has been criticized by geneticists, and will likely cause problems going forward. Likewise, the ruling raises questions about patentability of other 'natural' biotechnology, for example therapeutic monoclonal antibodies, entities that have been amongst the most clinically and financially successful medicines of the last decade. Patent-eligibility requirements will require further clarification to ensure efficient biotechnology innovation and a pipeline of beneficial products to consumers.

Conclusion

Through its decision in *AMP v. Myriad* and other cases, SCOTUS has recalibrated patent law. Ongoing empirical study is needed to measure the impacts of these rulings on innovation and patient access to diagnostic and genetic inventions, and inform policy development. In addition, further clarification of patentability requirements, as well as robust legal mechanisms to ensure equitable access to products of innovation are urgently needed.

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1. DNA patents and Diagnostics: Not a Pretty Picture (2010). Carbone J, Gold ER, Sampat B, Chandrasekharan S, Knowles L, Angrist M, Cook-Deegan R. Nature Biotechnology. 28(8) 784-791.