

## ***Implications of Policymaking and Court Decisions on Scientific Innovation***

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### INTRODUCTION

Recent court hearings and legislation proposals regarding biotechnology and biotechnological methods have proven to be unfavorable to several avenues of scientific research and innovation. There exists a tension between interests of the scientific community and the means through which legislation permits scientists to realize those interests. Factors larger than those of the scientific community must be taken into account when penning policy, and the same holds true for any interpretation by judiciary bodies. The presence of a strain between advocacy for the scientific community and objectiveness in order to allocate the products of scientific innovation permeates legislative decision-making. In recent years, it appears as though advocacy for private scientific innovation has decreased as issues surrounding distributive justice have increased.

### ANALYSIS

There has been a tightening of the reigns by the United States Supreme Court regarding patent cases involving biotechnology over the past few years. With landmark cases such as *Prometheus v. Mayo* (2012) and *AMP v. Myriad Genetics* (2013) there appears to be a trend of judicial precedence that is unfavorable to scientific innovation.<sup>1</sup>

In *Prometheus v. Mayo*, the court ruled that a patent is ineligible if it is deemed to be applying the laws of nature using conventional methods known to the field. In *AMP v. Myriad Genetics*, the court ruled that isolated human DNA was not patent-eligible, without applying existing case law, relaying that DNA is both “unique” in its own right, and a “physical embodiment of laws of nature” and therefore cannot be patented.<sup>2</sup> Both court decisions were deemed unfavorable by the scientific community. The current dispute over priority filing, scope of claim, and patent-eligibility of CRISPR/Cas9 technology<sup>3</sup> will be a critical determination that will likely have adverse legal consequences for the relationship between patent application, litigation, and scientific innovation.

The complexity of the bureaucratic process in which patents are granted (through the US Patent and

Trademark Office) leaves much room for error. The factors driving the discrepancies in the patent granting process are no doubt multifaceted, but the influx of patent applications and the limited resources of the patent office create a perfect storm for the spike in patent litigation cases filed within the past decade.<sup>4</sup> In addition, court rulings, such as the *Myriad* decision, have left many members of the scientific community confused. The verdict in *Myriad* misunderstands what scientific innovation is and as a result creates a tremendous gray area in which scientists have to be mindful of the law, thereby ignoring the reality of scientific innovation.

Patents assist scientific innovation due to their allowance of a government-granted monopoly for an extended period of time. However, considerations over the patentability of various prognostic and diagnostic methods may be considered an impediment to public health, precisely because of this monopoly. I assume that one (of many) purposes of policy is to allocate resources, in which case there is a delicate push and pull that occurs between private profits obtained from scientific innovation and public access to novel pharmaceuticals and biologics. While I do believe that the development of private enterprise is a critical component of driving scientific innovation, public access needs to be an equally important consideration. In preceding decades, the former has been granted greater weight, thereby detracting from the latter.

These policy implications illustrate larger issues and trends in statutory law. One major piece of legislation that recently passed and has questionable implications for the scientific community is the Biologics Price Competition and Innovation Act of 2009 (“Biosimilars Act”). It passed with the intention of promoting innovation of biologics and lowering their price, thereby increasing accessibility to the wider population. The Biosimilars Act is highly analogous to the Hatch-Waxman Act of 1984, which skyrocketed the production of generic drugs and tremendously lowered the price of small molecule drugs.<sup>5</sup> However, controversy exists over whether or not this is a realistic endeavor, given the scientific reality of the nature of biologics and the twelve-year exclusivity granted to innovator companies. The discrepancy between intention and outcome in the Biosimilars Act is speculative, but may be attributed to the lack of competition faced by biologic innovator companies.

## CONCLUSION

The discontinuity between policymaking, court interpretation, and their implications for scientific innovation that has emerged in recent years appears to be far from over. In fact, it is likely that such trends may lead to a battle between scientific innovation, legislation, and legal jurisdiction. The discontinuity also indicates that there is a delicate balance between the ability of self-regulation in the private sphere to promote scientific innovation and the oversight of government in its ability to properly allocate the products constructed from scientific progress.

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<sup>1</sup> Jost, Kenneth. “Patent Controversies.” *CQ Researcher*. CQ Press, 27 Feb. 2015. Accessed 10 Nov. 2015.

<sup>2</sup> Morrison, Alan J. “Rethinking the Gene Patent.” *Biotechnology Law Report* 29.6 (2010): 609–14.

<sup>3</sup> CRISPR/Cas9 is a molecular technology used for gene editing and gene regulation.

<sup>4</sup> Barry, Chris, et al. “2015 Patent Litigation Study: A Change in Patentee Fortunes.” PricewaterhouseCoopers LLP, May 2015.

<sup>5</sup> Lu, Ude. “Note: Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility.” *Minn J. L. Sci. & Tech.* 15.1 (2014): 613–51.