

# The Meaning of Myriad Conference

## Abstracts

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### Expressive Eligibility

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Patent eligibility law—in particular, the judicially-formulated litany of exceptions to eligible subject matter—has a heretofore underappreciated expressive function. In this Paper, we examine eligibility’s expressive function and pursue two lines of inquiry that the expressive perspective opens up. First, we analyze the eligibility exceptions as symbolic expression that is crucial in shaping public perceptions of the legitimacy of the patent grant. We argue that the eligibility exceptions serve this purpose by the mere fact of their existence, largely independent of the intensity of their enforcement. Second, we analyze the eligibility exceptions as expressive in a stronger sense: as a vehicle for expressing judicial preferences about desired norms in the patent community. More specifically, we articulate and defend the contrarian argument that the eligibility exceptions could be designed consciously to turn on claim format. That is, judges could structure eligibility jurisprudence so that it facilitates the development of desired claim drafting norms that minimize eligibility entanglements. This a controversial suggestion because it calls for courts to back away from eligibility law’s deeply-rooted anti-formalist commitment, usually encapsulated in tropes such as “eligibility should not depend on the drafter’s art.” We argue that eligibility rules should *facilitate* claim drafting, and we observe that the Court in *Myriad* missed an opportunity to deploy eligibility in this way.

## The New Genomic Semicommons

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In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court held that isolated DNA constitutes patent-ineligible subject matter. This result makes sense as a matter of innovation policy, in light of the promise and plummeting cost of genome sequencing. However, the decision's flawed reasoning based on a misconception of products and laws of nature could have wide-ranging negative effects on the nascent field of personalized medicine. Although *Myriad* ostensibly averts an anticommons tragedy associated with gene patenting, the decision may in fact worsen a growing commons problem in medical research. Heightened uncertainty surrounding the patentability of complex, data-driven discoveries could undermine socially productive sharing regimes by altering the private payoffs associated with cooperation. Rising patent eligibility hurdles coincide with intensifying regulatory scrutiny of medical diagnostics. The obvious concern is that the combination of an inability to patent genomic inventions and higher regulatory barriers to market entry could decimate the fledgling industry supporting personalized medicine. However, perhaps counter-intuitively, a carefully crafted regulatory scheme actually could promote innovation by acting as a "visible hand" to coordinate the generation and dissemination of patent-ineligible genomic information.

# **Myriad Genetics and the BRCA Patents in Europe: The Implications of the US Supreme Court Decision**

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Biotech patents are perhaps the most controversial form of property and the US Supreme Court decision in 2013 that simply isolated DNA constitutes natural products was applauded by many, particularly civil society groups and medical practitioners. From a legal perspective, the decision itself is brief and leaves much to be desired. Nevertheless, it is interesting to question what might be its potential impact on European research, the biotech industry and patent law. Given the fact that the Biotech Directive was in large part passed in order to keep the EU competitive with the US, it is possible that the EU gains an advantage over the US in terms of research and local industry. However, this is far from clear. At the same time, the US decision may re-light the fire surrounding the Biotech Directive, which was hotly debated and reluctantly implemented by the Netherlands, Germany and France. This article looks at patent law in Europe, as it pertains to biotechnology, before addressing what the potential possible implications may be of the US Supreme Court decision on research, the biotech industry and the policy debate in Europe.

**The Impact of *Myriad Genetics* on Scientific Research:  
Definitional Fluidity and the Legal Construction of Nature**

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Much of the attention surrounding *Myriad Genetics* has focused on the impact of “gene patents” on patient access to diagnostic tests. However, an important corollary issue is the impact of such patents on scientific progress. Accordingly, this Article examines the implications of the Supreme Court’s opinion for biomedical research, particularly focusing on its ruling that isolated DNA does not comprise patentable subject matter. At the outset, it argues that this issue is beset with complexity and definitional difficulties. For example, “commercial” uses of diagnostic tests may yield important research insights, and oftentimes perceptions of the law are more important than doctrinal reality. With this in mind, this Article explores the impact of *Myriad Genetics* from three perspectives. First, considering the conduct of Myriad Genetics itself, it argues that the Supreme Court’s decision creates greater real and perceived freedom to operate for uses of BRCA genes that may yield important scientific insights. Second, reviewing the literature on gene patents and anticommons more generally, this Article argues that the Court’s ruling may help accelerate biomedical research in broader areas related to diagnostic testing. Third, at a doctrinal level, this Article suggests that *Myriad Genetics* may have significant long-term implications. In articulating a strong policy approach to § 101 inquiries and drawing (arguably incorrect) distinctions between isolated DNA and cDNA, the Court exhibited a striking degree of malleability in its conception of patent-ineligible natural phenomena. Such a policy-oriented approach to patent eligibility may create significant flexibility to challenge patents in scientific research going forward.

## **Can *Myriad* be Reconciled with *Mayo*?**

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The Supreme Court decision in *Myriad Genetics* is only one of a series of recent Supreme Court decisions addressing the scope of patentable subject matter. In particular, the subject matter decision in *Mayo v Prometheus*, just previous to *Myriad*, set out a two part test for patent eligibility that seems inconsistent in fundamental respects with *Myriad*. But the Supreme Court has since confirmed *Mayo* as the fundamental approach to patentable subject matter in *Alice Corp v. CLS Bank Int'l*. It is not clear how that framework can be reconciled with the result in *Myriad*. Fitting the *Myriad* decision into the Supreme Court's subject matter jurisprudence requires an imaginative re-thinking of the basis for patent eligibility.

## **Patentable Subject Matter and Non-Patent Innovation Incentives**

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In four patentable subject matter cases in the past five Terms, the Supreme Court has repeatedly reaffirmed the judicially created prohibitions on patenting “abstract ideas” or “nature.” But since the Court has failed to give much guidance beyond its specific holdings, the boundaries of these exceptions remain highly contested. The dominant justification for patentable subject matter limitations is utilitarian, so debates often focus on whether patents are needed to provide adequate innovation incentives in disputed subject matter areas such as software or genetic research, and whether their costs outweigh these benefits. Yet many participants in these debates ignore that the absence of patents does not imply that there would be only private incentives such as reputational gains or first-mover advantage. Rather, federal and state governments facilitate transfers to researchers through a host of mechanisms—including tax incentives, direct grants and contracts, and prizes—which already provide substantial research support in the fields where patents are the most controversial.

Paying attention to non-patent incentives is particularly important in patentable subject matter cases, as it could prevent courts from being misled by the concern that a lack of patents for a certain type of invention would remove all incentives for nonobvious and valuable research in that field. Non-patent innovation incentives could also help ease the tension between utilitarian and moral considerations in the current patentable subject matter debates: if many people find patents on certain inventions (such as “human genes”) morally objectionable, utilitarian goals can still be served by using other transfer mechanisms to substitute for the incentive effect of patents. Indeed, non-patent incentives may be more effective than patents in these areas, where inventors who share moral objections find little incentive in patents, and those who don’t still find the patent incentive to be dulled by the persistent uncertainty that has plagued patentable subject matter doctrine in recent years. Wider appreciation of the range of innovation incentives would help bring patentable subject matter discussions in line with the realities of scientific research, and might even make this doctrinal morass more tractable.

## ***Myriad* Lessons Learned**

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This Article presents the *Myriad* litigation as a cautionary patent tale, one that explores a more fundamental question—how can patent law, in the words of Benjamin Cardozo, “mediate between the conflicting claims of stability and progress?” The commercialization of breast cancer diagnostic testing, chronicled from *Chakrabarty* to *Myriad*, demonstrates how stability within patent law’s eligibility doctrine, a limited ability to challenge gene patents despite vocal critics, and the strength of gene patents to exclude others within markets like those for genetic testing converged to slow progress within the law, resulting in a commercial monopoly based upon later-invalidated patents and unintended consequences for all stakeholders. This Article explores the age-old dilemma of stability and progress, using *Myriad* as an illustrative example—examining the doctrines of patent eligibility and standing in the case, as well as the consequences of *Myriad*’s monopolization of the breast cancer diagnostic testing market for genetic researchers, healthcare professionals, and their patients. The Article also offers several suggestions that might mitigate the mistake of relying too heavily on patent law stability at the cost of progress of both law and technology, especially in light of ever-changing social, scientific, and economic realities, as demonstrated in *Myriad* itself.

## **What Does It Mean To Invent Nature?**

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Over the last few years, there has been a lot written about Myriad Genetics' controversial patents in relation to its BRCA related patents for breast cancer. Most of the literature reads as if it was written either as an amicus curia brief or as a policy submission to some fictitious inquiry. The aim of this paper is to stand back from the debates about the relative merits of the Myriad patents to consider why it is that subject matter has created so many problems in both the United States and in Australia. In a sense the question that underpins this paper is: why is it that patent law has experienced so many problems in dealing with the type of 'invention' that is at stake in the Myriad litigation? In effect, it asks what is at stake in asking the question: what does it mean to invent nature? This is not intended as an apology for the decisions, or as a commentary on the patents at issue in those decisions. Instead it attempts to situate the US and Australian litigation as part of a broader discussion about subject matter jurisprudence and the challenges currently facing patent law in both jurisdictions.