THE 'SOCIO-TECHNICAL IMAGINARIES' OF BIOTECHNOLOGY PATENT LAW

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AIMS

In this presentation I will :

1. Discuss the concept of the 'socio-technical imaginary'.

2. Examine the 'imaginary' of biotechnology and patent law in the US from 1990-2020 (the HGP and 'gene patents').

3. Compare and contrast the 'imagined future' with the way events actually unfolded.

4. Draw insights to inform current patent policy debates.

1. What is a ‘socio-technical imaginary’?

DEFINITIONS

Socio-technical imaginaries are:

"collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of, advances of science and technology".

S. Jasanoff, S.H. Kim, *Dreamscapes of Modernity* (University of Chicago Press, 2015), p 4.

DEFINITIONS

"Imaginaries, in this sense, at once **describe attainable futures and prescribe futures that states believe ought to be attained.** Such visions, and the policies built upon them, have the power to influence technological design, channel public expenditure, and justify the inclusion or exclusion of citizens with respect to the benefits of technological progress."

- Sheila Jasanoff, Sang-Hyun Kim, Stefan Sperling , 'Sociotechnical Imaginaries and Science and Technology Policy: A Cross-National Comparison', National Science Foundation, Summary and Proposal, NSF Award No. SES-0724133 (awarded September 2007).

DEFINITIONS

"National policies for the innovation of science-based technologies … balance distinctive **national visions of desirable futures driven by science and technology against fears of either not realizing those futures or causing unintended harm in the pursuit of technological advances.** S&T policies thus provide unique sites for exploring the role of political culture and practices in **stabilizing particular imaginaries, as well as the resources that must be mobilized to represent technological trajectories as being in the "national interest"**.

'ATOMS FOR PEACE'

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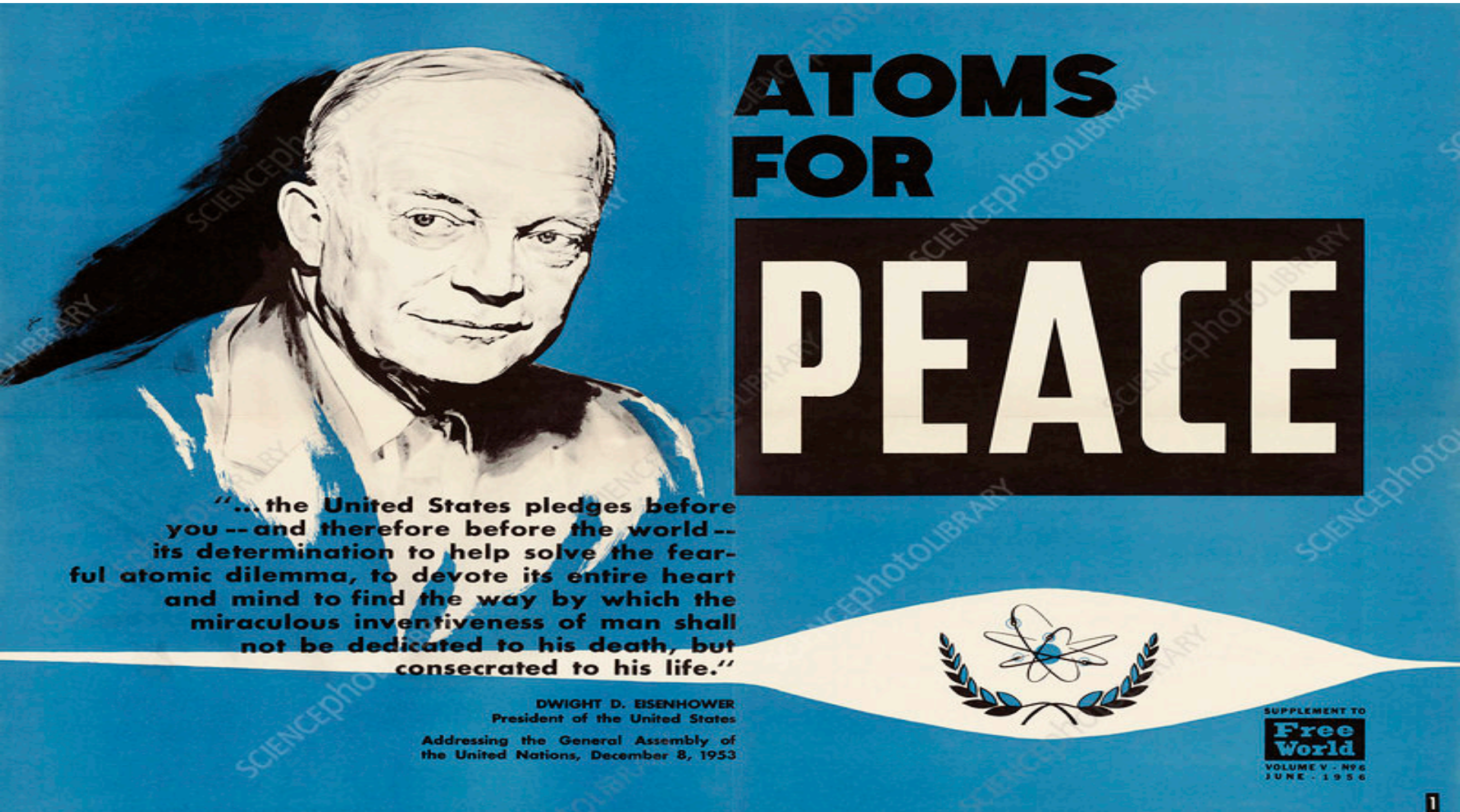


COMPARATIVE CASE STUDIES: US AND KOREAN NUCLEAR POWER POLICIES

	United States 'Atoms for Peace'	South Korea 'Atoms for Development'
Framing risks	Runaway accidents Catastrophic damage	Failure to develop Dependence on foreign powers
Policy focus	Containing radiation release	Building domestic capacity
Controversies	Safety of plants and disposal sites (e.g. Yucca mountain siting controversy)	Political inclusion and participation (e.g. Buan siting controversy)
Stakes	Responsible governance of hazardous technology	Accountable governance of (democratizing) nation
Closures	Legal decisions Nationalization of risk	Bureaucratic enforcement Appeal to "national interests"
Civic epistemologies	Quantitative risk assessment Expert-lay conflicts	Questioning national needs State-civil society conflicts

RISKS AND HAZARDS?

- Imaginaries may also warn of risks or hazards that might accompany innovation if it is pushed too hard or too fast.
- In activating collective consciousness, imaginaries may help create the political will or public resolve necessary to achieve them.

MULTIPLE SOURCES OF POWER

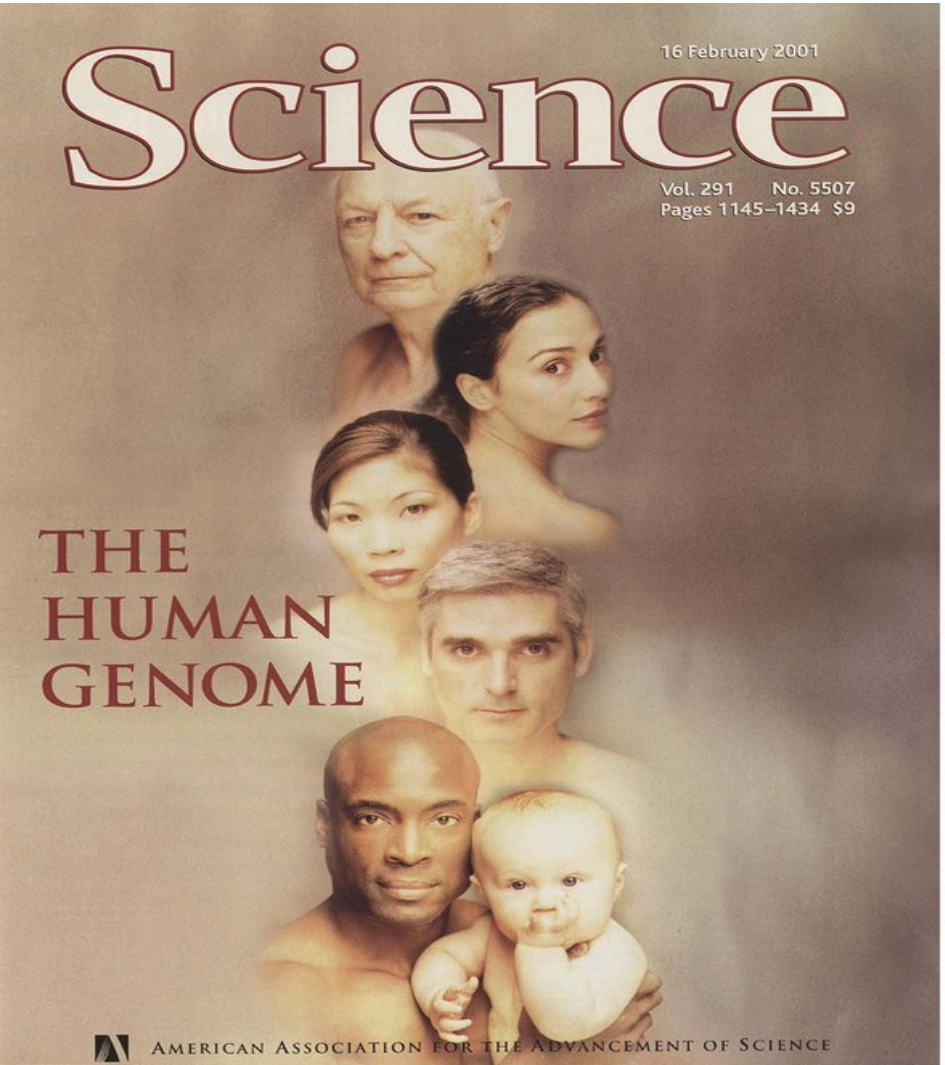
- Government is not viewed as a monolithic entity. Many parties are involved in attempts to regulate the conditions under which we (and/or others) live.
- These parties include not only diverse state agencies with competing visions, mandates and techniques, but scientists, activists and NGOs, both national and transnational, involved in arenas such as public health, welfare, agriculture, conservation, good governance etc.
- This perspective can allow us to see how different groups may be constituted as authoritative and powerful (perhaps in different ways).

LIMITS AND RESISTANCE

- Governmental interventions are important because they have effects. They seldom reform the world according to plan, but they do change things.
- Government interventions may also be resisted.
- Instead of seeing these situations as just ‘the people’ resisting ‘state power’, we can instead highlight the ways in which subjects are differently formed and differently positioned in relation to governmental programs (as experts, as targets), with particular capacities for action and critique.

2. The ‘imaginary’ of biotechnology and patent law in the US from 1990-2020.

SOCIO-TECHNICAL IMAGINARIES OF BIOTECHNOLOGY



IMAGINING THE FUTURE

In June 2000, President Bill Clinton and Prime Minister Tony Blair joined together via satellite link between Washington and London to unveil the first draft sequence of the three billion base pairs of the human genome. While it was a moment of profound scientific achievement, it was also cause for no small amount of hyperbole.

President. Clinton himself said at the time, "One day, we will know cancer only as a constellation of stars," a prediction which, while poetic, has certainly not yet been achieved."

HUMAN GENOME PROJECT – 1990 -2003

Molecular Medicine

- Improved diagnosis of disease
- Earlier detection of genetic predispositions to disease
- Rational drug design
- Gene therapy and control systems for drugs
- Pharmacogenomics "custom drugs"

IMAGINING THE FUTURE – HUMAN GENOME PROJECT

"On the horizon is a new era of molecular medicine characterized less by treating symptoms and more by looking to the most fundamental causes of disease. Rapid and more specific diagnostic tests will make possible earlier treatment of countless maladies. Medical researchers also will be able to devise novel therapeutic regimens based on new classes of drugs, immunotherapy techniques, avoidance of environmental conditions that may trigger disease, and possible augmentation or even replacement of defective genes through gene therapy."

THE NEED TO INVOLVE THE PRIVATE SECTOR

JOINT STATEMENT BY PRESIDENT CLINTON
AND PRIME MINISTER TONY BLAIR OF THE U.K. March 14, 2000

"To realize the full promise of this research, **raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere.** Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health around the world, and enhance the quality of life for all humankind. **Intellectual property protection for gene-based inventions** will also play an important role in stimulating the development of important new health care products."

PATENTS AND THE 'BIOECONOMY'

- Many actors argued that patent rights are integral to innovation, and worked successfully to remove barriers and expand the scope of patentability in relation to biotechnology.
- Isolated DNA was to be treated as a patentable 'invention', not an unpatentable 'discovery'.
- However, concern was expressed about the commercial framing and entanglement with patent rights.

US PATENT POLICY

- In 2001, the US Patent Office issued formal guidelines on what is acceptable patent material in the human genome. It stated that DNA is eligible if it is 'isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.' These guidelines specified that any gene or sequence patent also needs to show 'specific, credible, and substantial utility' .
- This policy change seems to have been viewed primarily as a technical matter by the USPTO, with little need for wider stakeholder or public consultation about the need, potential benefits and risks of the policy.
- In order to bring about the imagined bioeconomy and the associated medical benefits into being, DNA sequences would need to be viewed as 'man-made' (i.e. 'not a product of nature') through the steps of 'isolation' and 'purification'.

BIOTECH PATENTING – CRITICISMS AND CONCERNS

- By 2005, 40,000 'gene patents' had been granted associated with human genes.

Criticisms and concerns

1. Commercialisation would violate the norms of science, and undermine the free sharing of information, ideas and materials.
2. "Tragedy of the anticommons" – the possibility that the large set of patents on genes and their diverse set of owners would make it difficult to acquire all the rights to all necessary research inputs, which could, in turn, result in the underuse of valuable technologies.
3. Owners of patents on fundamental technologies will exercise their rights to exclude others from developing or accessing the technology.

3. Comparing and contrasting the ‘imagined future’ with the way events actually unfolded

EMPIRICAL STUDIES ON THE IMPACT OF 'GENE PATENTING'

- Despite the long-standing controversy surrounding patenting in the life sciences, only a small number of empirical studies have been conducted to date.
- **"There is no consensus about whether … patents hinder or help in the development and availability of genetic diagnostics, and empirical evidence about how these patents may affect commercialization of new genomic diagnostics is scarce**. This seemingly innocuous statement is an advance in the public debate, given that the alleged negative consequences and benefits of patents have so often been grossly overstated" (S Chandrasekharan and R. Cook-Deegan (2009).

MODEST SCIENTIFIC ADVANCES? TIME LAG?

- Carlota Perez, an economist who studies the effects of innovations on economic development, noted that:

" … the full fruits of technological revolutions … [are] … only reaped with a time lag. Two or three decades of turbulent adaptation and assimilation elapse from the moment when the set of new technologies, products, industries, and infrastructures make their first impact to the beginning of a 'golden age' or 'era of good feeling' based on them."

- C. Perez, *Technological Revolutions and Financial Capital* (Edward Elgar Publishing, 2002).

PRACTICAL PROBLEMS?

- According to some (limited) studies, neither anticommons nor restrictions on access were seriously limiting **academic research**, despite the fact that these researchers operate in a patent dense environment without a clear research exemption.
- But there is evidence of more secrecy and less sharing amongst university researchers.

IMPACT ON DIAGNOSTIC TESTING?

- Stronger evidence that gene patents covering diagnostic tests have caused problems in some cases.
- 25% of labs had abandoned one or more genetic tests as a result of patents. **Myriad Genetics'** patents were among the most frequently cited.
- 2010 – in several incidents, "patents have been used to narrow or clear the market of genetic testing, thereby limiting, rather than promoting availability of testing".
- US patients would struggle to pay for testing if their health insurance provider refused to cover.

ASSOCIATION FOR MOLECULAR PATHOLOGY V MYRIAD GENETICS (2013)

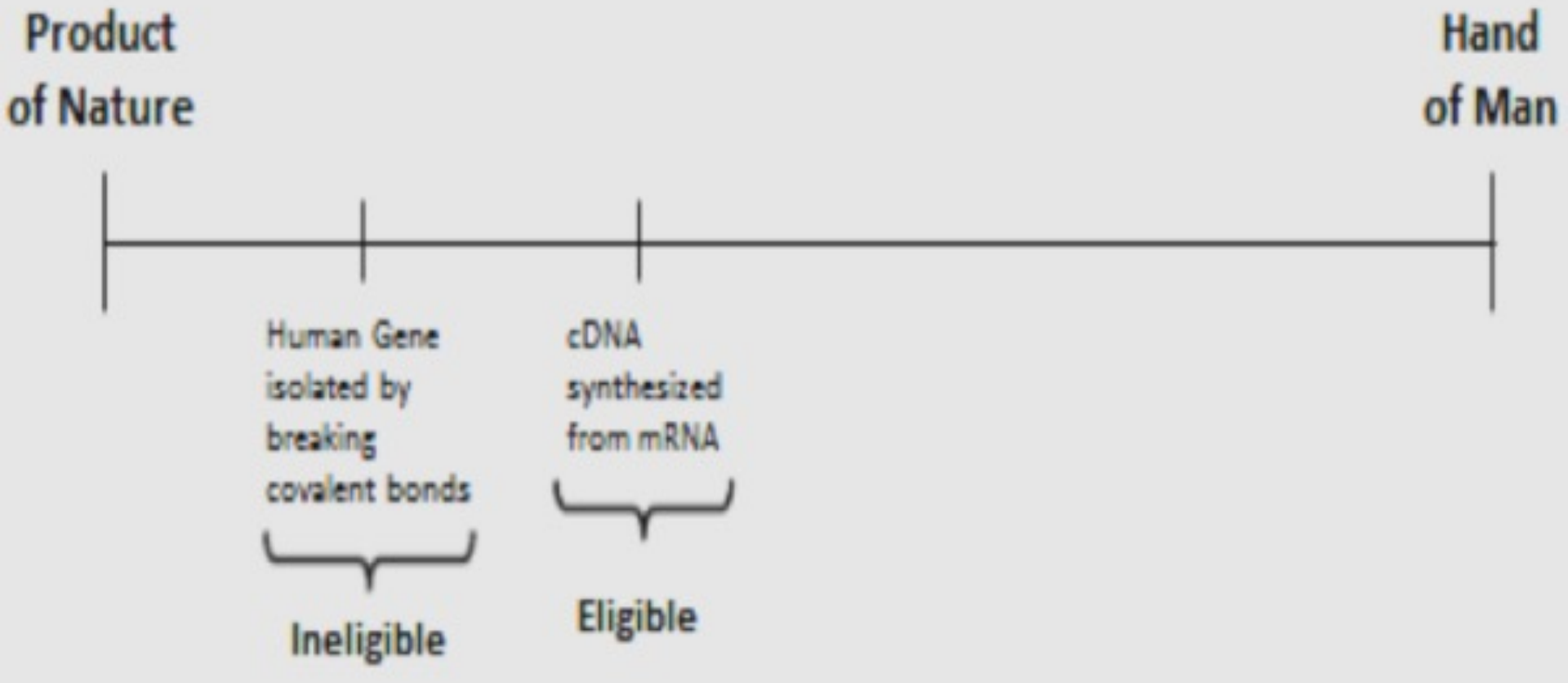
- Myriad refused to allow clinical laboratories to perform BRCA1 and BRCA2 tests, and threatened to sue US clinicians who did so.
- Negative publicity regarding Myriad and its business practices resulted in an advocacy suit, which aimed to invalidate gene patents on a large scale.
- In 2013, the US Supreme Court decided an appeal in A*ssociation for Molecular Pathology v Myriad Genetics, Inc*. It ruled that 'isolated human genomic DNA' is no longer patentable.

AMP V MYRIAD GENETICS (2013)

- Association for Molecular Pathology challenged several of Myriad's claims under 35 U.S. Code§101, arguing that genomic DNA and cDNA were unpatentable "**natural products**".
- Held: (9-0) A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but synthetic (not "naturally-occurring) cDNA is patent eligible if it is "distinct from the DNA from which it was derived".

AMP v. MYRIAD

Two Known Points on the Continuum



4. Drawing insights to inform current patent policy debates

PROPOSED US PATENT REFORMS

Jun 22 2023

- In June 2023, Sens. Tillis and Coons introduced the ***Patent Eligibility Restoration Act*** of 2023.
- Bipartisan legislation that aims to 'restore' patent eligibility to important inventions across many fields.
- The Bill asserts the basic principle that the patent system is central to promoting technology-based innovation and driving economic growth.

PROPOSED US PATENT REFORMS

- The socio-technical imaginary is partly framed in terms of a vision of an undesirable future that should be avoided.
- "Unfortunately, our current Supreme Court's patent eligibility jurisprudence is **undermining American innovation and allowing foreign adversaries like China to overtake us in key technology innovations."**

- It also aims to foster a 'new era' of the development of next-generation technologies across many innovative industries, including artificial intelligence, medical diagnostics, quantum computing, and telecommunications.

SEN. CHRIS COONS AND THOM TILLIS – DRAFT BILL TEXT, MAY 22 2019

(5) Under this Act, and the amendments made by this Act, the state of the law shall be as follows:

(A) All judicial exceptions to patent eligibility are eliminated

(D) The following inventions shall not be eligible for patent protection:

(iii) An unmodified human gene, as that gene exists in the human body.

(iv) An unmodified natural material, as that material exists in nature.

ASSUMPTIONS ABOUT THE PROPOSED BILL'S LIKELY IMPACT

"[W]e agree that nobody should be able to patent genes as they exist in the human body, but we do need to give researchers and business clarity on what medical innovations – including some that involve use of genetic material – can be patented. That's critically important, because if researchers and inventors don't have confidence that their work could lead to a patent, they might not pursue it at all, at least not in the United States."

Q: What does the evidence base suggest about the practical impact (positive or negative) of the *Myriad* decision on investment and innovation?

CONCLUSIONS

- 'Socio-technical imaginaries' may not be realised in the ways that we envision them, or within the anticipated timeframes. They can be useful (and are seemingly unavoidable), but should also be viewed with a healthy degree of scepticism.
- The degree to which patents supported the emergence of the desired bioeconomy and medical advances that were anticipated from around 1990-2020 is ambiguous. Are patents necessary but not sufficient?
- The pathways of scientific and technological development are not always linear and can be surprising and messy. Scientific challenges can be more complex than at first thought.
- The problems that emerged were not the ones that were initially predicted. A dispute between a company and a physician association?
- Patent law reforms are typically viewed instrumentally, and assume straightforward cause-effect relationships. The 'socio-technical imaginaries' lens questions and problematises this assumption.