

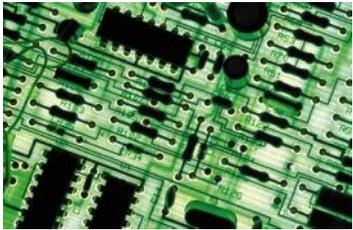
# **LAW AND TECHNOLOGY**

**SHEILA JASANOFF**

**HARVARD UNIVERSITY**

**TIJ-IGLP PUBLIC FORUM, BANGKOK, JANUARY 11, 2019**

# A CLASH OF CULTURES



## TECHNOLOGY

- Innovate
- Disrupt
- Change behavior
- Create winners
- Make possible new worlds

## LAW

- Conserve
- Follow rules
- Maintain order
- Compensate losers
- Decide how the world should be



# THE GOSPEL OF DISRUPTION

“YOU NEVER CHANGE THINGS BY  
FIGHTING THE EXISTING REALITY.  
TO CHANGE SOMETHING, BUILD A  
NEW MODEL THAT MAKES THE  
EXISTING MODEL OBSOLETE.”

**- BUCKMINSTER FULLER**



# “Law Lag”

## *In Genetic Testing for Paternity, Law Often Lags Behind Science*

By TAMAR LEWIN

BIG SPRING, Tex. — It should have been good news when Morgan Wise's doctor told him that genetic testing showed he was not a carrier of cystic fibrosis, the disease his youngest child, Rauli, has struggled with since birth.

But instead, the 1999 test results led to the complete unraveling of Mr. Wise's relationship with Rauli and his three other children.

“For a child to have cystic fibrosis, both parents have to be carriers,” Mr. Wise said. “When I got the results, my first thought was maybe we'd misdiagnosed Rauli. But the doctor came around from his desk and said, ‘I'm just going to come straight out with it: Is there any reason to think this boy may not be yours?’ He advised me to have DNA paternity testing. I was in such shock I couldn't even drive home.”

visitation rights, even with his biological daughter.

For centuries, courts have presumed that all children born within marriage are fathered by the husband. Because courts could not prove paternity, the thinking went, excluding any evidence of infidelity was the best way to protect children from the stigma of illegitimacy, men from the shame of cuckoldry — and society from marital disruption.

These days, though, genetic testing has made determining paternity simple, even routine. According to the American Association of Blood Banks, 280,000 paternity tests were conducted in 1999, three times as many as a decade earlier. And in 28 percent of the tests, the man tested was found not to be the father.

But in most states, the law has not caught up with the science. And in

“All the News  
That's Fit to Print”

# The New York Times

### Late Edition

New York Today, morning sun, some afternoon clouds, high 52. Tonight, mainly clear, breezy, low 33. Tomorrow, sunny skies, high 46. Yesterday, high 45, low 34. Details, Page 43.

# **A DIFFERENT VIEW**

**Law does not “lag” behind technology: it co-produces sociotechnical order**

- Intellectual property, for example

**Technological change tests and refines pre-existing social norms**

- Privacy, for example

**Law’s primary responsibility is to define and protect human values in contexts of change**

- Human dignity, for example

# US CONSTITUTION: INTELLECTUAL PROPERTY

## Article 1: The Legislative Branch

### Section 8

- The Congress shall have Power:

### Clause 8

- To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries

# REQUIREMENTS

## *Patentable subject matter*

- Any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof
- No prior publication
- Not obvious to a person having ordinary skill in the art to which said subject matter pertains

# ***SCIENCE MAY PATENT NEW FORMS OF LIFE, JUSTICES RULE, 5 TO 4***



## **DISPUTE ON BACTERIA**

Decision Assists Industry  
in Bioengineering in a  
Variety of Projects

By **LINDA GREENHOUSE**

Special to The New York Times

WASHINGTON, June 16 — The Supreme Court ruled today, 5 to 4, that new forms of life created in the laboratory are eligible for patents under current patent law.

The decision, upholding the award of a patent for a new bacterium that “di-

“anything under the sun that is made by man”

# **THE SUPREME COURT AND ITS “FRIENDS”**

**Genentech: “...it is not for this Court...to attempt like King Canute to command the tide of technological development”**

**Supreme Court: “... judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides”**

Do the words  
“composition of matter”  
and “manufacture”  
include  
higher life forms?  
Do they include genes?

# ONCOMOUSE (HARVARD MOUSE)

United States Patent [19]

Leder et al.

[11] Patent Number: 4,736,866

[45] Date of Patent: Apr. 12, 1988

- [54] TRANSGENIC NON-HUMAN MAMMALS
- [75] Inventors: Phillip Leder, Chestnut Hill, Mass.;  
Timothy A. Stewart, San Francisco,  
Calif.
- [73] Assignee: President and Fellows of Harvard  
College, Cambridge, Mass.

[21] Appl. No.: 623,774

[22] Filed: Jun. 22, 1984

[51] Int. Cl.<sup>4</sup> ..... C12N 1/00; C12Q 1/68;  
C12N 15/00; C12N 5/00

[52] U.S. Cl. .... 800/1; 435/6;  
435/172.3; 435/240.1; 435/240.2; 435/320;  
435/317.1; 935/32; 935/59; 935/70; 935/76;  
935/111

[58] Field of Search ..... 435/6, 172.3, 240, 317,  
435/320, 240.1, 240.2; 935/70, 76, 59, 111, 32;  
800/1

[56] References Cited

#### U.S. PATENT DOCUMENTS

4,535,058 8/1985 Weinberg et al. .... 435/91  
4,579,821 4/1986 Palmiter et al. .... 435/240

#### OTHER PUBLICATIONS

Ucker et al, Cell 27:257-266, Dec. 1981.  
Ellis et al, Nature 292:506-511, Aug. 1981.  
Goldfarb et al, Nature 296:404-409, Apr. 1981.  
Huang et al, Cell 27:245-255, Dec. 1981.

- Blair et al, Science 212:941-943, 1981.  
Der et al, Proc. Natl. Acad. Sci. USA 79:3637-3640,  
Jun. 1982.  
Shih et al, Cell 29:161-169, 1982.  
Gorman et al, Proc. Natl. Acad. Sci. USA



[57] ABSTRACT

A transgenic non-human eukaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal, or an ancestor of the animal, at an embryonic stage.

12 Claims, 2 Drawing Sheets

# LIMITS OF OWNERSHIP

**Canadian Supreme Court's "murine metaphysics"**

**"Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic characteristics of which they are composed. A person whose genetic characteristics are modified by radiation does not cease to be him or herself. *Likewise the same mouse would exist absent the injection of the oncogene into the fertilized egg cell: it simply would not be predisposed to cancer.*"**

# THE PATENTABLE GENE

“An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an **excised gene** is eligible for a patent as a composition of matter or as an article of manufacture **because that DNA molecule does not occur in that isolated form in nature**, or (2) **synthetic DNA** preparations are eligible for patents **because their purified state is different from the naturally occurring compound.**”

- USPTO, Utility Examination Guidelines, *Federal Register*, Vol. 66, No. 4, January 5, 2005, p. 1093.

# MYRIAD GENETICS: PROFITS FROM CANCER



**What Myriad claimed:**

**Patents on breast cancer test based on BRCA1 and BRCA2 genes**

**Patents on BRCA1 and BRCA2 genes**

**Patents on “methods” of using tests**

They're our breast cancer genes — we identified them.

It's kind of you to let us have the disease for free

LABORATORY



# ENTER: AMERICAN CIVIL LIBERTIES UNION

**Chris HANSEN (for ACLU), April 15, 2013:**

**“One way to address the question presented by this case is what exactly did Myriad invent? And the answer is nothing.**

**Myriad unlocked the secrets of two human genes. These are genes that correlate with an increased risk of breast or ovarian cancer. But the genes themselves, their -- where they start and stop, what they do, what they are made of, and what happens when they go wrong are all decisions that were made by nature, not by Myriad.**

**Now, Myriad deserves credit for having unlocked these secrets. Myriad does not deserve a patent for it.”**

# DISRUPTIVE LAW

- **Tania Simoncelli**
- **A.B. (Biology and Society) Cornell; M.A. UC Berkeley**
- **Senior thesis on bovine growth hormone**
- **ACLU senior scientist**
- **Constructing the case (defendant, patent, plaintiffs, experts)**



# **HOLDING: HUMAN GENES NOT PATENTABLE**

**It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them.**

**Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.**

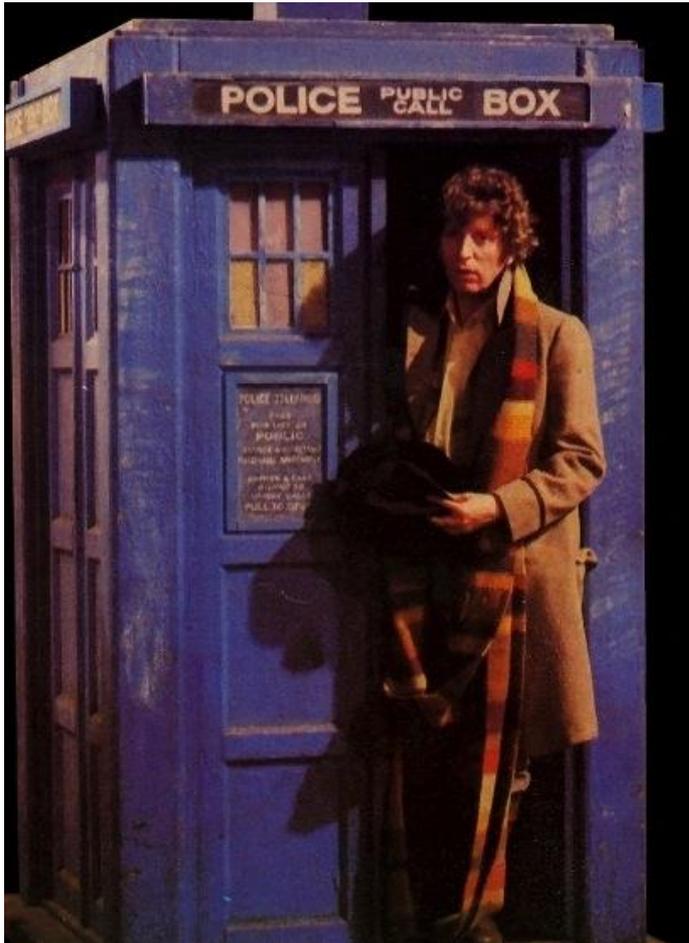
**Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.**

*In a pervasively  
monitored world  
what is a reasonable  
expectation of  
privacy?*

# FOURTH AMENDMENT AND PRIVACY

The **right** of the people **to be secure** in their persons, houses, papers, and effects, **against unreasonable searches and seizures**, shall not be violated, and **no Warrants shall issue, but upon probable cause**, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

# **KATZ V. UNITED STATES (1967)** **(OR WHAT IS A TELEPHONE** **BOOTH?)**



**Illegal gambling wagers being telephoned from LA to Miami and Boston**

**Wiretap of phone booth**

**No physical intrusion**

**No search warrant**

**Violates 4<sup>th</sup> Amendment?**

**7-1 decision in favor of Katz**

# JUSTICE HARLAN'S OPINION

“(a) that an enclosed telephone booth is an area where, like a home, and unlike a field, a person has a constitutionally protected reasonable expectation of privacy;

(b) that electronic as well as physical intrusion into a place that is in this sense private may constitute a violation of the Fourth Amendment; and

(c) that an invasion of a constitutionally protected area by federal authorities is, as the Court has long held, presumptively unreasonable in the absence of a search warrant.”

# TECHNOLOGICAL CHANGE



# **GPS CASE: US v. JONES (2012)**



**Drug trial of Antoine Jones**

**28 days of secret tracking of Jones via GPS device on Jeep**

**Trial on conspiracy to distribute drugs**

**Sentence: life imprisonment**

# JUSTICE BREYER IN JONES

"If you win this case then there is nothing to prevent the police or the government from monitoring 24 hours a day the public movement of every citizen of the United States. And no one, at least very rarely, sends human beings to follow people 24 hours a day. That occasionally happens. But with the machines, you can. So if you win, you suddenly produce what sounds like 1984."

# *Major Ruling Shields Privacy of Cellphones*

Supreme Court Says Phones Can't Be Searched Without a Warrant

By ADAM LIPTAK JUNE 25, 2014

“This is a bold opinion,” said Orin S. Kerr, a law professor at George Washington University. “It is the first computer-search case, and it says we are in a new digital age. You can’t apply the old rules anymore.”

Chief Justice John G. Roberts Jr., writing for the court, was keenly alert to the central role that cellphones play in contemporary life. They are, he said, “such a pervasive and insistent part of daily life that the proverbial visitor from Mars might conclude they were an important feature of human anatomy.”

# Tech Industry Pursues a Federal Privacy Law, on Its Own Terms

The New York Times

By Cecilia Kang

Aug. 26, 2018



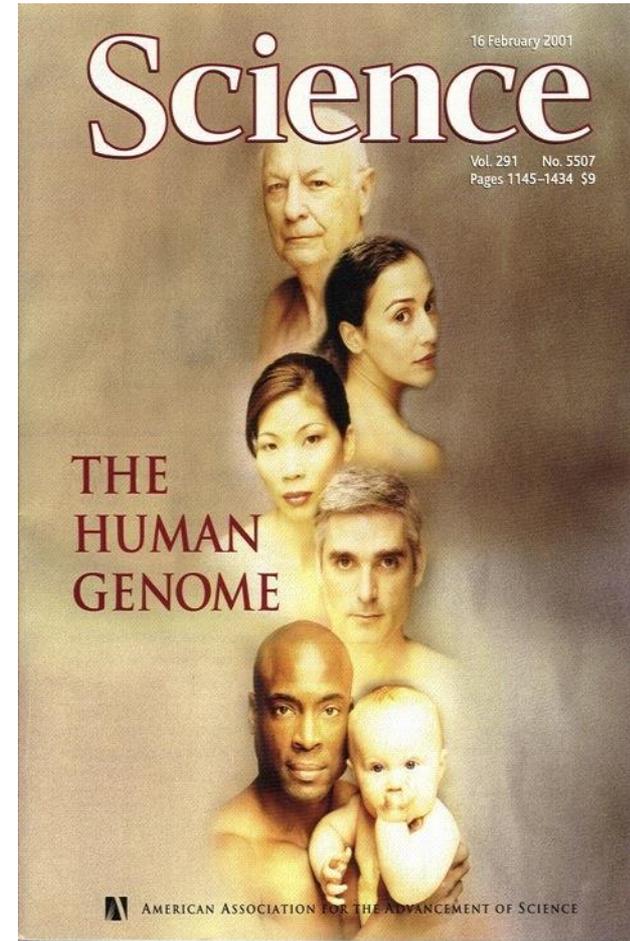
WASHINGTON — Technology companies have taken plenty of hits on privacy this year. In May, [Europe began enforcing a sweeping new law](#) that lets people request their online data and restricts how businesses obtain and handle the information.

Then in June, [California passed its own law](#) that gives people the right to know what information companies are collecting about them, why the companies are collecting that data and with whom they are sharing it — setting a privacy benchmark for the United States.

Now top tech companies are going on the offensive.

*Who decides what  
human dignity  
means in the age of  
gene editing?*

# A FAMOUS FIRST



# CRISPR: A NEW PRECISION?



# Engineering Ambitions



He Jiankui reminds us scientists can use CRISPR to quietly meddle with the human genome – without oversight.

By Julia Belluz | @juliaoftoronto | julia.belluz@voxmedia.com | Updated Dec 3, 2018, 11:07am EST

f   SHARE



He Jiankui, a Chinese researcher, at the Human Genome Editing Conference in Hong Kong on Wednesday, November 28, 2018. He claims to have made the world's first gene-edited babies. | AP

### **MOST READ**



Tucker Carlson has sparked the most interesting debate in conservative politics



Trump accidentally admits there's no actual

# **A GENETIC BILL OF RIGHTS**

## **COUNCIL FOR RESPONSIBLE GENETIC**



- 1. All people have the right to preservation of the earth's biological and genetic diversity.**
- 2. All people have the right to a world in which living organisms cannot be patented, including human beings, animals, plants, microorganisms and all their parts.**
- 3. All people have the right to a food supply that has not been genetically engineered.**

**10. All people have the right to have been conceived, gestated, and born without genetic manipulation.**

taking or storing of bodily samples for genetic information without their voluntary informed consent.

- 8. All people have the right to be free from genetic discrimination.**
- 9. All people have the right to DNA tests to defend themselves in criminal proceedings.**
- 10. All people have the right to have been conceived, gestated, and born without genetic manipulation.**

# **OVIEDO CONVENTION**

## **Article 1 – Purpose and object**

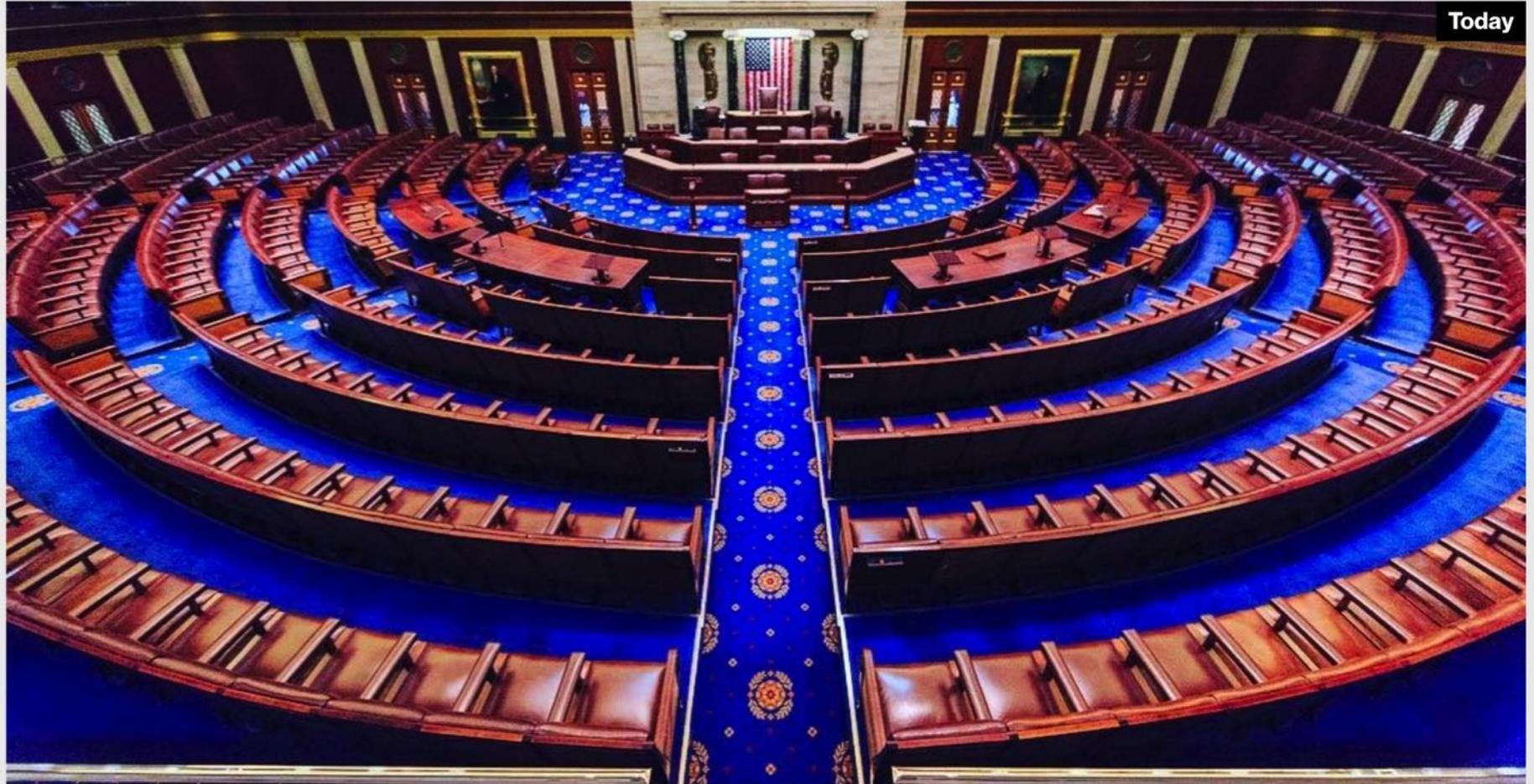
**Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.**

## **Article 2 – Primacy of the human being**

**The interests and welfare of the human being shall prevail over the sole interest of society or science.**

## **Article 13 – Interventions on the human genome**

**An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.**



## Congress is about to renew its ban on creating CRISPR babies in the US

In an effort to get critical parts of the US government funded, the House of Representatives is going to vote today on a bill, [H.R. 265](#), that would pay for health inspectors, food stamps, and drug approvals, according to [Politico](#).

It would also would renew the prohibition on genetically modified human beings in the US.

# THREE MODES OF MANAGING GLOBAL DIVERSITY

## Coexistence

- Live and let live
- Manage borders to prevent contamination
- Principles of conflict of laws

## Cosmopolitanism

- Accord hospitality
- Accommodate difference without adopting universality
- Principles of mutual respect

## Constitutionalism

- Adopt common norms
- Difference only within shared normative framework
- Principles of common humanity

Thank you!