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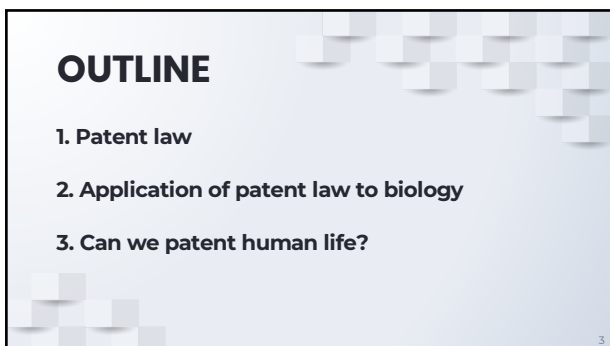
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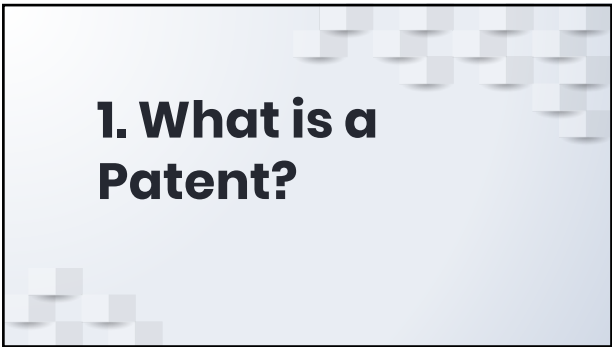
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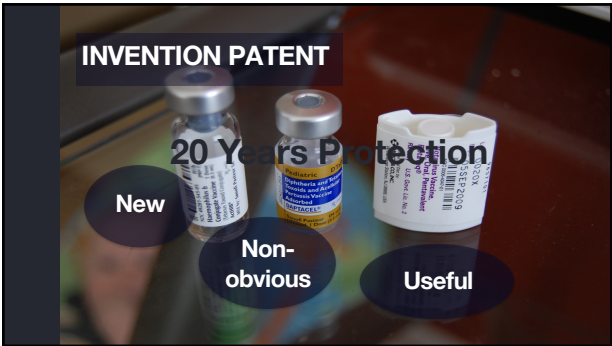
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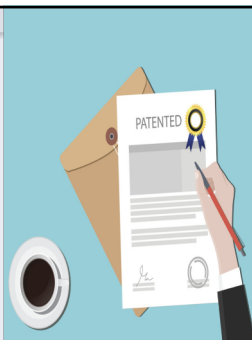
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### What is not patentable?

Laws of nature, natural phenomena, abstract ideas, and products of nature have long been deemed ineligible for patent protection

Can you make any example?




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### Patent

Legal temporary right for the owner to **exclude** others from making, using, selling, offering to sell, or importing the invention

In addition, other laws, such as FDA drug regulation, may prevent an inventor from practicing his invention



patents can be bought, sold, assigned, licensed, mortgaged, securitized, abandoned, devised by will, or simply given away.



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### Facts



Patent lawsuit costs each party roughly **\$2.8** million through trial

It takes two-and-a-half years to resolve.



If patent holder wins, the damage award has been approximately **\$5** million.



Very few patents survive wholly intact during litigation.

A **defendant** can challenge a patent on the ground that it is invalid.



These invalidity defenses are successful, at least in part, in more than **46%** of the cases that ultimately go to trial.

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## 2. THE APPLICATION OF PATENT LAW TO BIOLOGY

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**PARKE-DAVIS**

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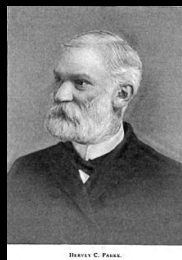
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### History

Company founded in 1860 by Dr. Duffield who owned a small drugstore in Detroit

In 1871 the company sent expeditions to South America in search of medicinal plants.

In 1900, Parke-Davis & Co., identified the extracts' adrenaline.



Dr. Duffield

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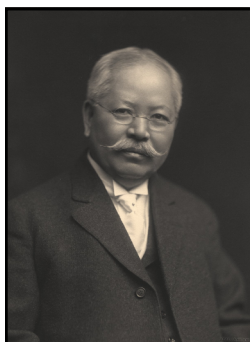
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**Jokichi Takamine**

successfully isolated and purified the hormone from the adrenal glands of sheep and oxen

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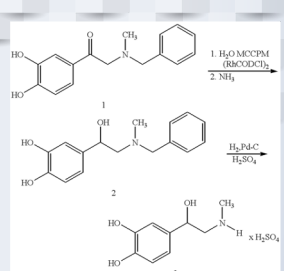
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Like Bayer with heroin, before the criminalization of cocaine, the drug was sold by Parke-Davis in various forms, including cigarettes, powder, and even a cocaine mixture that could be injected directly into the user's veins with the included needle.



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☐ The company promised that its cocaine products would "supply the place of food, make the coward brave, the silent eloquent and ... render the sufferer insensitive to pain."

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## Parke-Davis

**FIRST PATENT OF GENETIC MATERIAL**

In 1900, Parke-Davis & Co., identified the extracts' adrenaline.

Parke-Davis secured a patent on the chemical compound and sued several of its competitors, who defended that the patent was invalid, as it encompassed a product of nature.

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### Judge Hand's Decision

adrenaline was isolated and purified from its natural surroundings

It was not a product of nature

it became for every practical purpose a new thing commercially and therapeutically."

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After Parke-Davis patent, the researchers began to patent their genetic materials and nucleotide derivatives, some of them naturally occurring

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## Five ground-breaking events during the 70's and 80's

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## A. Diamond V. Chakrabarty

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### Who is Chakrabarty?



- Prof. Chakrabarty of University of Illinois created a bacterium (*Pseudomonas*) capable of breaking down crude oil, which he proposed to use in treating oil spills.

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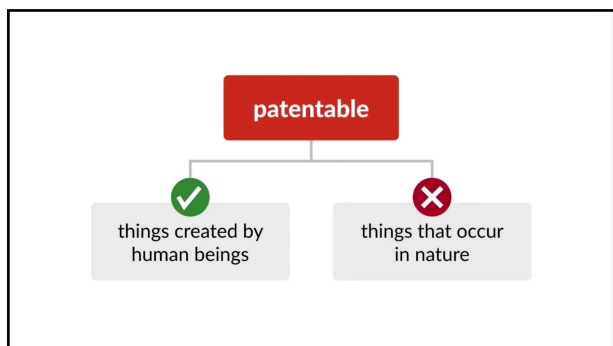
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**Chakrabarty: Claims**

- How he produced the bacterium
- The bacterial species itself

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**Patent Application**

Ananda Mohan Chakrabarty

**REJECTED**

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**May a live, man-made  
microorganism be  
patented?**

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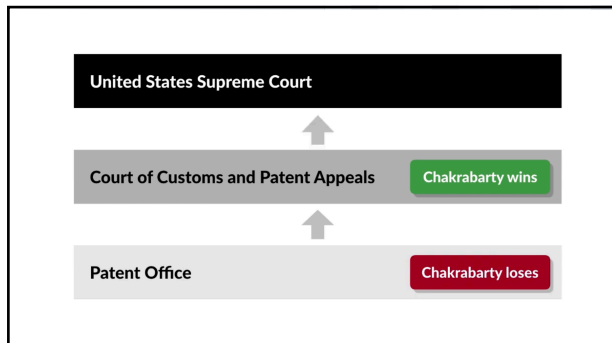
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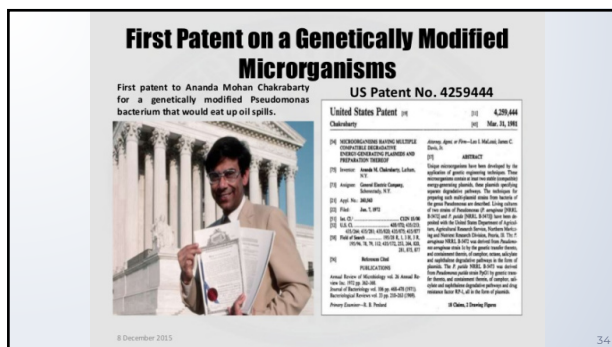
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## Supreme Court *Diamond v. Chakrabarty*

- Chief Justice Warren Burger, who wrote the majority opinion, famously noted, "anything under the sun that is made by man" is patentable

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## Implications

- Ruling set up the premise for the patenting of genetically modified microbes, plants, and animals.
- entities can own a life, and sell and manipulate it as they see fit, as they have exclusive rights to

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## B. Genentech



Genentech, one of the world's first "biotech" companies IPO offered one million shares at \$35 per share.

The first licensed drug generated using recombinant DNA technology was human insulin, developed by Genentech

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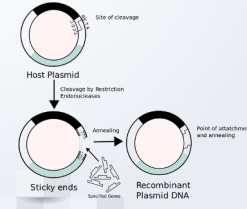
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## C. Recombinant DNA Patent



Recombinant DNA patent—based on an invention by Herbert W. Boyer and Stanley Cohen.

Stanford University applied for a US patent on recombinant DNA in 1974, listing the inventors as Boyer and Cohen and this patent was awarded in 1980.

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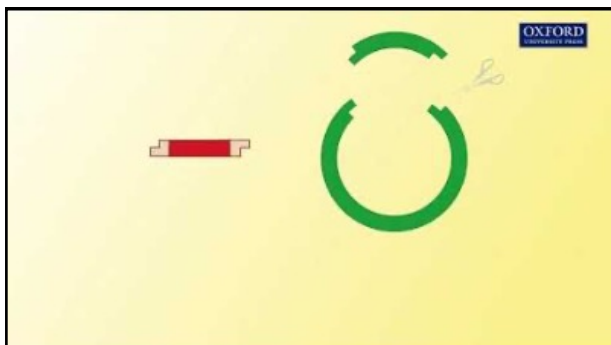
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## D. Bayh-Dole Act



It encouraged universities to engage in patentable research

"when a university develops a new technology, the institution is entitled to patent it"

Profits must be shared with the inventor

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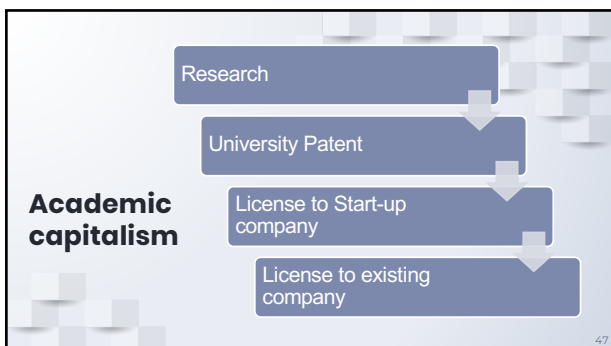
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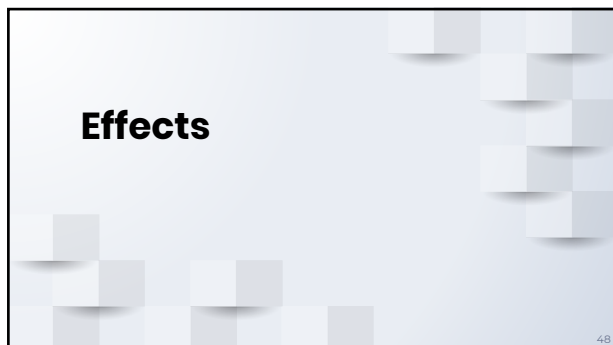
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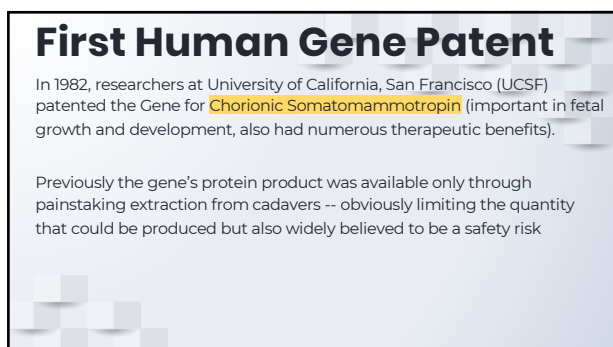
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## FIRST GENE PATENT

### WAR

- ☐ Professor Seeburg stole several clones used by UCSF and gave them to Genentech
- ☐ A few months later Genentech announced it had inserted human genes into harmless germs and getting them to produce human growth hormone.
- ☐ The University sued Genentech

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**Protropin** is an injectable, recombinant pharmaceutical that is used to treat children with growth problems stemming from an inability to produce their own growth hormone



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## Patents on Transgenic Animals

- In 1984, Harvard filed for a patent on the "Harvard Oncomouse," the PTO granted the patent in 1988



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### Human Genome Project



Massive international effort to map the entire sequence of 3.2 billion DNA base pairs and 22,300 protein-coding genes of the human genome.

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Leading researchers recommended that all human DNA sequences be placed in the public domain (Collins of the National Institutes of Health)

Biotech industry, however, argued that patents on genes should be encouraged (Venter of Celera Genomics)



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\$3,000,000,000	2003 Human Genome Project	
\$20,000,000	2006 1 <sup>st</sup> individual genome	
\$2,000,000	2007 1 <sup>st</sup> NGS Genome	
\$200,000	2008 1 <sup>st</sup> 30x genome	
\$10,000	2010 1 <sup>st</sup> sub-10K genome	
\$1,000	2014 1 <sup>st</sup> \$1,000 genome	
\$100	2017 1 <sup>st</sup> \$100 genome	

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[illegible]

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### 3. Can we Patent Human Life?



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### Gene Patent

1980

It was not until much later that opposition to patents on genes themselves, as opposed to patents on animals or humans, began to grow.

Academic concern — a belief that preexisting human genetic sequences were not inventions to be owned

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### Myriad Genetics and breast cancer risk testing

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### Key actors:

- Prof Mark Skolnick
- University of Utah
- Financial support from pharmaceutical giant Lilly

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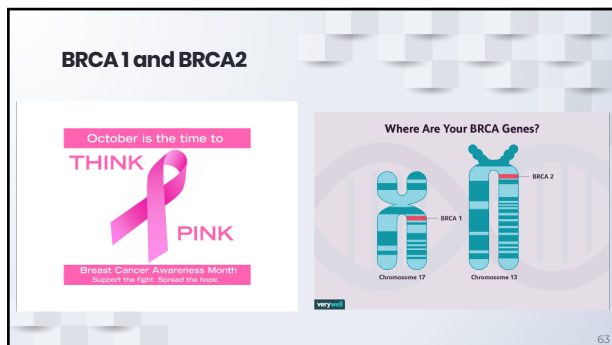
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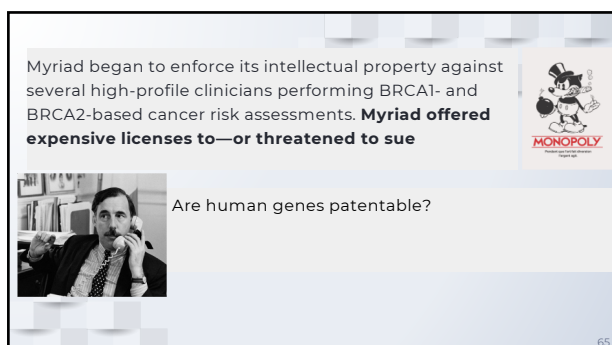
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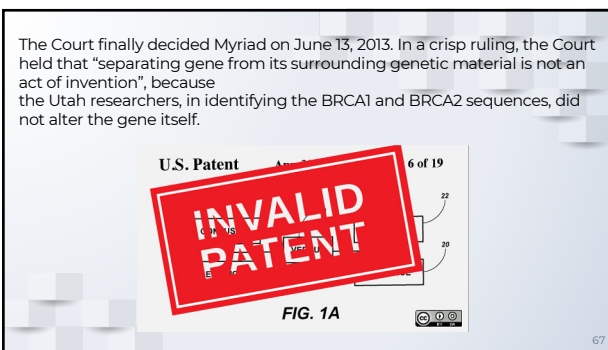
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