

Primer on Intellectual Property, or...

....Who owns your genes?

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Strategists and Advisors
specializing in the protection,
transfer and enforcement of
Intellectual Property Rights.

Outline

- What forms of IP are there?
- What is a patent ?
- How can there be patents on genes?
- Who does own your genes?
- Obtaining & enforcing gene patents
- The Patent System and gene patents
- Conclusions and recommendations

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Why Have Intellectual Property?

- To...
- ...protect ideas and expressions and to promote investments in these activities
- ...encourage disclosure of new ideas from otherwise secret sources
- ...assist consumers in distinguishing among different products or services

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What Is the Source of U.S. Intellectual Property Laws?

- Article I, Section 8 of the U.S. Constitution:
 - “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”

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Types of Intellectual Property

- Trade Secrets
- Trademarks (and Service Marks)
- Copyright
- Patents
 - Utility
 - Design
 - Plant

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Trade Secrets: Formula for Coke

- What is a trade secret?
 - Knowledge that confers an advantage to an entity and that the entity keeps as a secret
- Advantage
 - Lasts as long as the knowledge is kept a secret
- Disadvantages
 - Secrets can be hard to keep
 - No right to exclude – cannot stop another who independently figured out the secret
 - To enforce in court, must show a loss of competitive advantage
 - Knowledge is not placed in the public domain (disadvantage to the public)



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Trademarks: “EPOGEN” for Amgen’s erythropoietin

- What is a trademark?
 - That which distinguishes the goods and services of one company from those of another
 - **EPOGEN** for EPO from Amgen vs **EPREX** for EPO from J&J in Europe
- What can be a trademark?
 - Name of a product or service
 - Stylized building (McDonald’s golden arches)
 - Sound (e.g., Intel)
 - Color (e.g., UPS)

Trademarks



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- Advantages
 - Lasts as long as it is used
 - Can prevent others from using similar marks or dress
 - Reduces administrative costs (i.e., time) to the consumer (advantage to the public)
- Disadvantage – use it or lose it

Copyright on a Book

Watson's "Molecular Biology of the Gene"



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- What is a copyright?
 - Legal protection for an expression
 - There are many ways to describe molecular biology, but the style / expression/ format used by Watson is copyrighted by B. Cummings, Inc., and cannot be copied
 - Expression independently created, not unique
 - Expression must be capable of being fixed in a tangible medium (writing, recording, etc.)

Copyrights

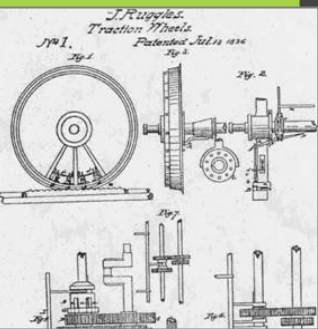


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- What can be copyrighted?
 - Literary works
 - Musical works and sound recordings
 - Dramatic works (including choreography)
 - Pictorial, graphic, and sculptural works
 - Motion pictures
 - Architectural works
- For businesses outside these fields?
 - Most common: software
 - Gene sequences? ... Nah!

Patents

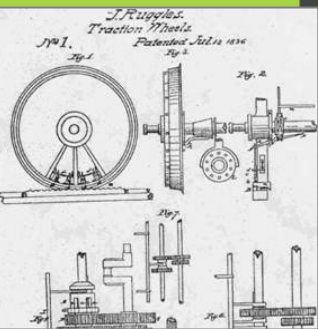
- What is a patent?
 - Right of limited duration to exclude others from making, using, selling, offering for sale, or importing that which is claimed; the right is granted by the Government in exchange for the patentee disclosing her invention or design to the public



**Patent No. 1
issued on
July 13, 1836
To inventor
John Ruggles
for traction
wheels**

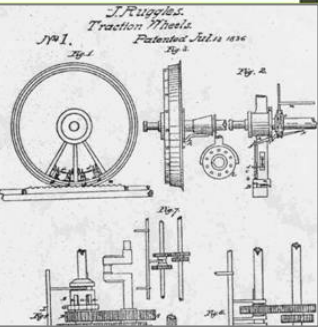
Patents

- Types of patents
 - Utility
 - Term of 20 years from filing of application (typically 17 years from issue of patent)
 - Invention must be: (1) useful, (2) novel, and (3) not obvious in light of what has been done before
 - Design
 - Term of 14 years from issue of patent
 - For decorative design for article of manufacture that is novel and not obvious in light of what has been done before
 - Plant
 - Term of 20 years from filing of application
 - For novel, asexually reproduced plants



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Patents

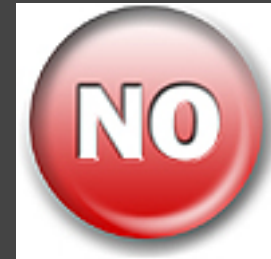


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What Can Be Protected With a Utility Patent?

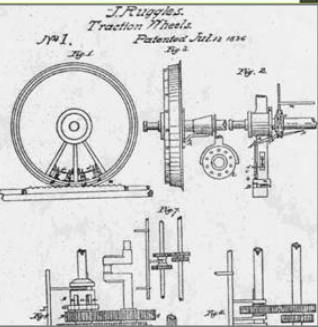


- Process
- Machine
- Manufacture
- Chemical / Genetic
- Software
- Method of Doing Business
(that involves technology)



- Abstract idea
- Mathematical Equation
- Law of Nature

Patents

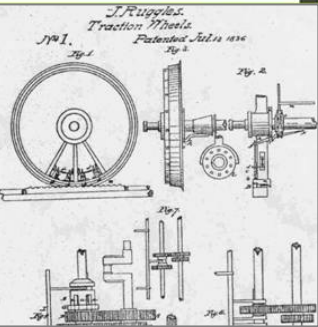


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- Advantages
 - Encourages disclosure of the workings of inventions to the public (advantage to the public)
 - Encourages investment by providing a barrier to entry to those who would misappropriate an innovation
 - Can prevent others from using invention as a trade secret (if they were doing so)

Patents

- Disadvantages
 - Thorough public disclosure of invention (easy to copy)
 - Expensive to obtain and to litigate
 - May need to seek patents in several countries
 - May be of limited value if technology quickly evolves



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Patents on Genes

- Such patents claim **isolated** molecules with a given DNA sequence, not their natural form in the chromosomes
- Legal Precedents
 - 1912: Adrenalin... **practically free** from gland tissue
 - 1970: Prostaglandin... in **sufficiently pure form...**
 - 1977: **Biologically pure culture** of *Streptomyces vellosus*
 - 1979: Strawberry flavoring comprising... **substantially pure** 2-methyl-2-pentanoic acid
 - 1980: Chakrabarty decision: “...**anything under the sun** made by man...”

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Anatomy of Kirin- Amgen's Patent on "Human" EPO

Lin *et al* , US Patent 4,703,008, issued Oct 1987

What is claimed is:

1. A purified and isolated DNA sequence [statutory requirement] encoding erythropoietin, said DNA sequence selected from the group consisting of:
 - (a) the DNA sequences set out in FIGS. 5 and 6 or their complementary strands [the "human" EPO gene] ; and
 - (b) DNA sequences which hybridize under stringent conditions to the DNA sequences defined in (a) [expands the "human" gene to a family of similar isolated orthologous EPO genes]

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First, a Clarification:

Q: Who does “own” your genes?

A: Depends if they are:
(1) in your body (you do) or
(2) having been extracted, and
now in a test tube (the
hospital or lab)

See: Moore v. Regents of U. of California (1990)

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Clarification (II)

Q:

If you arrange with the lab for you to preserve ownership of your genes after isolation, who owns them?

A:

You do.

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Clarification (III)

Q: If I have a patent on your isolated genes, can you commercialize them?

A: No. You own the tangible, *personal* property, but I own the intangible, *intellectual* property.

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Clarification (IV)

Q: Can I use my patent on the isolated genes I now own to stop you from metabolizing?

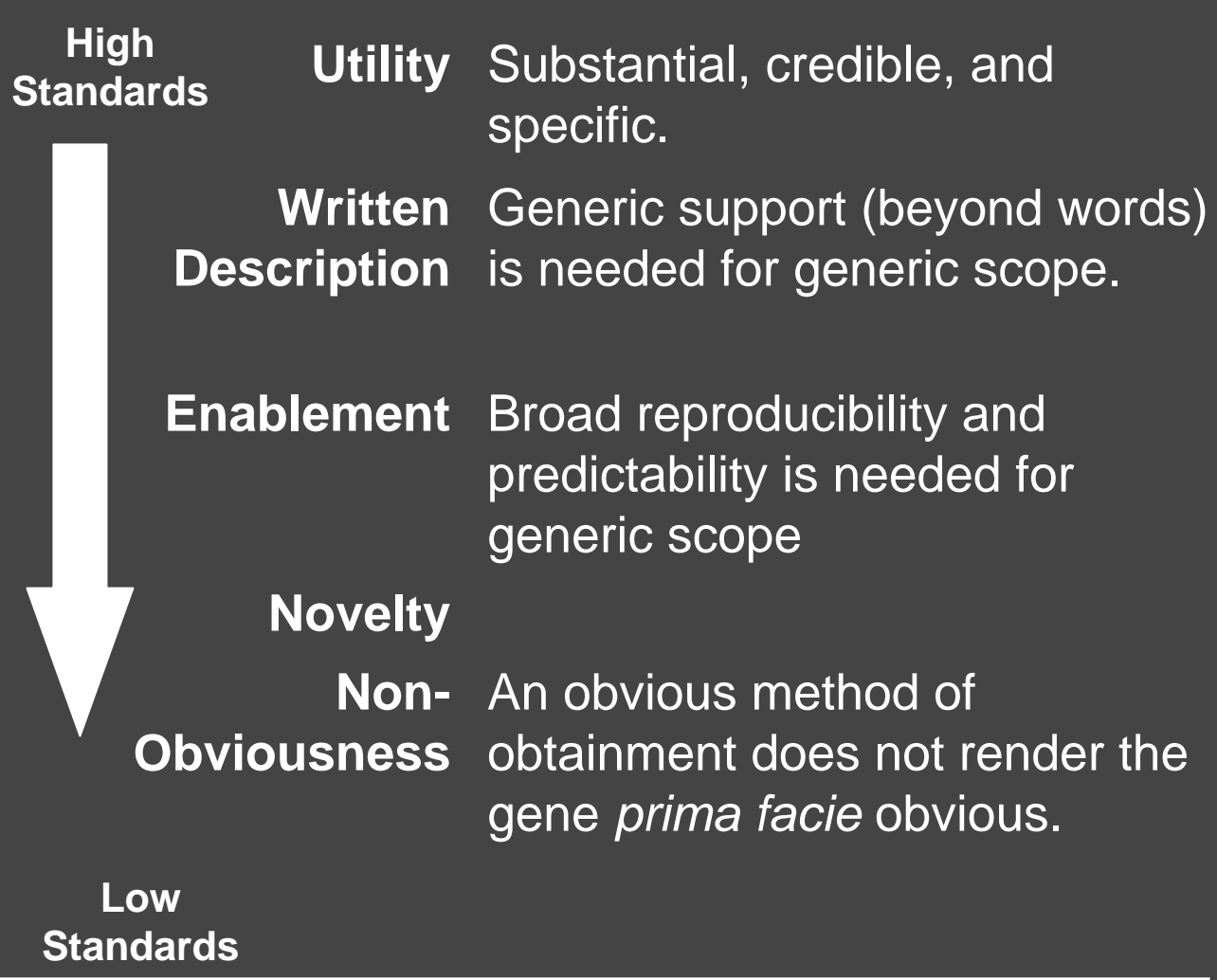
A: Of course not! Patents cover isolated genes not the genes in the natural context.

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Obtaining Gene Patents

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The news from the courts and the PTO:



Enforcing Gene Patents (I)

- The essence of a patent right is the right to exclude others from commercializing anything within the scope of the claims
- The right to exclude encompasses:
 - The right to an injunction
 - The right to extract damages (lost profits, reasonable royalties)
 - The ability to leverage the possibility of injunction/damages to license technology

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In the U.S. the right to exclude has been historically broad ...

- Any activity that “unmistakably furthers the institution’s legitimate business objectives” is an infringement (*Madey v. Duke U.* (Fed. Cir. 2002))
- Experimental use defense is essentially non-existent
- But: Clinical (and maybe even pre-clinical) research are exempt (35 U.S.C. § 271(e)(1); *Integra v. Merck*)
- *In vivo* operations or procedures are exempt, but use therein of patented genes is not (35 U.S.C. § 287(c)(2)(a)(i))

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But... The Right to Exclude Has Recently Been Cut Back: *Ebay v MercExchange*

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- Injunctions are no longer automatic
- Patent holders who do not manufacture or license may not readily get injunctions
- Health is a major public policy concern, so ...
- Patent holders in the health sciences who do not work their inventions are now vulnerable to not getting injunctions
- The door has opened to compulsory licenses in the health sciences...

Economic/Social Foundations of any Patent System (I)

1. Encourages full disclosure of otherwise secret technology in exchange for **time-limited** exclusivity
2. Encourages **capital formation** for technologies with **risky outlook**
3. Privatizes technology to encourage its development and avoid its waste (“The **Tragedy of the Commons**”)

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Patents in Different Industrial Sectors

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Arguments for Patent
Protection

Stronger
Argument

**Synthetic
Drugs**

Major investments; long delay;
high risk of failure; long life of
product



**Semi-
conductors**

Investments needed; copying still
a risk... but there is a need for
numerous patent licenses per
product

Weaker
Argument

**Business
Methods**

No high risk investments; product
life relatively shorter

Question:

Q: Are isolated human genes more like synthetic drugs or like business methods?

A: **It depends...** on the function/use of the genes, and thus on the potential defendants.

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Legal Taxonomy of Gene Patents

- Three Main Categories:
 - A. DNA encoding **Protein Drugs**: e.g., TPA, EPO, INF- β
 - Potential defendants : Biopharmaceutical companies
 - B. DNA encoding **Diagnostic Probes**: e.g., BRCA 1
 - Potential defendants : Diagnostic companies; medical community
 - C. DNA encoding **Targets/Receptors**: e.g., CCR5
 - Potential defendants : Drug discovery companies; research community

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DNA Encoding Protein Drugs - Example: The TPA Gene

- Commercial applications higher; research applications lower
- Patenting the gene, not the protein, rewards the innovator of large-scale production
- Risk is high: \$750 million/many years
- High enough that without patents protein drugs will not be developed, even though gene supply is limited
- Narrowly interpreted patents will not encumber development of downstream second generation mutants (e.g., Genentech's TPA claims did not dominate second generation "TPA." (*Genentech v The Wellcome Foundation*))

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DNA Encoding Receptors – Example: The EPO Receptor Gene

- Research applications higher; commercial ones lower
- Development risks and costs not very high
- Used primarily as research tools/platforms
- Patent enforceability unclear: use abroad/data importation; pre-clinical/clinical use may be exempt; damages may be limited to reach-through royalties on sales of products outside the patent scope
- NIH requires non-exclusive licenses
- Patents are perceived to impede dissemination of research tools
- Big pharma does not like stacked royalties

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DNA Encoding Diagnostic Probes - Example: The BRCA1 Gene

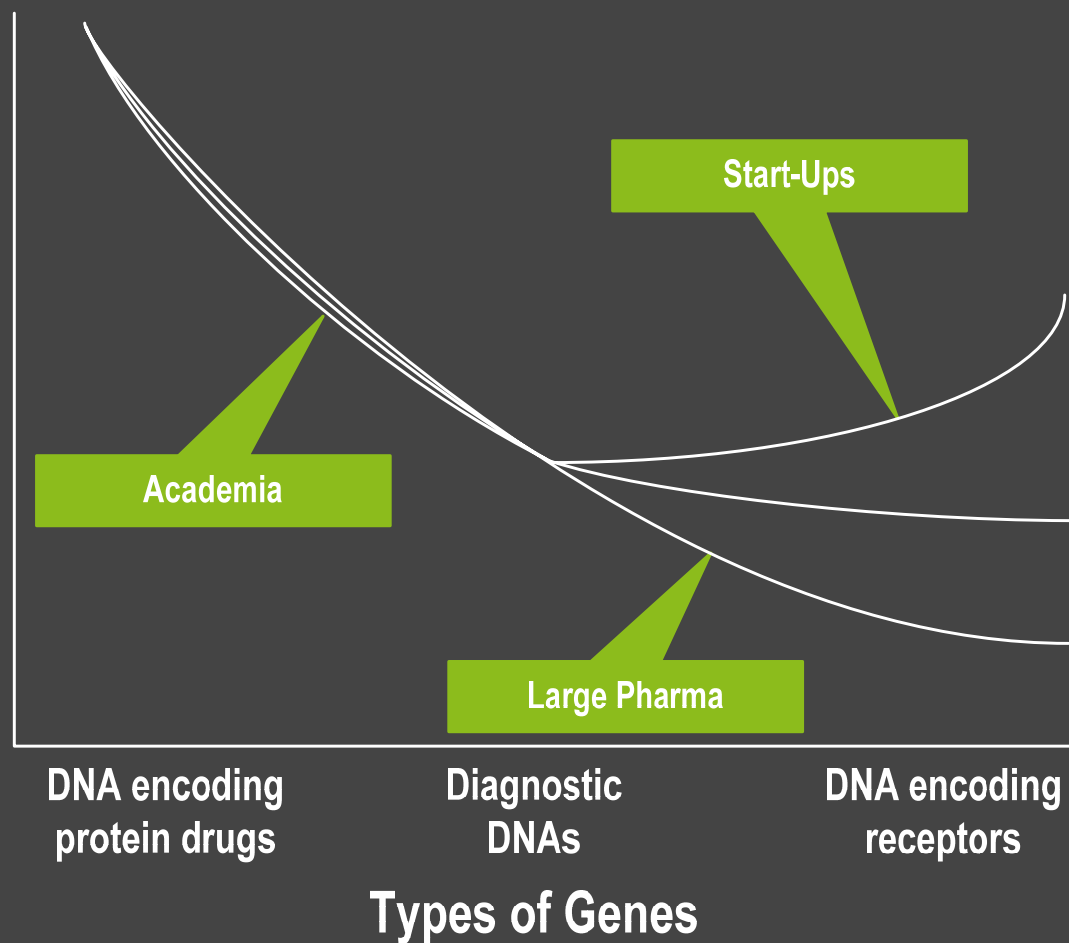
- Commercial and research applications are in tension.
- Worldwide manufacturers and distributors of kits and rapid tests still need patent protection.
- Patent owner may also have to enforce against end users, not just manufacturers (as with protein drugs).
- Incremental developments in genetic tests may lead to large fragmentation of the patent field (as with semiconductors)
- Limits on who performs genetic tests may interfere with good medical practice, and may inhibit others from finding new mutations.

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Perceived Values of Different Types of Gene Patents by Institution

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*Perceived
Value of
Patents on
Human
Genes*



Suggestions from Commentators

Goldstein, *et al* "Patent Pools and Standard Setting in Diagnostic Genetics," *Nature Biotechnology*, 23 (8), August 2005

Following the model of consumer electronics, create patent pools for DNAs encoding diagnostic genes using internationally recognized diagnostic medical standards (e.g the ACMG standard for Cystic Fibrosis) to define essential pool patents

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Conclusions and Recommendations

No one other than you “owns” your genes

Others may own patents on isolated
versions of your genes

Such gene patents provide commercial
exclusivity for limited periods of time

But, not all “gene patents” are created equal

Protein drugs...diagnostic probes...research tools

Severe danger that the baby will be thrown
out with the bathwater.

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Conclusions and Recommendations (II)

Injunctions: Post *eBay*, continue to clarify the conditions for health-based compulsory licenses

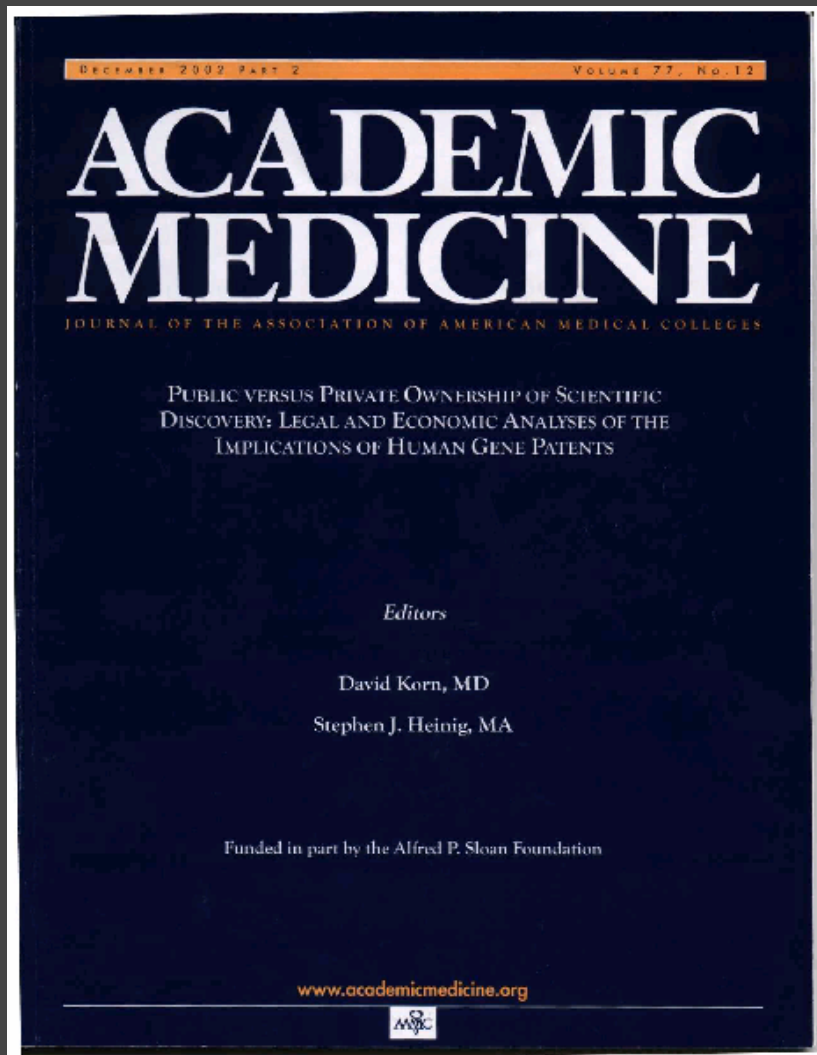
Diagnostic Patent Pools: Work in conjunction with international health authorities (PAHO, WHO, ACMG) to establish universal standards for diagnostic genetics

Research Tool Patents: Better define experimental / pre-clinical research exemptions without undermining all research tool patents

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Additional Reading... Although Already 4 Years out of Date

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Thank You