Dividing the Spoils of CRISPR: Surrogate Licensing and Scientific Discovery

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Jorge L. Contreras and Jacob S. Sherkow, *CRISPR, surrogate licensing, and scientific discovery.* 355 SCIENCE 698-700 (2017)

CRISPR's "inventors" and competing patents

Jennifer Doudna
UC Berkeley

Emmanuelle Charpentier
U Vienna

Feng Zhang
Broad Inst.

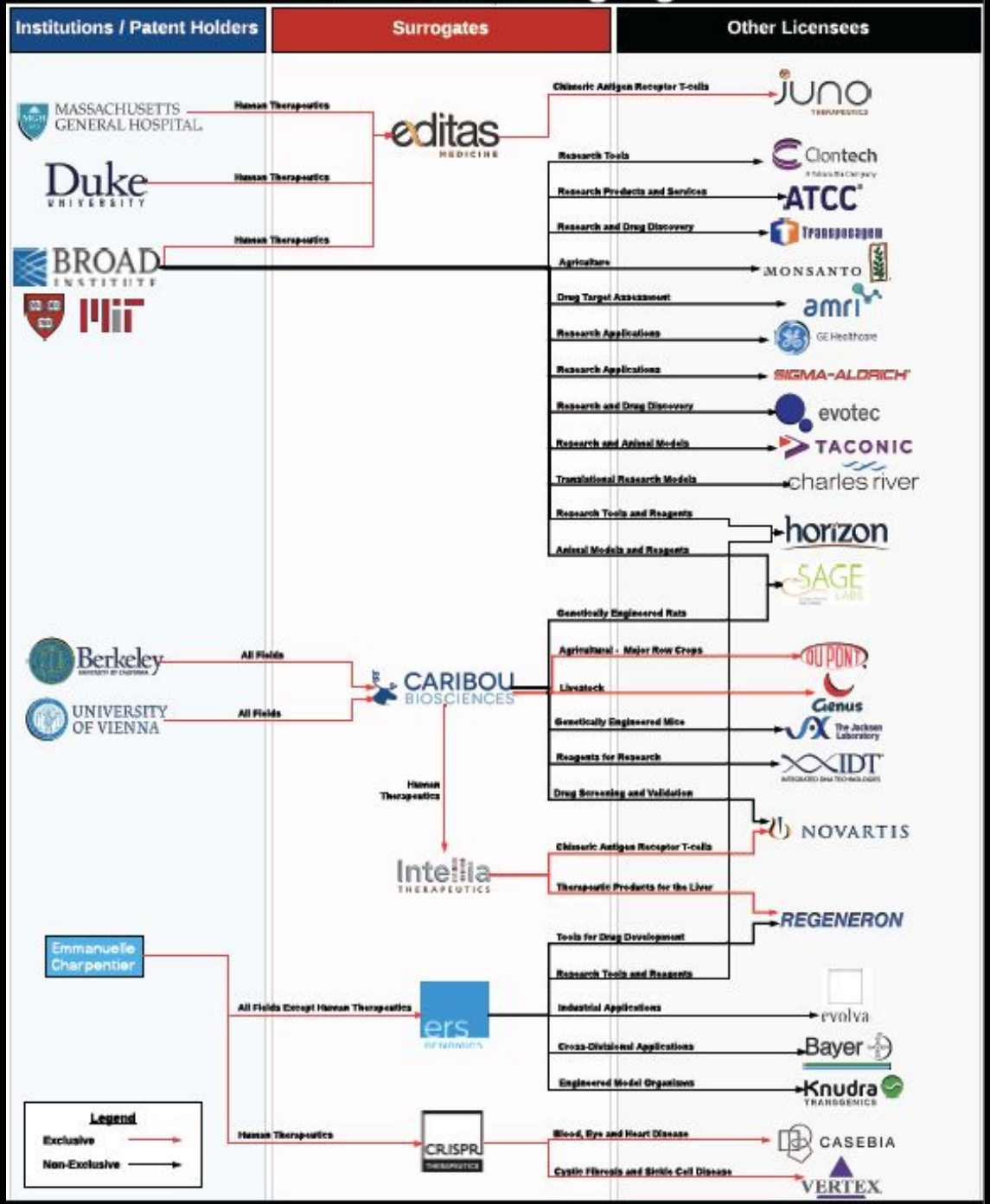
Patents and Licenses

- IP rights are **divisible**
- Patent rights can be **licensed** in different **Fields of Use**
- Licensee usually pays Patentee a **royalty** based on net revenue from exploiting the patent
- Licenses can be **exclusive** or **non-exclusive**

Scope of CRISPR Licenses

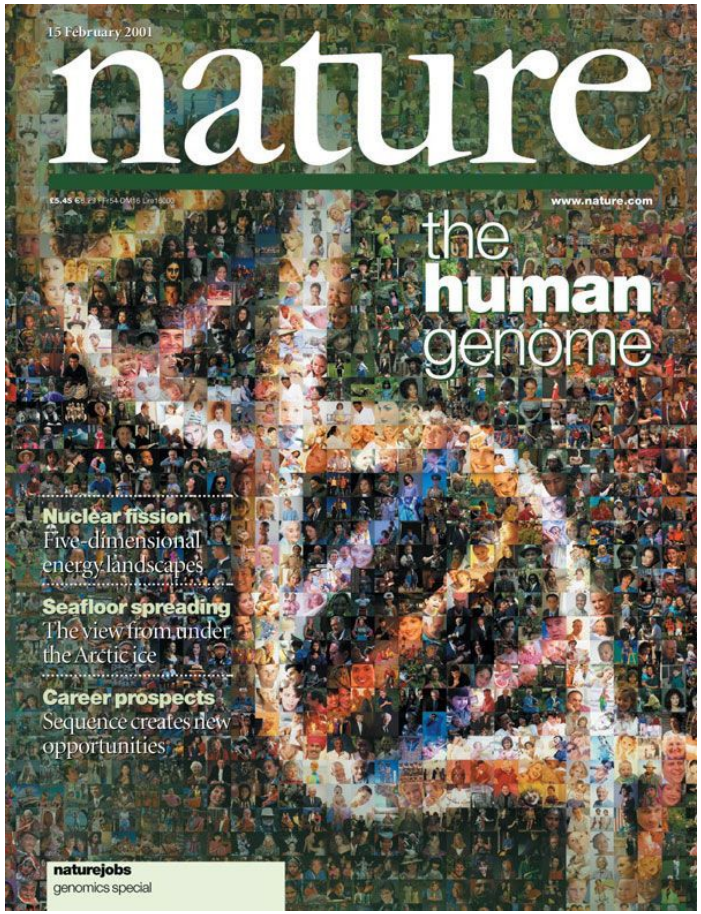
Field	Exclusivity
Non-commercial research	Non-Exclusive
Tool Development	Non-Exclusive
CRISPR Applications	
Agriculture	Non-Exclusive (mostly?)
Veterinary	Non-Exclusive
Human Therapeutics	Exclusive ($$$)
[Human Enhancement]*	None

CRISPR CAS9 Licensing Agreements



The Human Therapeutics Field is BIG

- ~20,000 human genes
- Field covers <u>every</u> edit to address <u>every</u> disease using <u>every</u> gene



The "Surrogate" Licensing Model

University cedes exclusive control over a large and lucrative market to a private firm that is not aligned with the university's public mission

Exclusive

Exclusive

The standard case for exclusive licenses in biopharma

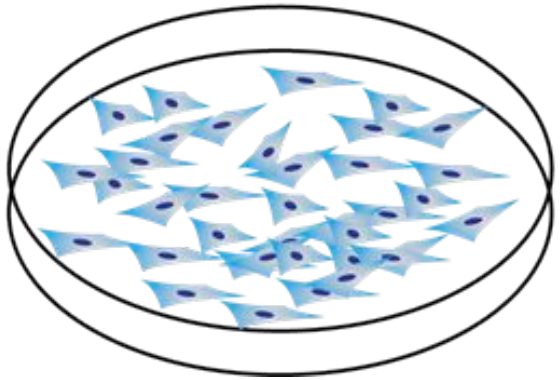
- Provides greater financial **incentive** to develop technology
- Enables R&D **cost-recovery** during exclusive period
- Enables external **fundraising** (VC + markets) to support commercialization
- Allocates sublicense identification, recruitment and negotiation role to **experts**

But not for "research tools"

NIH (1999)

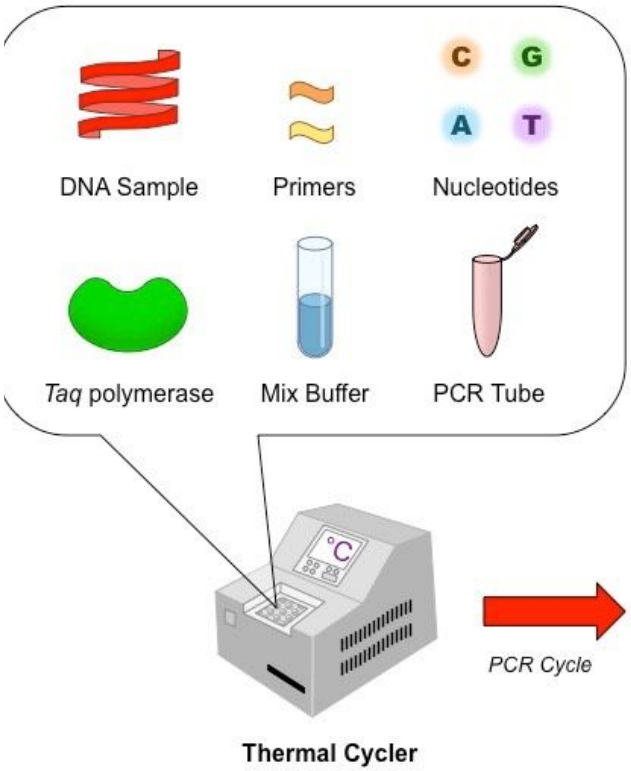
Patents on research tools developed using federal funding should be licensed non-exclusively to promote their greatest utilization, commercialization and public availability.

Equipment

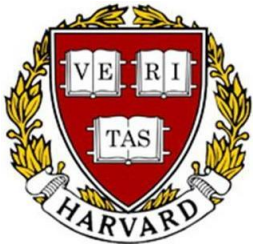


Cell lines

Processes



University Licensing – Nine Points (2007)

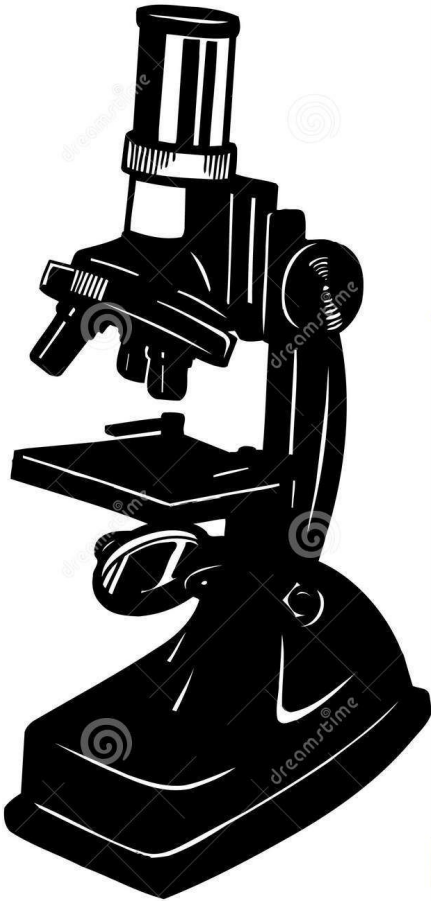


1. Research exceptions
2. Limited exclusivity for research tools
3. Minimize future improvement licensing
4. Manage tech transfer conflicts
5. Ensure broad access to research tools
6. Limited enforcement
7. Export regulations
8. Be careful of patent aggregators
9. Developing world provisions

*Is CRISPR a Research Tool?

- It is a broadly applicable *technique*
- But CRISPR edits may themselves be therapeutics
- *But* CRISPR is so broadly applicable that it is *like* a research tool

→ *CRISPR should be licensed broadly and with narrow exclusivity*



Effects of Surrogate/Exclusive Licensing for Research Tools

- **Firm** profits substantially from control of field
- **Inventors** and **university** profit substantially from equity in firm
- Firm is not bound, legally or morally, to university's public mission
- University pays lip service to public goals, but avoids compliance with 9 Points and public mission
- Development is bottlenecked by single firm choke point/control over rights

A Development Bottleneck

Assume: 100 firms capable of developing a CRISPR human therapy

Model 1 (PCR)

- University grants **100** firms a non-exclusive license in a limited field (one disease or gene)
- 100 therapy targets created over 5 years
- Avg. university revenue = low

Model 2 (typical biotech molecule/indication)

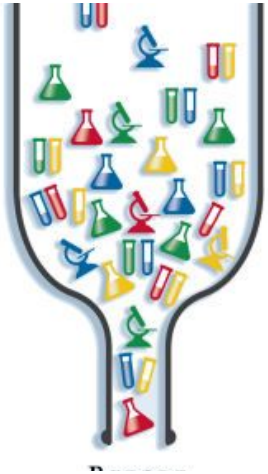
- University grants **50** firms an exclusive license in a limited field (one disease or gene)
- 50 therapy targets created over 5 years
- Avg. University revenue = medium

Model 3 (Surrogate – CRISPR)

- University grants one **surrogate** exclusive rights to entire field
- Surrogate focuses on 5 targets, 20 on "back burner"
- Surrogate exclusively sublicenses/options 25 targets to others
- Avg. University revenue = high

→ But results in least development

- → Surrogate may not be optimal developer of all 25 targets (competitors foreclosed)
- → Surrogate cannot develop all targets simultaneously -> time lag



A New Hope for CRISPR?

- With two key sets of patent rights, Broad and Berkeley may have to renegotiate and deal with each other
- Licenses to surrogates can be made *non-exclusive* or limited to specified candidate genes

Thank you!

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