BIOTECHNOLOGY ENTREPRENEURSHIP WORKSHOP

Intellectual Property, Licensing, and Commercialization in BioTech

Lisa Dhar, Associate Vice President for Innovation
John Haugen, Associate General Counsel
Arjan Quist, Executive Director of Innovation Management

BIOTECHNOLOGY
TRAINING PROGRAM

INVO's Mission

To catalyze the translation of Northwestern innovations to benefit the public and to promote economic growth

- Become a source of impactful innovations and products that improve lives
- Become a magnet for entrepreneurial talent

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Agenda

- Session 1
  - IP Quiz
  - Patent Basics, Patenting in the University Environment
    - INVO: “Disclosure” & Evaluation
    - Patentability requirements and process
    - Differences between patent filings and academic publications
  - Licensing Basics
  - Case Studies (time permitting)
    - CRISPR
    - Zolgensma

Patent Basics

Give the owner an exclusive right to exclude others from practicing the claimed technology

- When granted, provides a legal right to stop others from making, using, offering for sale, and importing the claimed invention
- Only when granted, only for subject matter in patent claims

Provide incentives for companies to invest in innovation and provide public benefits

Patent Basics

QUESTION: WHY GET PATENTS?

- Protect incentive for private investment in R&D
- Promote the public good
- Prevent others from copying the invention unless they have permission

- Monetization – e.g., licensing revenue
- Career progression (e.g., build résumé, enhance award/grant likelihood) and prestige

Patenting in the University Environment

Disclosure Process and Considerations (INVO)

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Patent Filings: How They Differ from Academic Publications

	Patents Applications and Patents
Who Reviews?	Patent Examiner PhD generally, may or may not have academic, industry experience Experts on patentability and patent office procedures
Why Reviewed?	Examiner review guarantees only inventions meeting 35 U.S.C. §101, §102, §103, and §112 result in granted patents and right to exclude others
Focus	New, useful inventions to promote progress and support investment and development for public benefit
Data Quality Data Quantity	Case dependent Data requirements generally higher for broad issued, valid claims Many experiments, embodiments generally needed to support claims
Timing	Drafting: ideally 1-2 months, Examination 1-7 years

Why INVO Evaluates Disclosures | The Audience

- Who do we draft patents for?
  1. Patent Examiners
     - PhD generally, may or may not have industry experience
     - Experts on patentability and patent office procedures
  2. Potential Investors, Entrepreneurs, Startups
     - Business and/or technical backgrounds
  3. Established Companies
     - Generally deep patent knowledge (sophisticated business, technical, legal, and patent teams)
  4. Federal Judges
     - Lawyers
     - Typically have no science background except from patent lawsuits, expert witness testimony

Why INVO Evaluates Disclosures

ALL INVENTIONS MUST MEET THE LEGAL REQUIREMENTS FOR PATENTABILITY:

NEW, USEFUL, ELIGIBLE, SUFFICENTLY DESCRIBED, AND NONOBVIOUS

INVO'S DECISION NOT TO FILE DOES NOT REFLECT THE SCIENTIFIC MERIT OF THE INVENTION

- Not all disclosed innovations are eligible and/or ready for patenting
- Not all inventions may be commercialized
- There may not be a market for the potential product
- There may be significant regulatory hurdles associated with the invention
- Cost of patenting: US is $25k-30k; Other countries is >$100k

* process, machine, manufacture or composition of matter

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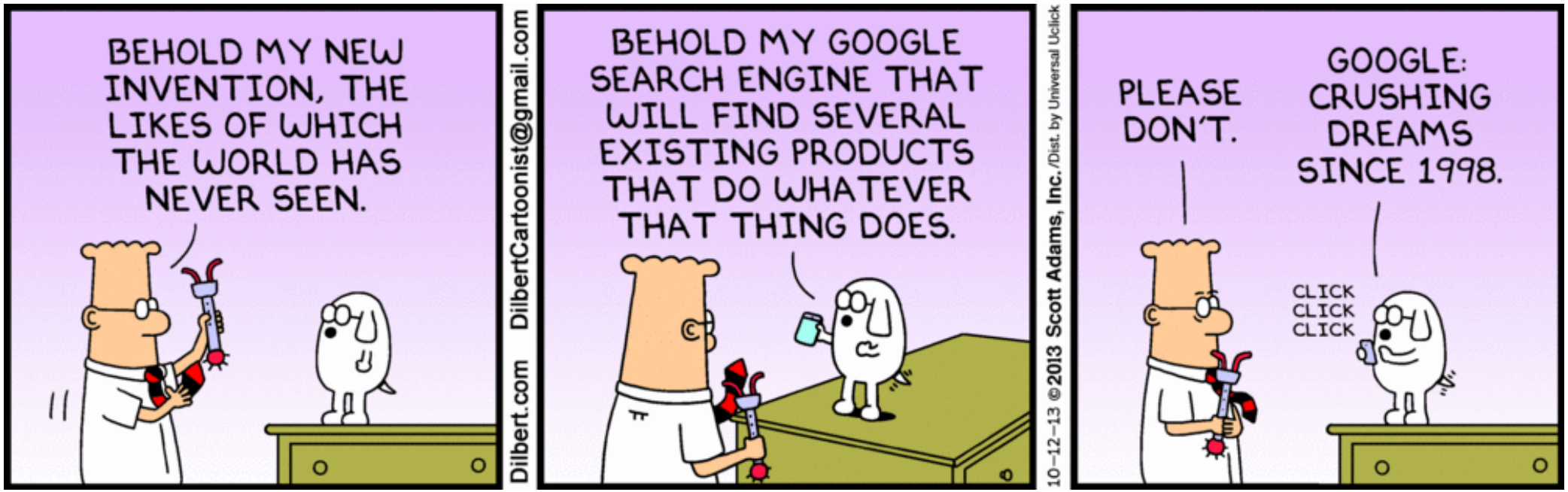
Cartoon Break



Ideas and Theories: Not patentable

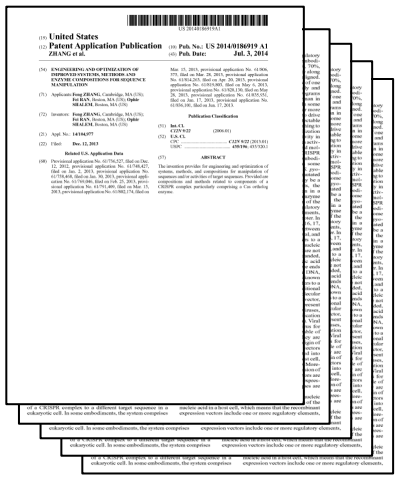
"Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others … A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.
(Fed Cir 2010)(*en banc*)

The INVO Process

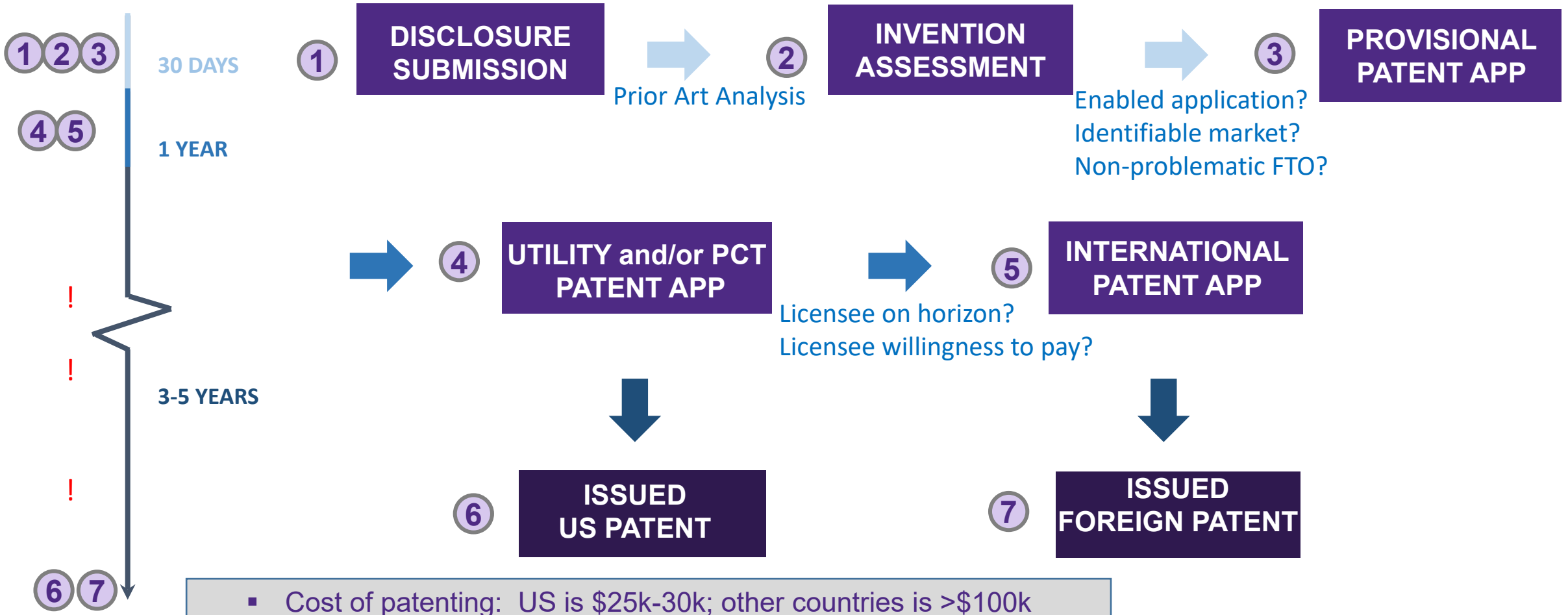
1. **DISCLOSURE SUBMISSION**
2. **INVENTION ASSESSMENT**
   - Prior Art Analysis
3. **PROVISIONAL PATENT APP***
   - Enabled application?
   - Identifiable market?
   - Non-problematic Freedom to Operate?
4. **UTILITY PATENT APP***
   - Is Licensee on horizon?
   - Is Licensee willingness to pay?
5. **PCT APP & NATIONALIZATION***
6. **ISSUED PATENT***

*if applicable



Patent Application

INVO Review Process & Patent Timeline



- Cost of patenting: US is $25k-30k; other countries is >$100k
- PTO determines speed of patent review
- Patent life is 20 years
- Abandonment is possibility throughout the IP life

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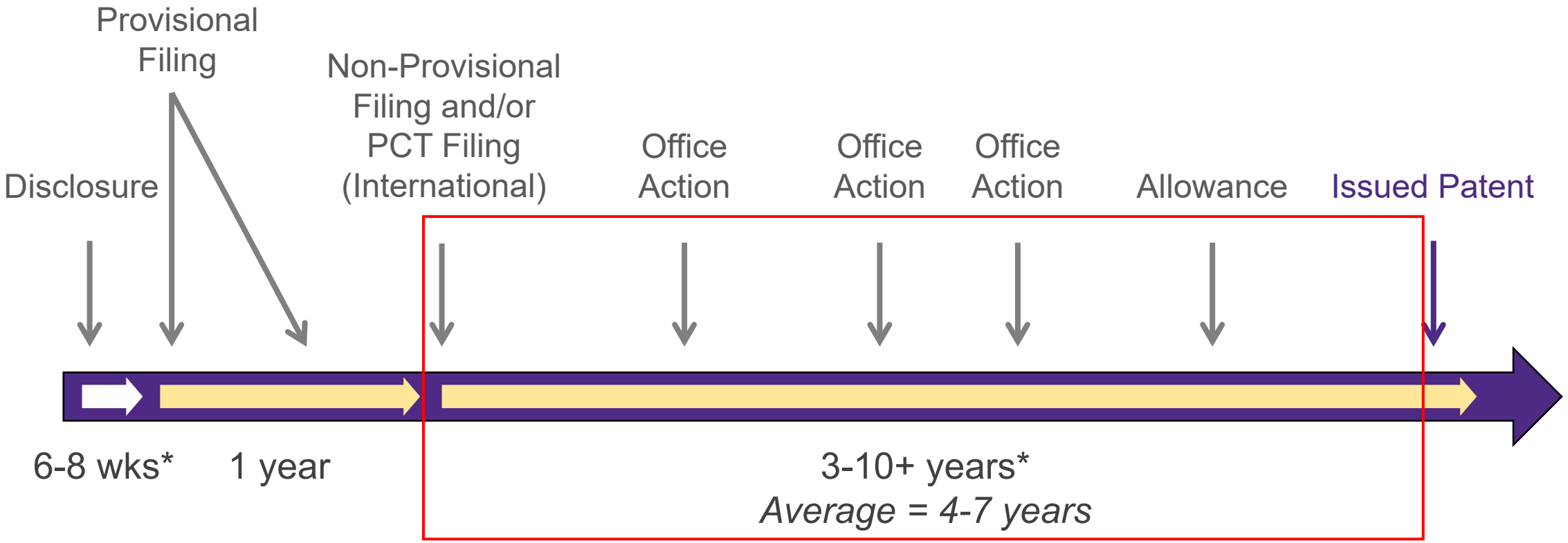
Sample Patent Timeline



- PTO determines speed of review
- Maintaining faculty input is crucial here
- Abandonment is a possibility throughout the IP life

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4 Key INVO Evaluation Factors | Patentability

1. PATENTABILITY

- Are there other papers or patent applications that describe inventions that may be similar?
- **Is there enough description or data collected to file the application?**
- **Is there a research plan that will provide more data related to the invention?**
- What potential claims can be pursued?
- Are potential claims broad or narrow?

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4 Key INVO Evaluation Factors | FTO

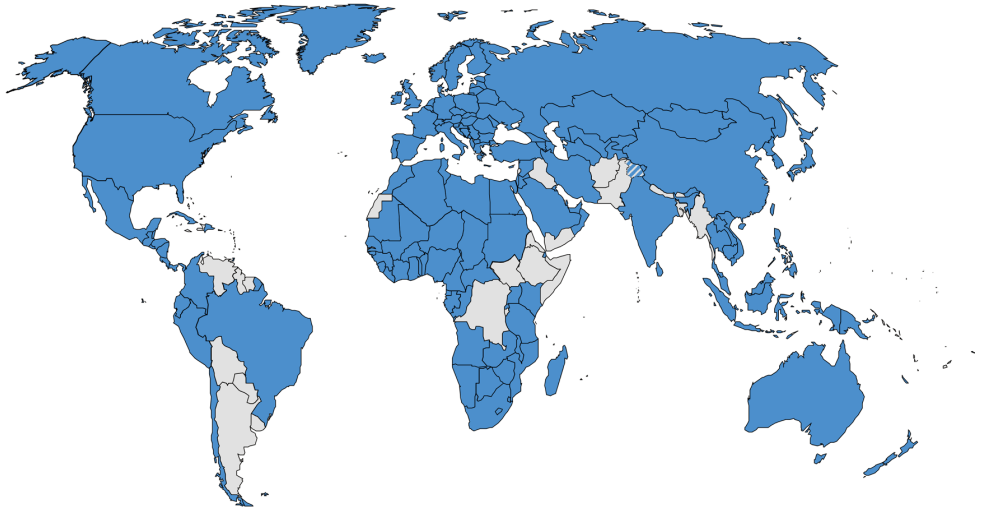
2. FREEDOM TO OPERATE (FTO)

- Are there others with patents in the space that may block use of a patent?
- Are licensing options limited?

4 Key INVO Evaluation Factors | Enforcement

3. ENFORCEMENT

- Would a licensee ever be able to detect infringement?
- Would a company be able to avoid infringement?
  - Would a company be able to make and sell your invention somewhere outside of patent protection?



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4 Key INVO Evaluation Factors | Commercial Potential

4. COMMERCIAL POTENTIAL

- Is there a market for the technology today? What size? What market challenges?
- Do we expect that a market will exist in the future?
- Are there a lot of competitors? What are the benefits of this invention over others?
- What level of interest do those in industry or investors have?
- **Is there enough description and data to attract investment?**
- How close is the invention to a commercial product?
- How does a product fit with what is already available in the market?

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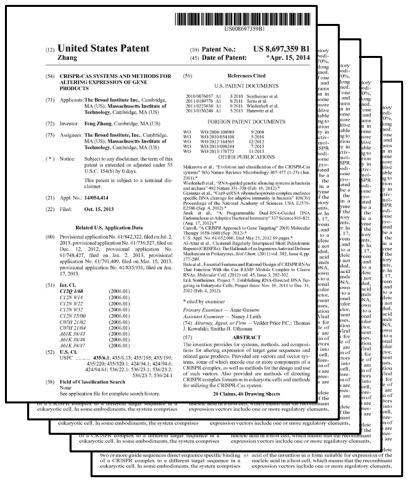
Patentability Requirements
&
Patent Office Procedures

Patent Drafting and Patent Prosecution

- Patent Applications are drafted to meet legal requirements
- After patent filing, patent applicants engage in a back and forth with patent office to establish a public record of what is truly patentable
- Patent Claims in Issued Patent may differ from Claims in Patent Application

Patent Application

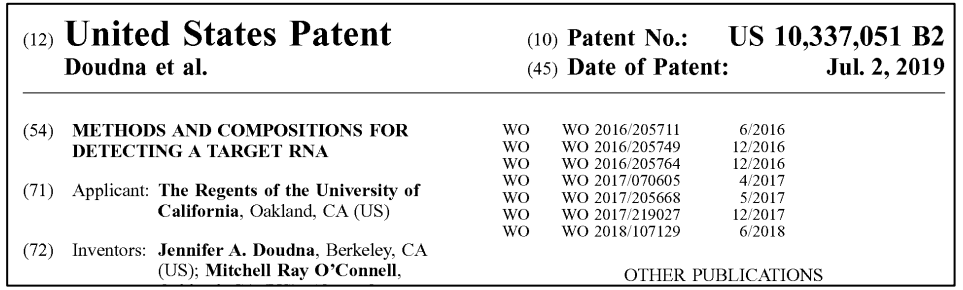


Issued Patent

Recap: Patent vs. Patent Application

Patent

- Issued by the patent office
- Can enforce rights
- Defined claims



(12) **United States Patent**
Doudna et al.

(10) **Patent No.: US 10,337,051 B2**
(45) **Date of Patent: Jul. 2, 2019**

(54) **METHODS AND COMPOSITIONS FOR DETECTING A TARGET RNA**

(71) Applicant: **The Regents of the University of California**, Oakland, CA (US)

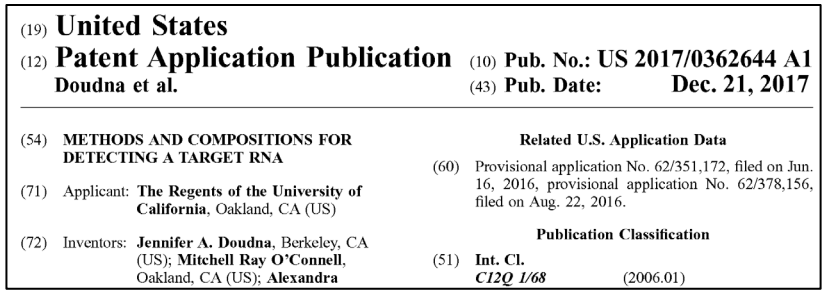
(72) Inventors: **Jennifer A. Doudna**, Berkeley, CA (US); **Mitchell Ray O'Connell**,

WO	WO 2016/205711	6/2016
WO	WO 2016/205749	12/2016
WO	WO 2016/205764	12/2016
WO	WO 2017/070605	4/2017
WO	WO 2017/205668	5/2017
WO	WO 2017/219027	12/2017
WO	WO 2018/107129	6/2018

OTHER PUBLICATIONS

Patent Application

- Request for a patent - nothing is issued
- Generally is broader than what will be allowed
- Can file an application on anything … it just won't be granted
- Can make competitors aware of pending application



(19) **United States**
(12) **Patent Application Publication**
Doudna et al.

(10) **Pub. No.: US 2017/0362644 A1**
(43) **Pub. Date: Dec. 21, 2017**

(54) **METHODS AND COMPOSITIONS FOR DETECTING A TARGET RNA**

(71) Applicant: **The Regents of the University of California**, Oakland, CA (US)

(72) Inventors: **Jennifer A. Doudna**, Berkeley, CA (US); **Mitchell Ray O'Connell**, Oakland, CA (US); **Alexandra**

Related U.S. Application Data

(60) Provisional application No. 62/351,172, filed on Jun. 16, 2016, provisional application No. 62/378,156, filed on Aug. 22, 2016.

Publication Classification

(51) **Int. Cl.**
C12Q 1/68 (2006.01)

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What is a “Public Disclosure”?

1. PRINTED PUBLICATIONS (e.g. journal articles, book chapters)
   - Likely to be public disclosures
     - Posters/abstracts/proceedings
     - Oral disclosures such as conference presentations
   - Might be public disclosures…
     - Departmental seminars and thesis defense
     - Grant proposals

2. INVENTIONS USED BY PUBLIC (e.g. research materials and prototypes)
   If materials are provided only for testing and/or evaluation or for research purposes under written agreement, this may not be a disclosure

3. INVENTIONS ON SALE

4. INVENTIONS AVAILABLE TO THE PUBLIC

PLAN TO SUBMIT YOUR DISCLOSURE 3-4 WEEKS PRIOR TO YOUR PUBLIC DISCLOSURE

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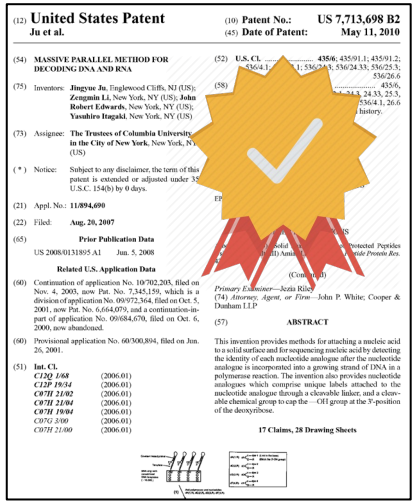


(12) **United States Patent**
Ju et al.

(10) **Patent No.: US 7,713,698 B2**
(45) **Date of Patent: May 11, 2010**

(54) **MASSIVE PARALLEL METHOD FOR DECODING DNA AND RNA**

(75) Inventors: **Jingyue Ju**, Englewood Cliffs, NJ (US); **Zengmin Li**, New York, NY (US); **John Robert Edwards**, New York, NY (US); **Yasuhiro Itagaki**, New York, NY (US)

(73) Assignee: **The Trustees of Columbia University in the City of New York**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **11/894,690**

(22) Filed: **Aug. 20, 2007**

(65) **Prior Publication Data**

US 2008/0131895 A1 Jun. 5, 2008

Related U.S. Application Data

(60) Continuation of application No. 10/702,205, filed on Nov. 4, 2003, now Pat. No. 7,345,159, which is a division of application No. 09/972,364, filed on Oct. 5, 2001, now Pat. No. 6,664,079, and a continuation-in-part of application No. 09/684,670, filed on Oct. 6, 2000, now abandoned.

(60) Provisional application No. 60/300,894, filed on Jun. 26, 2001.

(51) **Int. Cl.**

C12Q 1/68	(2006.01)
C12P 19/34	(2006.01)
C07H 21/02	(2006.01)
C07H 21/04	(2006.01)
C07H 19/04	(2006.01)
C07G 3/00	(2006.01)
C07H 21/00	(2006.01)

(52) **U.S. Cl.** **435/6**; 435/91.1; 435/91.2; 536/24.33; 536/25.3; 536/26.6

(58) 435/6, 24.33, 25.3, 536/4.1, 26.6
history.

Protected Peptides

(Continued)

Primary Examiner—Jezia Riley
(74) *Attorney, Agent, or Firm*—John P. White; Cooper & Dunham LLP

(57) **ABSTRACT**

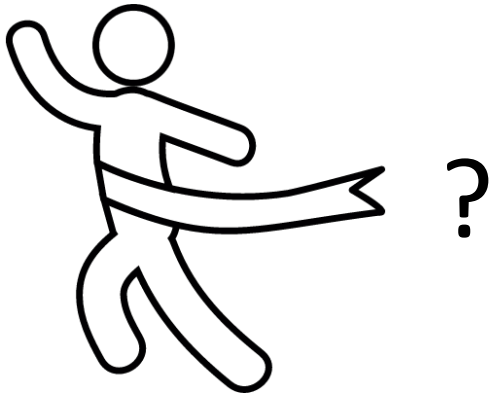
This invention provides methods for attaching a nucleic acid to a solid surface and for sequencing nucleic acid by detecting the identity of each nucleotide analogue after the nucleotide analogue is incorporated into a growing strand of DNA in a polymerase reaction. The invention also provides nucleotide analogues which comprise unique labels attached to the nucleotide analogue through a cleavable linker, and a cleavable chemical group to cap the —OH group at the 3'-position of the deoxyribose.

17 Claims, 28 Drawing Sheets

File Patent Application

Examination

Patent Grant



?

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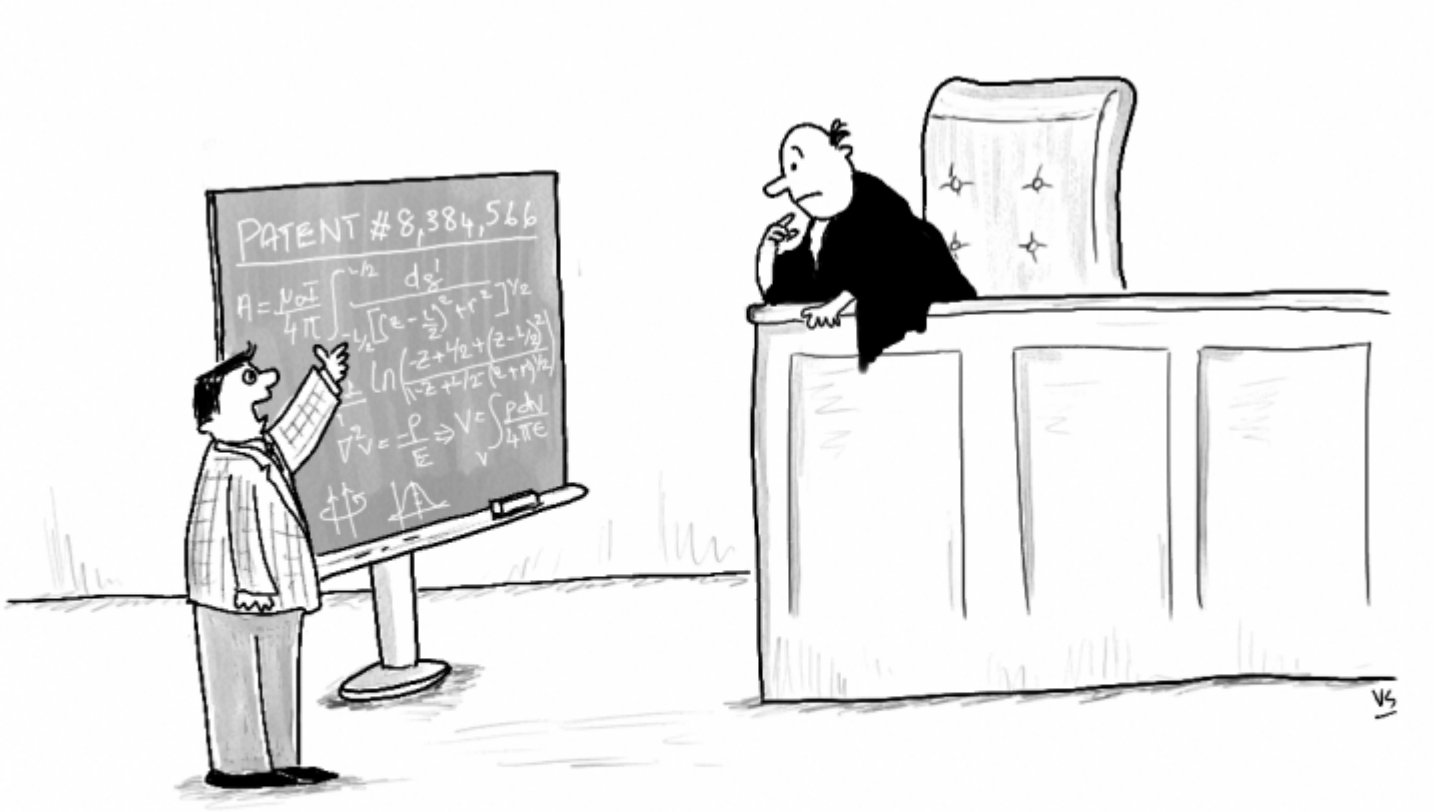
After Patent Grant

- Patent holder may detect company/competitor is using their patented technology
- Patent holder tells competitor about patent, please license my technology or stop 


- Competitor reaction:
  - Okay, I'll license
  - Okay, I'll stop
  - No. Your patent doesn't cover what I do, or your patent should never have been granted
    - Patent office challenges
    - Patent litigation

Enough – cartoon break



"So you see your honor, it's obvious."

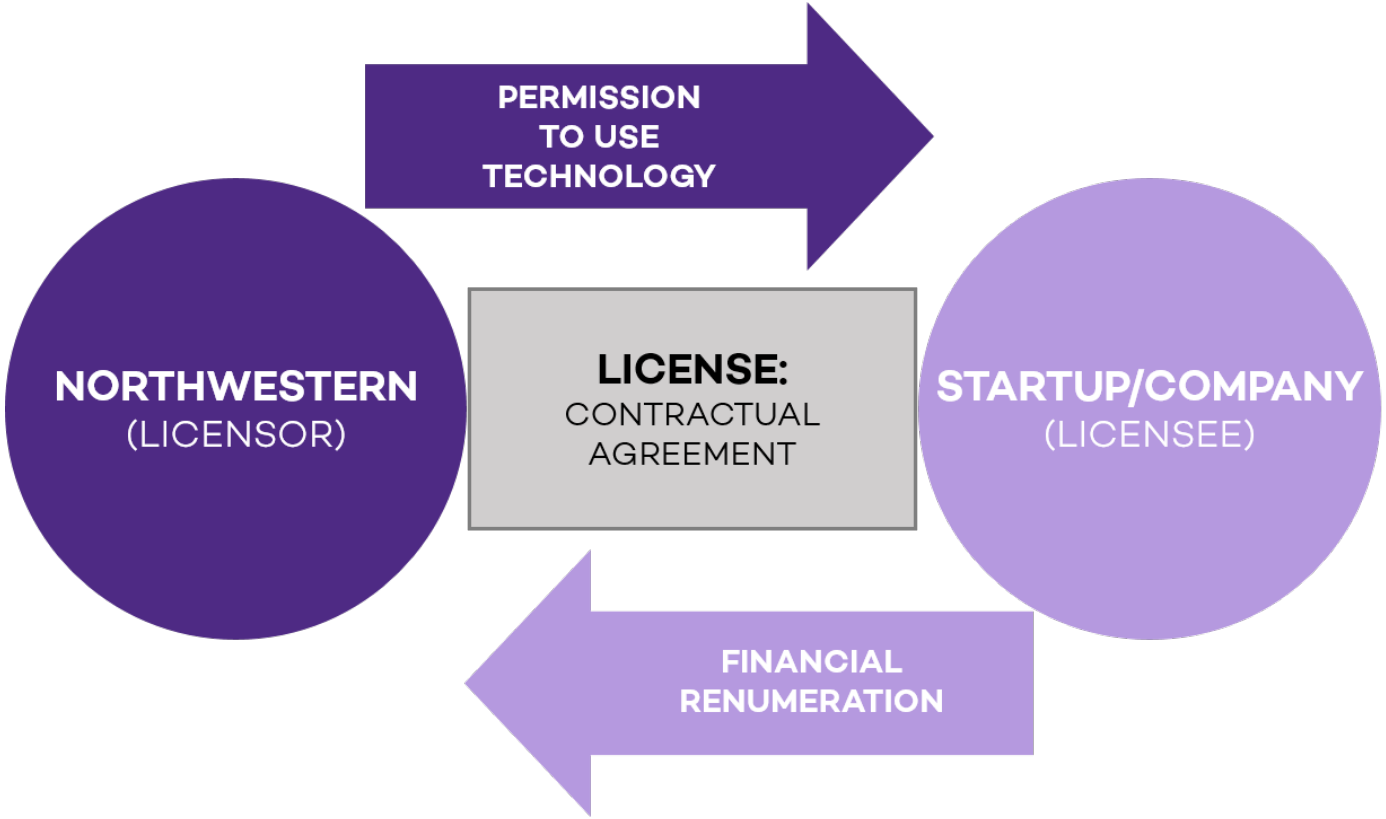
Intro to Licensing

What Does Northwestern License?

- Patent Rights
  - Rights covered under our patents or patent applications
- Materials
  - Generally, may not be patented
  - Often biological (cell lines, animal models, antibodies) or chemicals/materials
- Software
  - Generally not patented, but protected by copyright

License | Formal Agreement

A contractual agreement between the intellectual property owner (licensor) and normally a R&D company, manufacturer, or retailer (licensee)



PERMISSION TO USE PROPERTY

subject to specific terms and conditions, which may include the purpose of use, a defined territory and a defined time period.

FINANCIAL REMUNERATION

normally in the form of a guaranteed fee and/or royalty on a percentage of sales, sometimes equity

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Licensing Considerations

- Overall goal is to get innovation to the public
  - Financial terms are only one consideration
- Structure to ensure development of the invention
- Ensure continued academic use
- Protect ability to publish
- Minimize inclusion of future improvements
- Maintain access to research tools

Licensing | Exclusivity and Field Licensing

- **Licenses** can be granted **exclusively** (to one and only one licensee) or **non-exclusively** (to many licensees)
  - Generally, therapeutics & devices are licensed ***exclusively***
  - Generally, research tools are licensed ***non-exclusively***
- **Fields of Use**
  - Separate markets or applications
    - E.g., Human use, veterinary use, agricultural use
  - Allow licensing to multiple entities
  - May maximize impact of invention, foster focused development
- Concepts can be combined
  - E.g., an antibody may be licensed ***exclusively*** for **therapeutic use** to one company, and ***non-exclusively*** for diagnostic uses to multiple companies

Licensing | Types and Models

- Direct to large established company
- Direct to small company
- Faculty Startup
  - What NU looks for in Startups
  - More on Startups another day, if interest

Contents of a License Agreement

- Recitals
- Definitions
- Grant
- Confidentiality
- Milestones/Diligence
- Payment
- Reports and Records
- Publication
- Patent Prosecution
- Infringement
- Product Liability
- Term and Termination
- Assignment
- Dispute Resolution

Milestones and Due Diligence

- Define activities a licensee must achieve to keep the license in effect
- Often associated with a time frame
- Examples of milestones:
  - -Business Plan
  - -Clinical approval phases
  - -Launch product in marketplace
  - -Annual Progress Reports
  - -Prototype development
  - -Generate sales
- Generally borrowed from licensee's development plan

Payments

- Numerous ways to structure payments
- Payments can be structured to shift cost to later date
- Payments can include:
  - Upfront fees (cash and/or equity)
  - Milestone payments
  - Patent Expenses
  - Sublicense Fee
  - Maintenance Fees
  - Royalty & Minimum Royalty
  - Assignment Fee

Case Studies

Licensing Case Study | Zolgensma

- Gene Therapy Technology discovered at U. Penn
- Developed by REGENXBIO
  - Exclusively Licensed to AveXis
- AveXis
  - Conducted preclinical research done at OSU, Nationwide Children's
  - Licenses from U. Penn, Minnesota, Genethon, Nationwide Children's
- AveXis acquired by Novartis

Penn
University of Pennsylvania

University of Minnesota
Driven to Discover℠

The Ohio State University

Nationwide Children's
When your child needs a hospital, everything matters.

NOVARTIS

avexis

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Patent and Licensing Case Study | CRISPR/Cas9

- **CRISPR**: Clustered Regularly Interspaced Short Palindromic Repeats
  - Segments of prokaryotic DNA containing short, repetitive base sequences
- **Cas9**: a protein derived from the CRISPR-Cas immune system
  - A programmable nuclease which acts as a type of molecular scissors
- **Guide RNAs**: short RNA molecules used to target the protein to a specific sequence within cellular DNA
  - By changing the sequence of the guide RNA, Cas9 can be directed to almost any DNA sequence, enabling simple and flexible targeting of nearly any site in a given genome

CRISPR/Cas9 History

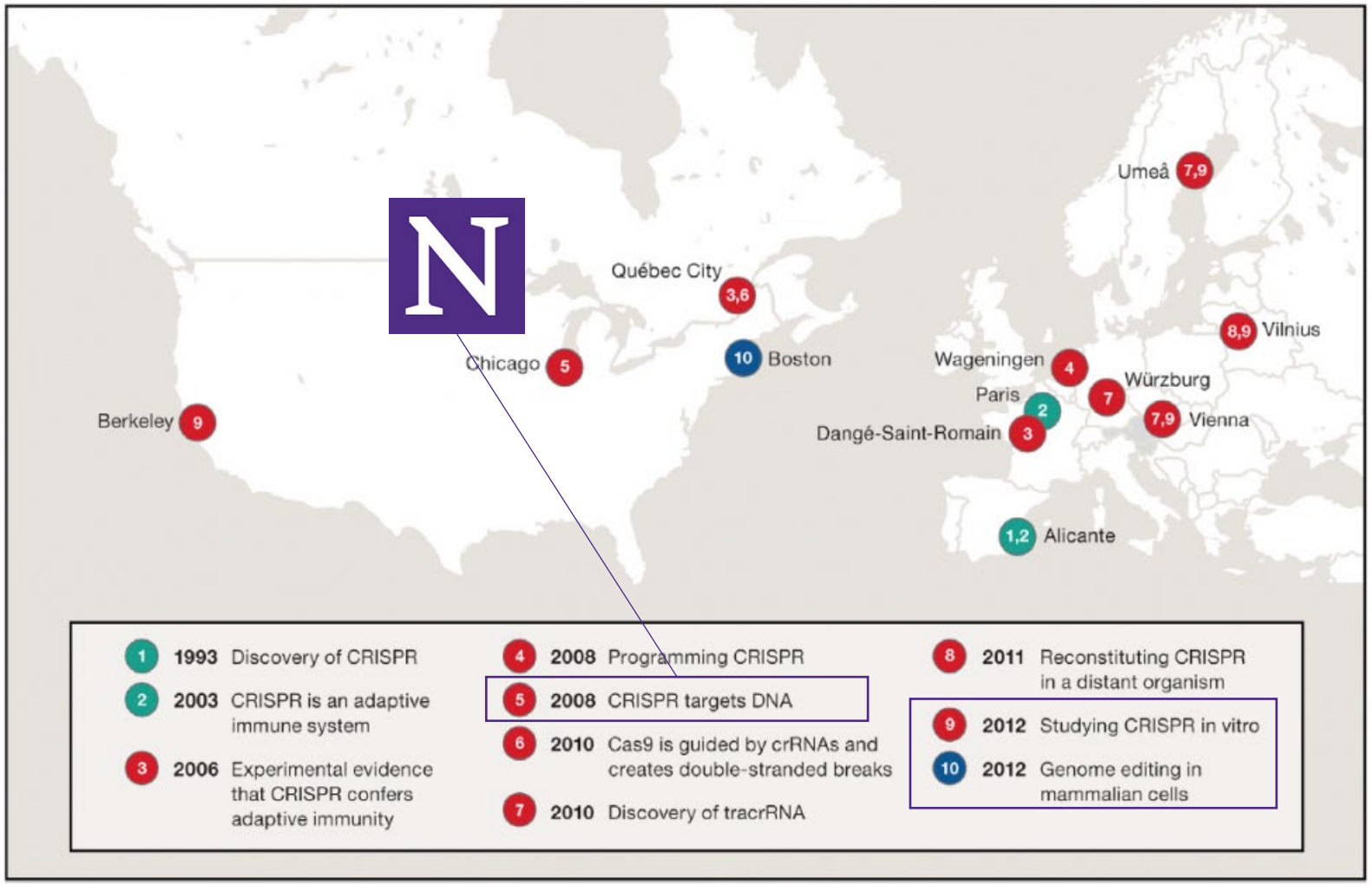

Figure 2. The Twenty-Year Story of CRISPR Unfolded across Twelve Cities in Nine Countries
For each "chapter" in the CRISPR "story," the map shows the sites where the primary work occurred and the first submission dates of the papers. Green circles refer to the early discovery of the CRISPR system and its function; red to the genetic, molecular biological, and biochemical characterization; and blue to the final step of biological engineering to enable genome editing.

- In the 1980's scientists at Osaka University identified repeated DNA sequences in bacterium (1980s)

  http://www.michaeleisen.org/blog/?p=1825

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CRISPR/Cas9 History - CRISPR acts on DNA targets

- *December, 2008 — Luciano Marraffini and Erik Sontheimer, Northwestern University, Illinois*
- The next key piece in understanding the mechanism of interference came from Marraffini and Sontheimer, who elegantly demonstrated that the target molecule is DNA, not RNA (Marraffini and Sontheimer, 2008)
- This was somewhat surprising, as many people had considered CRISPR to be a parallel to eukaryotic RNAi silencing mechanisms, which target RNA
- Marraffini and Sontheimer explicitly noted in their paper that this system could be a powerful tool if it could be transferred to non-bacterial systems

https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline

NU CRISPR/Cas9

- NU filed patent application related to Sontheimer 2008 discoveries
  - Provisional application filed ahead of December 2008 Science publication
  - Little additional data 12 months later for non-provisional filing
  - USPTO rejections based on lack of enablement and written description
  - Application abandoned with no patents issued

- NU filed patent application on 2013 improvement by Sontheimer
  - Focus on use of Cas9 from *Neisseria meningitides*-better specificity
  - Licensed to Intellia Therapeutics 2016
  - Sontheimer and Marraffini are co-founders of Intellia

CRISPR

Cal-Berkeley and the Broad Institute

CRISPR/Cas9 Background

- The Doudna lab – Cal-Berkeley
  - http://rna.berkeley.edu/crispr.html
- The Zhang Lab – Broad Institute
  - http://zlab.mit.edu/research.html

Berkeley UNIVERSITY OF CALIFORNIA

BROAD INSTITUTE

"It all began in 2012, when Doudna and others … published a seminal *Science* paper on CRISPR. In this paper, Doudna showed that the gene-editing technology can be used to cut DNA in a test tube at targeted sites. Later, Doudna filed a patent application for CRISPR."
https://www.theverge.com/2017/4/13/15278478/crispr-gene-editing-tool-patent-dispute-appeal-ucb-mit-broad

http://science.sciencemag.org/content/337/6096/816.long - paper Aug 17, 2012

CRISPR/Cas9 Background

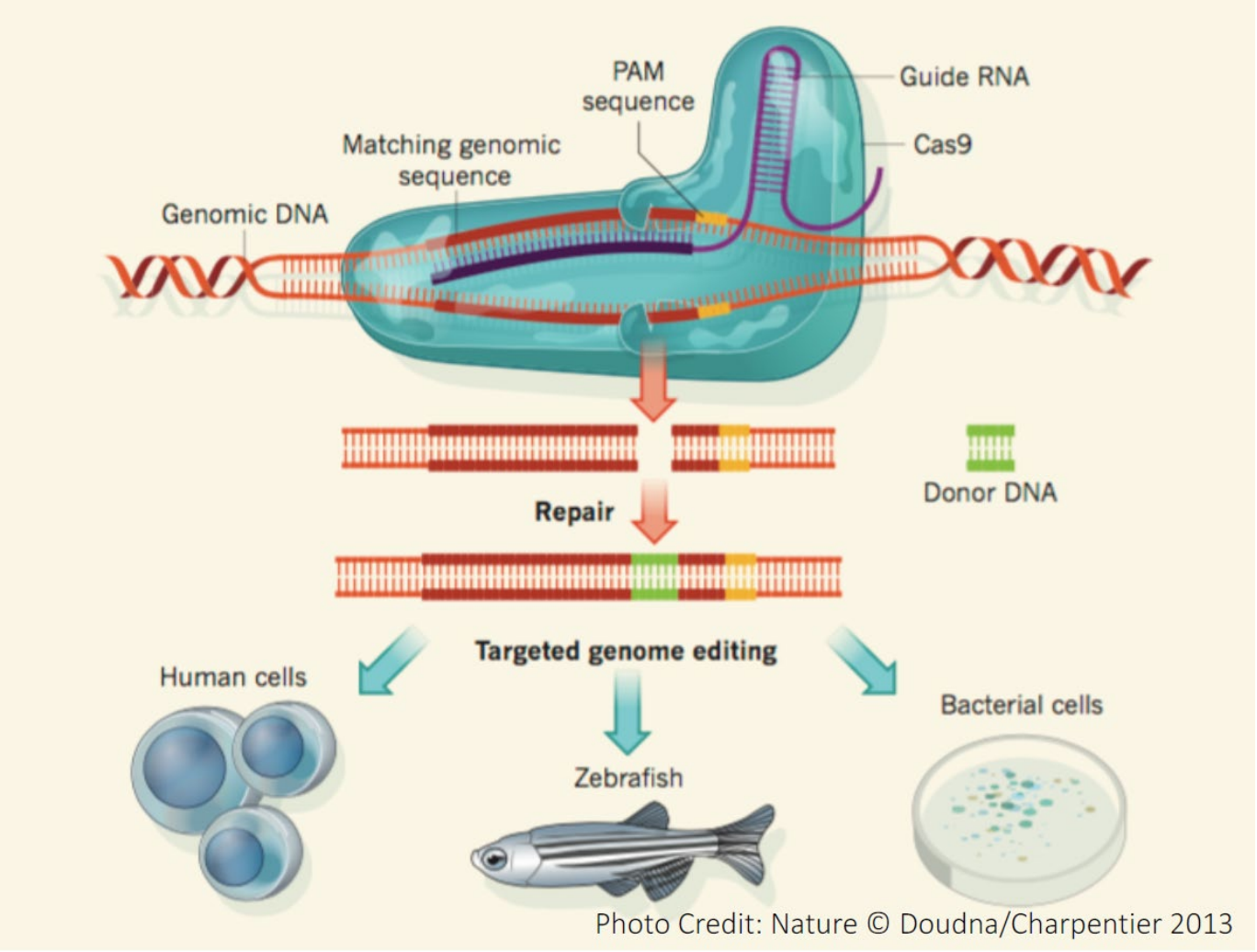

Photo Credit: Nature © Doudna/Charpentier 2013

CRISPR/Cas9 Background

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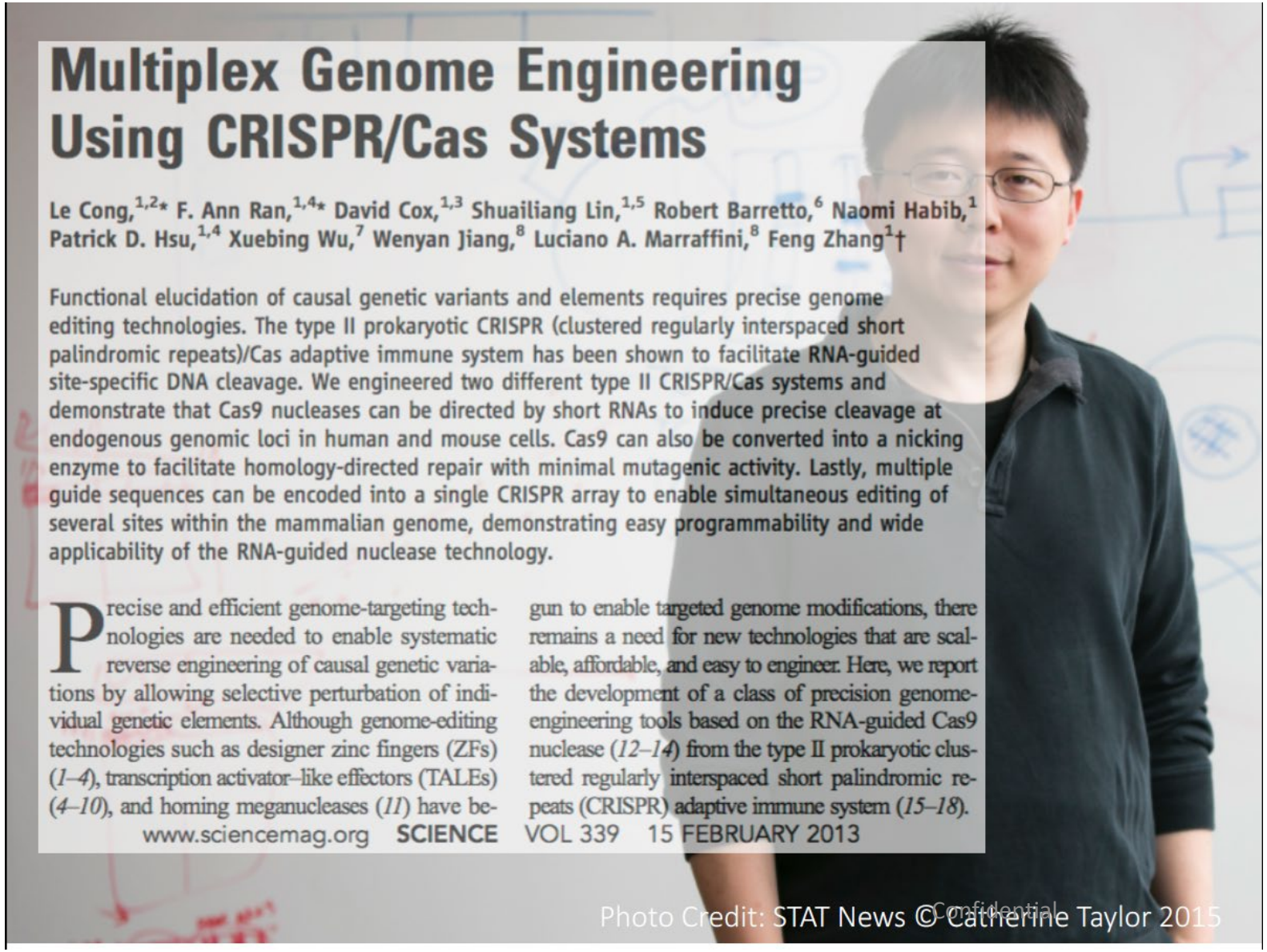

Multiplex Genome Engineering Using CRISPR/Cas Systems

Le Cong,[1,2]* F. Ann Ran,[1,4]* David Cox,[1,3] Shuailiang Lin,[1,5] Robert Barretto,[6] Naomi Habib,[1] Patrick D. Hsu,[1,4] Xuebing Wu,[7] Wenyan Jiang,[8] Luciano A. Marraffini,[8] Feng Zhang[1]†

Functional elucidation of causal genetic variants and elements requires precise genome editing technologies. The type II prokaryotic CRISPR (clustered regularly interspaced short palindromic repeats)/Cas adaptive immune system has been shown to facilitate RNA-guided site-specific DNA cleavage. We engineered two different type II CRISPR/Cas systems and demonstrate that Cas9 nucleases can be directed by short RNAs to induce precise cleavage at endogenous genomic loci in human and mouse cells. Cas9 can also be converted into a nicking enzyme to facilitate homology-directed repair with minimal mutagenic activity. Lastly, multiple guide sequences can be encoded into a single CRISPR array to enable simultaneous editing of several sites within the mammalian genome, demonstrating easy programmability and wide applicability of the RNA-guided nuclease technology.

Precise and efficient genome-targeting technologies are needed to enable systematic reverse engineering of causal genetic variations by allowing selective perturbation of individual genetic elements. Although genome-editing technologies such as designer zinc fingers (ZFs) (*1–4*), transcription activator–like effectors (TALEs) (*4–10*), and homing meganucleases (*11*) have begun to enable targeted genome modifications, there remains a need for new technologies that are scalable, affordable, and easy to engineer. Here, we report the development of a class of precision genome-engineering tools based on the RNA-guided Cas9 nuclease (*12–14*) from the type II prokaryotic clustered regularly interspaced short palindromic repeats (CRISPR) adaptive immune system (*15–18*).

www.sciencemag.org SCIENCE VOL 339 15 FEBRUARY 2013

Photo Credit: STAT News © Catherine Taylor 2015

Massachusetts Institute of Technology

HARVARD UNIVERSITY

+

- Beth Israel Deaconess Medical Center
- Brigham and Women's Hospital
- Children's Hospital Boston
- Dana-Farber Cancer Institute
- Massachusetts General Hospital

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The Patent Story

Berkeley
UNIVERSITY OF CALIFORNIA

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] This invention was made with government support under Grant No. GM081879 awarded by the National Institutes of Health. The government has certain rights in the invention.

BROAD INSTITUTE

STATEMENT AS TO FEDERALLY SPONSORED RESEARCH

[0004] This invention was made with government support awarded by the National Institutes of Health, NIH Pioneer Award DP1MH100706. The government has certain rights in the invention.

Feng Zheng - Early CRISPR Publications

BROAD INSTITUTE

1. **Multiplex Genome Engineering Using Crispr/Cas Systems**. *Science* 339, no. 6121 (**Epub Jan 3, 2013**)(Feb 15 2013): 819-23.
2. RNA-Guided **Editing of Bacterial Genomes** Using Crispr-Cas Systems. *Nature biotechnology* 31, no. 3 (**Epub Jan 29, 2013**) (Mar 2013): 233.
3. One-Step Generation of **Mice** Carrying Mutations in Multiple Genes by Crispr/Cas-Mediated Genome Engineering. *Cell* 153, no. 4 (**May 9 2013**): 910-18.
4. Programmable Repression and Activation of **Bacterial Gene Expression** Using an Engineered Crispr-Cas System. *Nucleic acids research* 41, no. 15 (**Epub Jun 12, 2013**)(Aug 2013): 7429-37.
5. **Double Nicking** by RNA-Guided Crispr Cas9 for **Enhanced Genome Editing Specificity**. *Cell* 154, no. 6 (**Epub Aug 29, 2013**; Sep 12 2013): 1380-89.
6. Efficient Genome Editing in **Plants** Using a Crispr/Cas System. *Cell research* 23, no. 10 (**Epub Aug 20, 2013**) (Oct 2013): 1229.
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8. Genome-Scale Crispr-Cas9 Knockout Screening in **Human Cells**. *Science* 343, no. 6166 (**Epub Dec 12, 2013**) (Jan 3 2014): 84-87.

Feng Zheng - Early CRISPR Publications

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10. Development and **Applications** of Crispr-Cas9 for Genome Engineering. *Cell* 157, no. 6 (**Jun 5 2014**): 1262-78.
11. Improved Vectors and Genome-Wide Libraries for Crispr Screening. *Nature methods* 11, no. 8 (**Aug 2014**): 783.
12. Crispr-Mediated Direct Mutation of Cancer Genes in the **Mouse Liver**. *Nature* 514, no. 7522 (**Epub Aug 5, 2014**) (Oct 16 2014): 380.
13. Mageck Enables Robust Identification of Essential Genes from Genome-Scale Crispr/Cas9 Knockout Screens. *Genome biology* 15, no. 12 (**Dec 5 2014**): 554.

Crispr/Cas9 | An Exceptional Opportunity

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- Patent filings and patent strategies reflect significant commercial opportunity
- Precise gene editing has potential to produce numerous products and services
  - Human therapeutics
  - Human treatments & cures
  - Animal Health
  - Agriculture / Food Science
  - Chemical production
  - Green technology / BioFuels
  - Pest control
  - Pet breeding
- Startup company & potential licensee forming before patent filings
- Patent filings were generally free of encumbrances
  - Subject to U.S. Government, Bayh-Dole obligations

Broad Institute | PATENT STRATEGY

- Filed well-developed patent applications
  - Substantial number of experiments in provisional applications
    - Numerous Guide RNA sequences
    - Dozens of target sequences
  - Significant data in provisional applications
  - Included mouse and human cell data
    - Supporting claims to mammalian systems
  - Filed frequently, whenever significant new data was generated
    - Included data beyond what was going in manuscripts
    - Always before publication

Broad Institute | PATENT STRATEGY

- The patent applications
  - Use technical language where appropriate
  - Use clear, not overly technical language elsewhere
  - Describe unmet need / problems to be solved
  - Interdisciplinary - include contributions from multiple disciplines
  - Drafted and filed to support field-specific licensing
- Inventions reflect extensive collaboration between lab, tech transfer office, and patent attorneys

Broad Institute | LICENSING STRATEGY

- Broad inventions generally free of encumbrances
  - No limiting industry sponsored research IP Terms

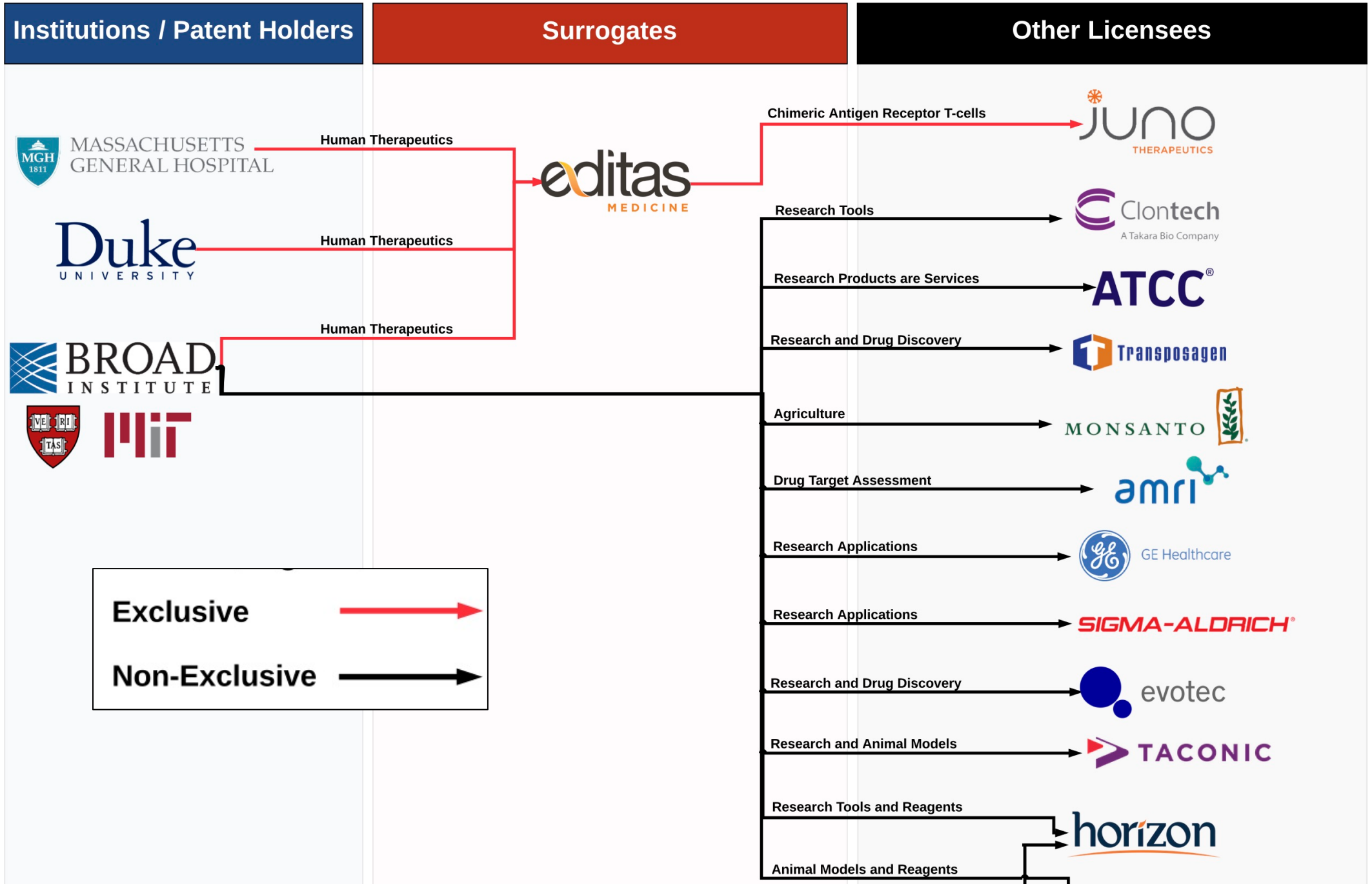
Broad Institute | LICENSING STRATEGY

- Broad used "inclusive innovation model"
  - **Academic and non-profit use** – *no license* needed
  - **Company research** – *non-exclusive* licenses available
  - **Tools and Reagents for genome editing** – *non-exclusive* licenses available
- **Broad** *exclusively* licensed **Field** of human therapeutics to Editas, Medicine, Inc.

https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-edi

Broad Institute | LICENSING CASE STUDY

- Broad led CRISPR/Cas9 licensing efforts for several universities
  - Broad, Harvard, MIT, HHMI – Oct 2014
    - Rockefeller added Mar 2017
  - Broad, MGH, UTokyo, Wageningen, Iowa – Dec 2016 (CPF1)
- Universities entered inter-institutional agreements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Human Therapeutics
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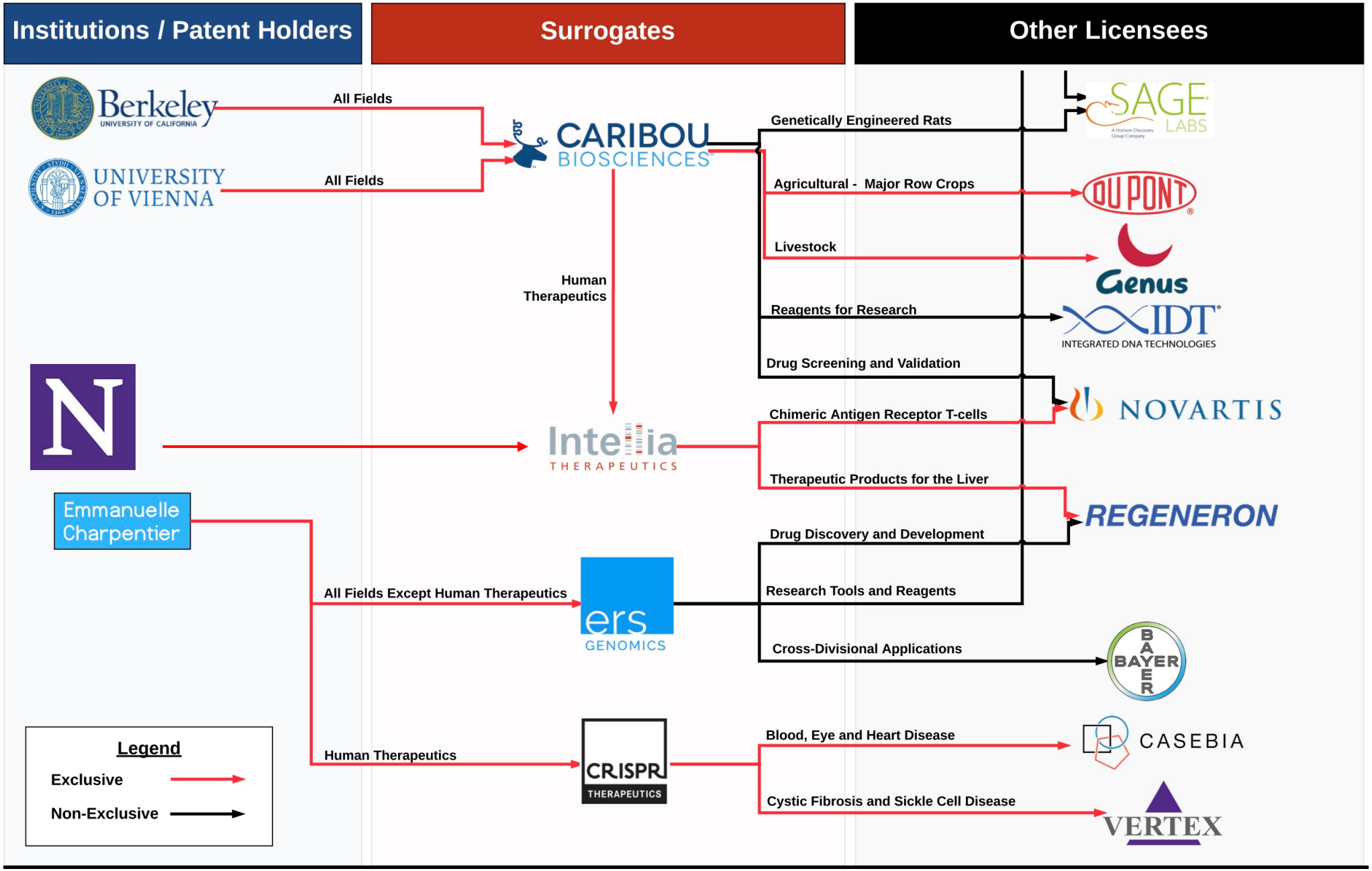
Research and Drug Discovery
evotec
Research and Animal Models
TACONIC
Research Tools and Reagents
horizon
Animal Models and Reagents
Exclusive
Non-Exclusive

Cal-Berkeley | LICENSING STRATEGY

- Full Surrogate model
  - Licensed All Fields Exclusively to Caribou Biosciences
  - Caribou *exclusively* licensed **Field** to Intellia Therapeutics
    - "All therapeutic, prophylactic and palliative uses and applications for any or all diseases and conditions in humans, with the sole exceptions of anti-microbial and/or anti-fungal applications
  - Caribou licensed *exclusively* certain **Fields** (agriculture, livestock) and other **Fields** *non-exclusively*

https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-edi



NYU CRISPR Contract Database

https://dataverse.harvard.edu/dataverse/crisprlicenses

Northwestern | INVO

A Few Final Takeaways

Strong patents support outside investment and licensing

- In certain markets, strong patents are necessary to ensure products and services make it to market
- NU goal is to provide public benefits

Researchers and INVO together can create strong patents, patent strategies, and licensing strategies

- Early engagement is key
- Data and research will drive patent filings and patent strategy
- Commercial and other factors may inform decision not to file for patent protection

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