

# INTRODUCTION OF U.S. PATENTS

JIE LIAN

E-MAIL: [JIE.LIAN@KLARQUIST.COM](mailto:JIE.LIAN@KLARQUIST.COM)

Disclaimer: Any views expressed through this presentation are those of the author and may not reflect the views of Klarquist, or any of its respective clients. This presentation is for information purposes only and not for the purpose of providing legal advice. Use of the any information contained within this presentation does not create an attorney-client relationship.

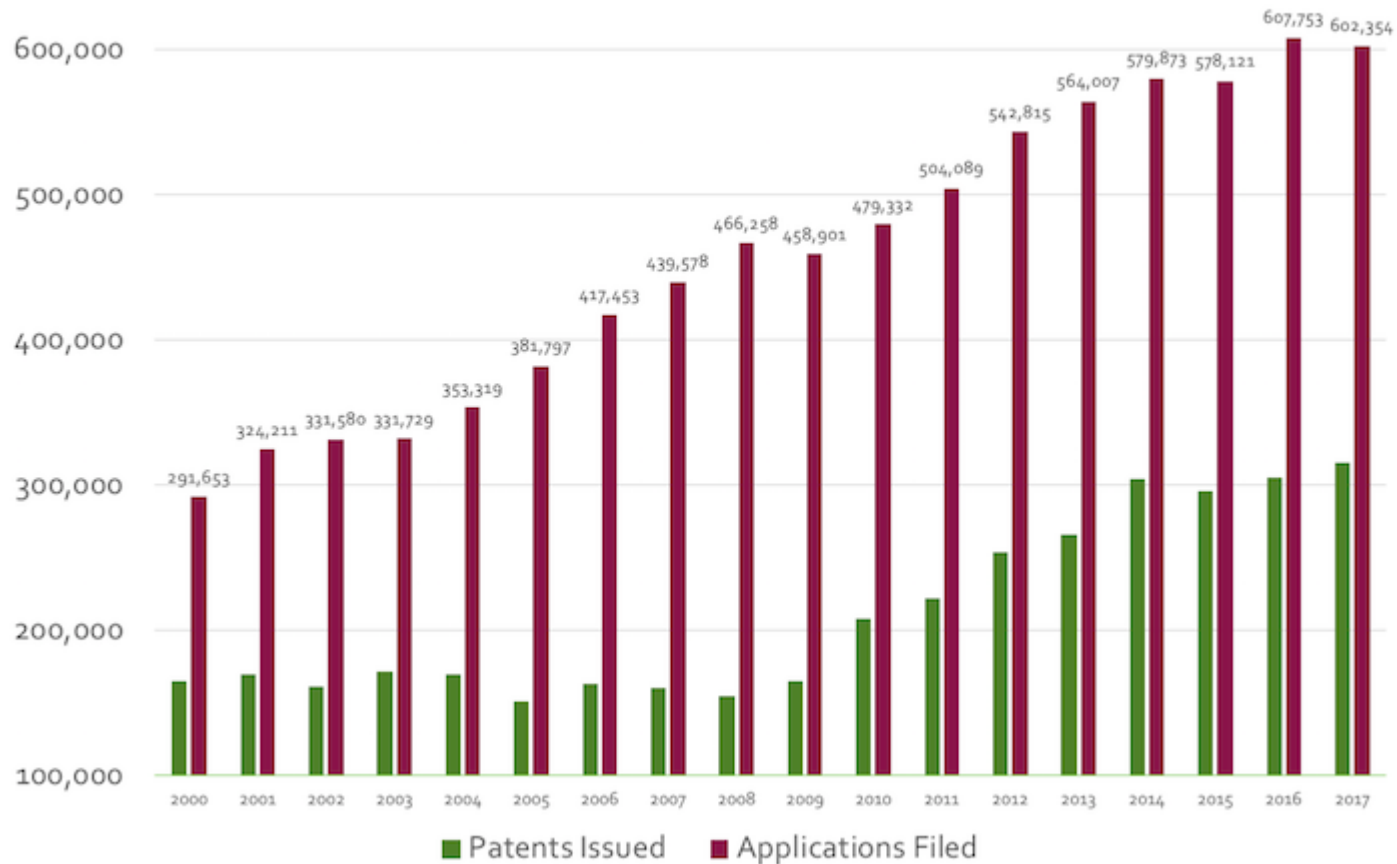
# AGENDA

- \* Overview of U.S. Patent System
- \* Requirements for a utility patent
- \* Patentability vs. Freedom to Operate
- \* Inventorship vs. Patent Ownership
- \* Provisional vs. Nonprovisional Patent Application
- \* General Process of U.S. Patent Prosecution
- \* Case study: CRISPR patent battle
- \* Other considerations
- \* Q&A



# U.S. Patenting Statistics

## Utility Patents at the USPTO



# U.S. Patent No. 10,000,000



US010000000B2

(12) **United States Patent**  
**Marron**

(10) **Patent No.:** **US 10,000,000 B2**

(45) **Date of Patent:** **Jun. 19, 2018**

(54) **COHERENT LADAR USING INTRA-PIXEL  
QUADRATURE DETECTION**

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

(71) Applicant: **Raytheon Company**, Waltham, MA  
(US)

5,093,563 A \* 3/1992 Small ..... G02B 27/58  
250/201.9

(72) Inventor: **Joseph Marron**, Manhattan Beach, CA  
(US)

5,751,830 A 5/1998 Hutchinson  
2003/0076485 A1 4/2003 Ruff et al.  
2006/0227317 A1\* 10/2006 Henderson ..... G01B 11/026  
356/28

(73) Assignee: **Raytheon Company**, Waltham, MA  
(US)

**FOREIGN PATENT DOCUMENTS**

WO WO 2005/080928 A1 9/2005

(\* ) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 430 days.

**OTHER PUBLICATIONS**

Li; "Time-of-Flight Camera—An Introduction"; Texas Instruments  
White Paper; SLOA190B; Jan. 2014; revised May 2014; 10 pp.

(Continued)

(21) Appl. No.: **14/643,719**

*Primary Examiner* — Luke D Ratcliffe

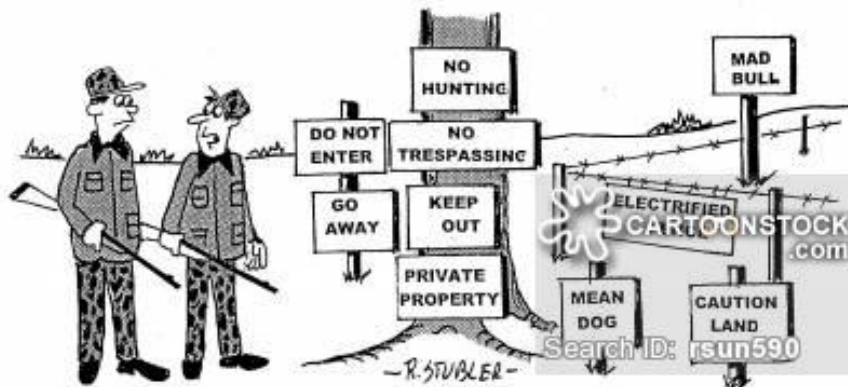
(74) *Attorney, Agent, or Firm* — Munck Wilson Mandala,  
LLP

(22) Filed: **Mar. 10, 2015**

(57) **ABSTRACT**

# What Is A Patent?

- \* Right to ***exclude others*** from making, using, selling, offering for sale or importing the claimed invention
- \* Limited term
- \* Territorial: protection only in territory that granted patent; NO world-wide patent



"THINK WE SHOULD ASK PERMISSION FIRST?"



# Why Patent An Invention?



- \* Gain entry to a market
- \* Exclude others from a market
- \* Marketing tool to promote unique aspects of a product
- \* Sold or licensed, like other property

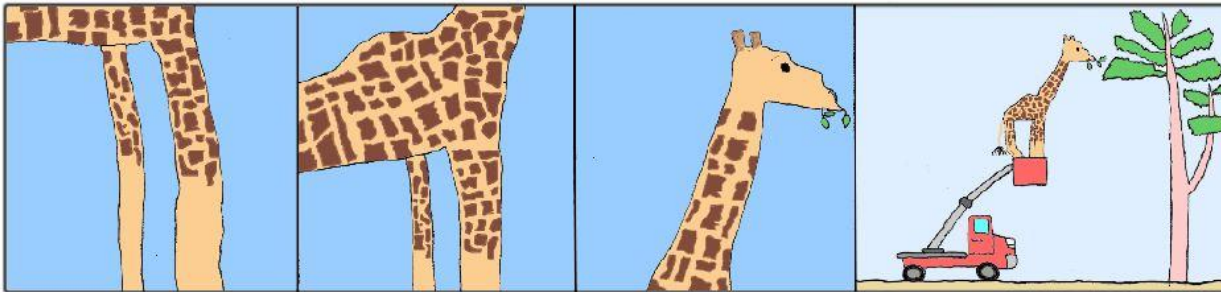


# What Can Be Patented?

- \* “Anything under the Sun that Is Made by Man”

## OUT OF CONTEXT

PAUL MCGEOWN (pmcgeown@imprint.uwaterloo.ca)



- \* “A person may have invented a machine or a manufacture, which may include *anything under the sun that is made by man*, but it is not necessarily patentable under section 101 ... unless the conditions of the title are fulfilled.”

Charles H. Duell , Commissioner of US patent office in 1899

# U.S. Patent Law

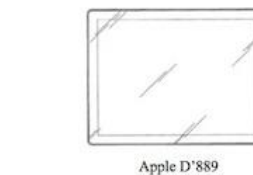
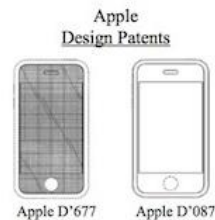
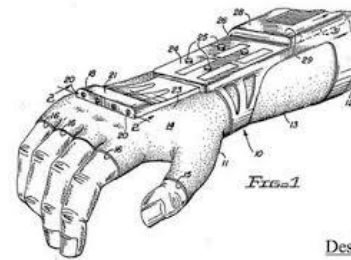
- \* Statutory
  - \* 35 U.S.C. (Patent Code)
- \* Rules: 37 C.F.R. (Patent Regulations)
  - \* Rules governing the operation of the USPTO; may be changed by the USPTO following the proper procedure
- \* Case Law
  - \* The United States has a common law system  
Court cases shape the interpretation of laws





# Type of U.S. Patents

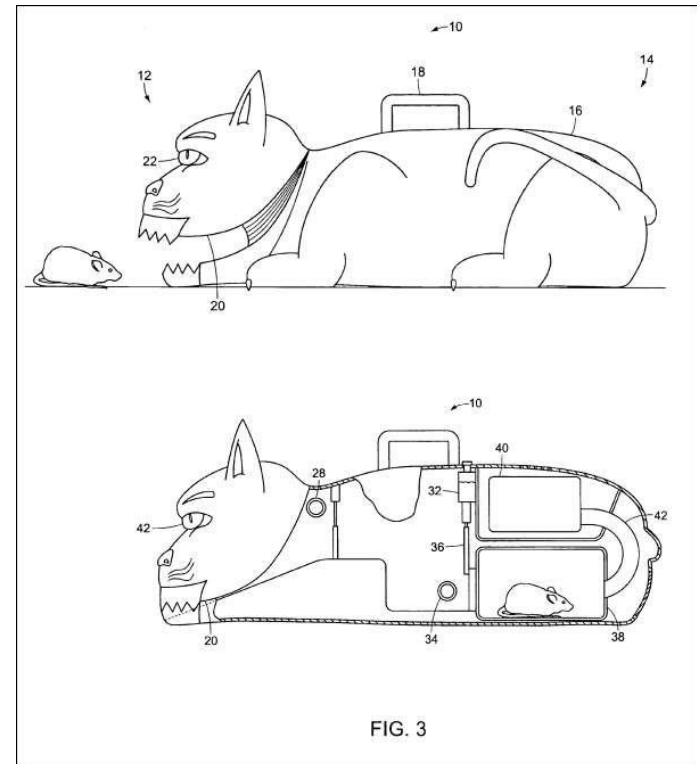
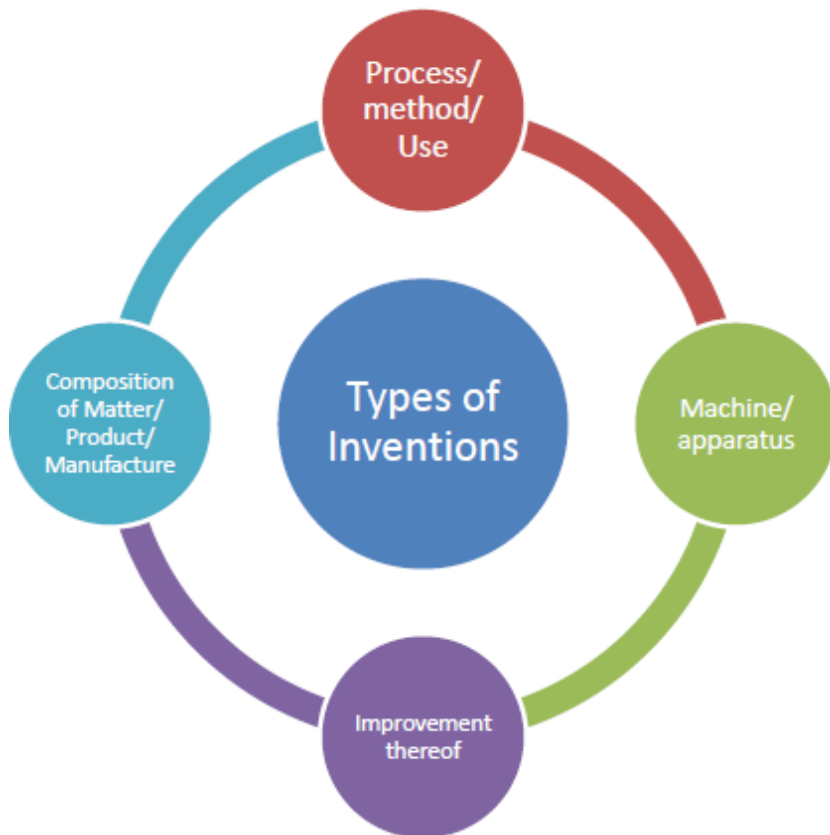
- \* **Utility:** how an invention works
  - \* Inventions
  - \* Functionality
  - \* 20-year term from filing date
- \* **Design:** how it looks
  - \* ornamental design described & shown
  - \* 15-year term from grant date
- \* **Plant:** new variety of asexually reproduced plant
  - \* 20-year term from filing date



imlaw.com



# Utility Patents



# Requirements for Patentability



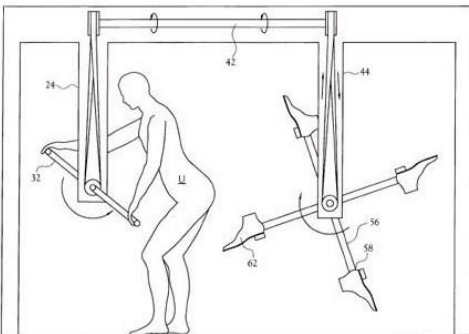
35 USC §101 – Utility, Statutory Subject Matter

35 USC §112 (a) – Enablement, written description, and best mode

35 USC §112 (b) – Definiteness

35 USC §102 – Anticipation

35 USC §103 – Obviousness



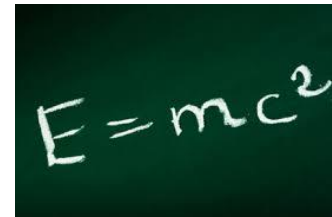
# Patent Eligibility (§ 101)

## 35 U.S.C. § 101

Whoever invents or discovers *any new and useful process, machine, manufacture, or composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### Judicial Exceptions

- Laws of nature
- Natural phenomena
- Abstract ideas



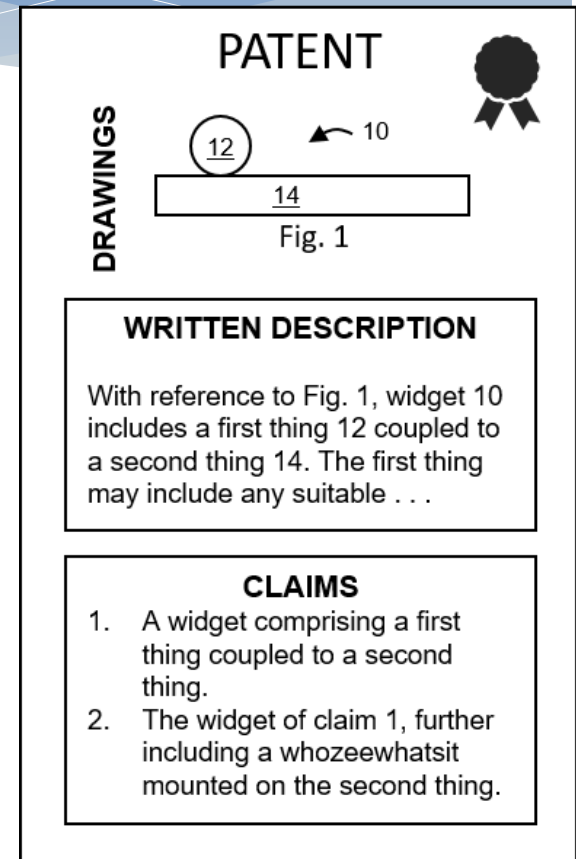
# Enablement & Written Description (§ 112(a))

## Written Description

Requires that the specification objectively demonstrate that the applicant actually invented –was in possession of- the claimed subject matter.

## Enablement

Requires the inventor to describe his or her invention in a manner that would allow others in the industry to make and use the invention.



# Indefiniteness (§ 112(b))

## Indefiniteness

A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.



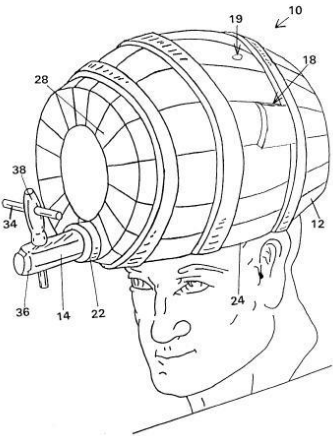
# Novelty (§ 102)

## § 102 (a)

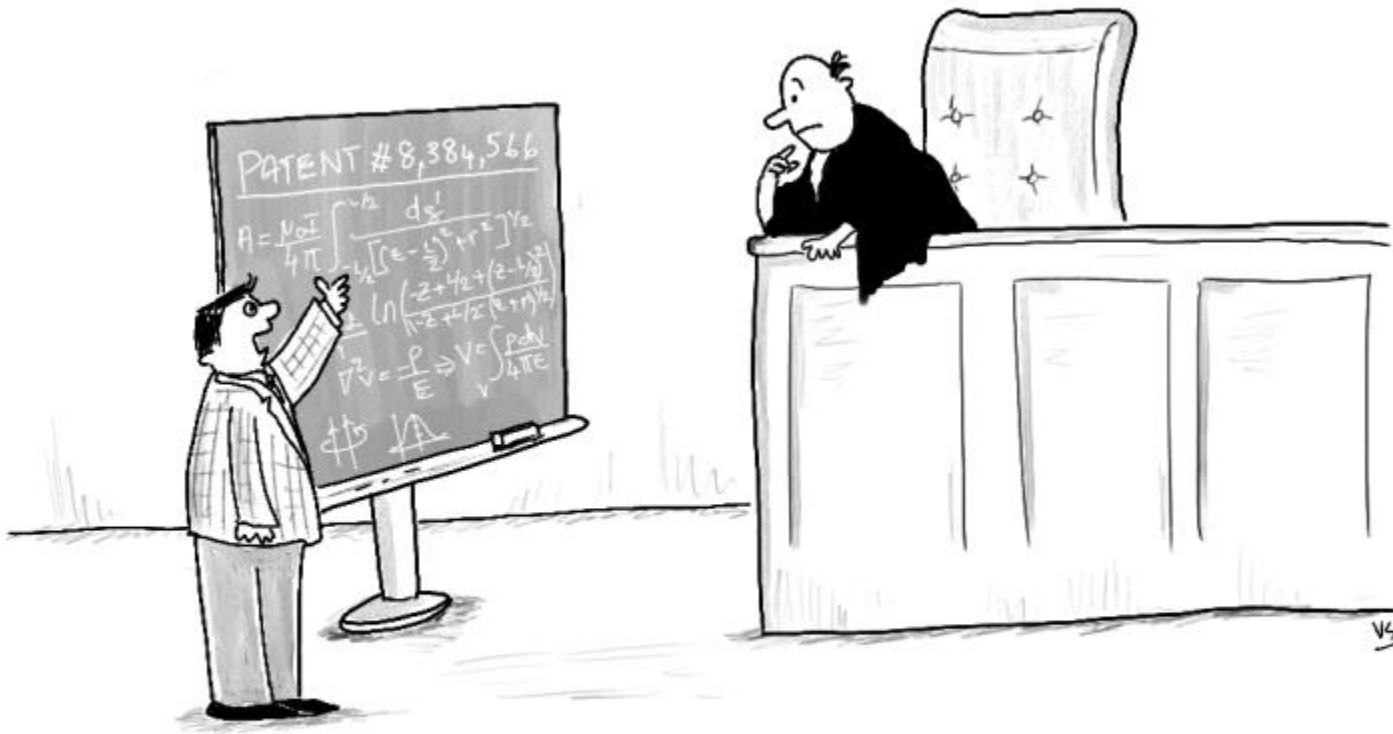
A person shall be entitled to a patent unless—

- 1) the claimed invention was **patented, described in a printed publication, or in public use, on sale, or otherwise available to the public** before the effective filing date of the claimed invention; or
- 2) the claimed invention was **described in a patent** issued under section 151, **or in an application for patent published or deemed published** under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention

U.S. Patent Oct. 19, 1999 Sheet 1 of 6 5,966,743



# Non-obviousness (§ 103)



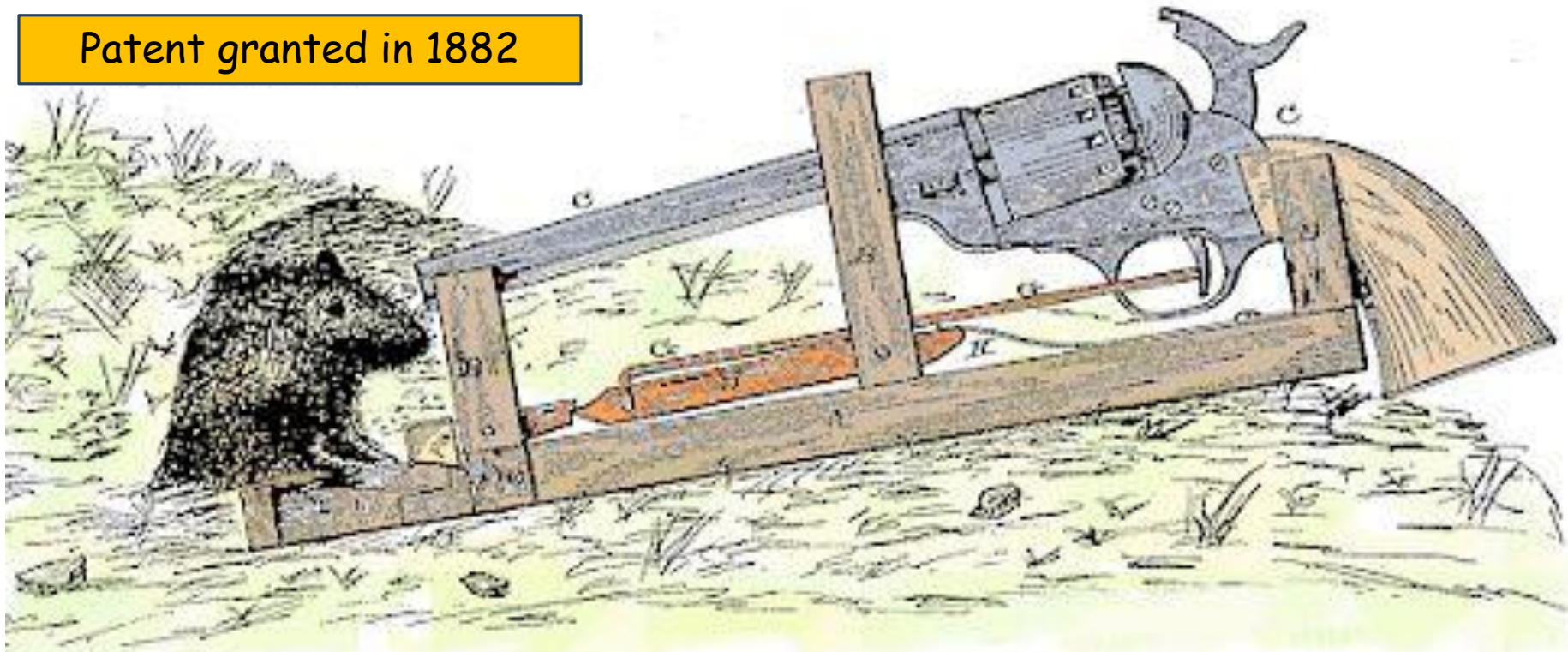
*"So you see your honor, it's obvious."*



# Is It Patentable?

"The Better Mousetrap"

Patent granted in 1882



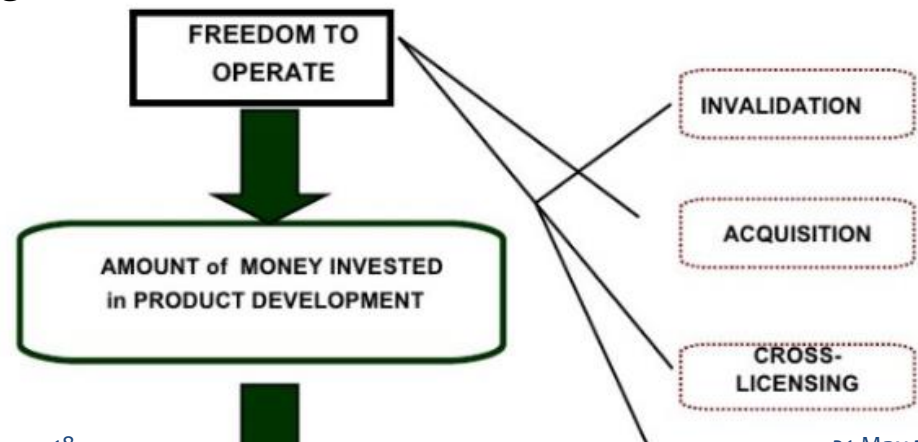
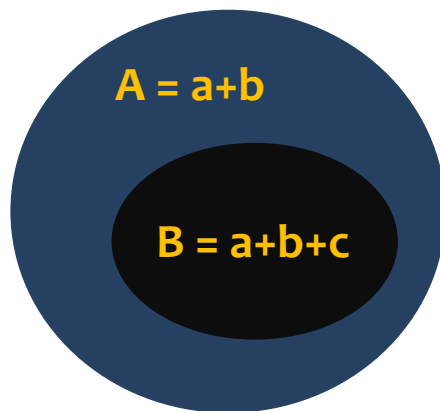
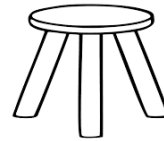
**Novel? Non-obvious? Useful? Enabled?**

# FREEDOM TO OPERATE

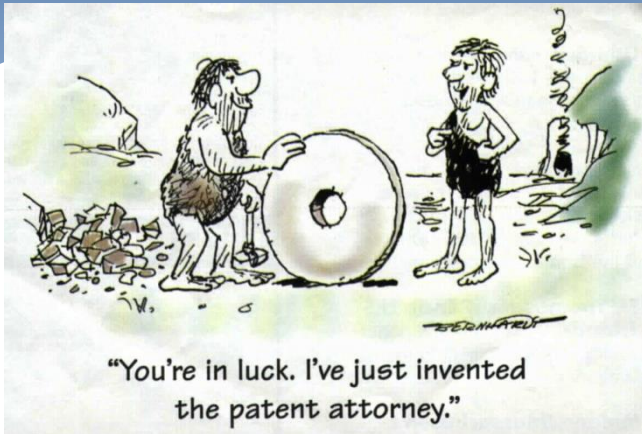
**Claim A:** A seating structure comprising a seating platform and *at least three legs*.

**Claim B:** A seating structure comprising a seating platform and *four legs*.

**Claim C:** A seating structure comprising a seating platform, a plurality of legs, and a *stretcher connecting each pair of the legs*.



# Inventorship



## Who is an Inventor?

An inventor is a person who contributes to the “**conception**” of the invention; and

Contribution is shown in **at least one claim of the patent.**

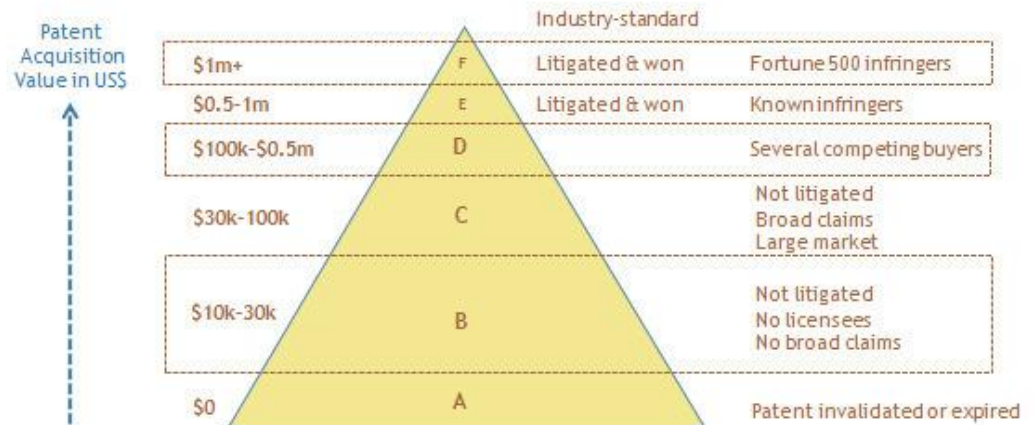
- \* IT'S ALL ABOUT CONCEPTION
- \* Conception is not reduction to practice
- \* Inventorship is determined on a claim-by-claim basis
- \* Inventive entity can change during prosecution

# Patent Ownership

- \* Ownership of a patent gives the patent owner the **right to exclude** others from **making, using, offering for sale, selling, or importing** into the U.S. the invention claimed in the patent.



- \* Initial ownership
- \* Transfer of ownership
- \* Patent valuation



Pending (unissued) patent applications: value is triggered when patent is approved.  
Value is contingent on approval.

# Provisional vs. Non-Provisional

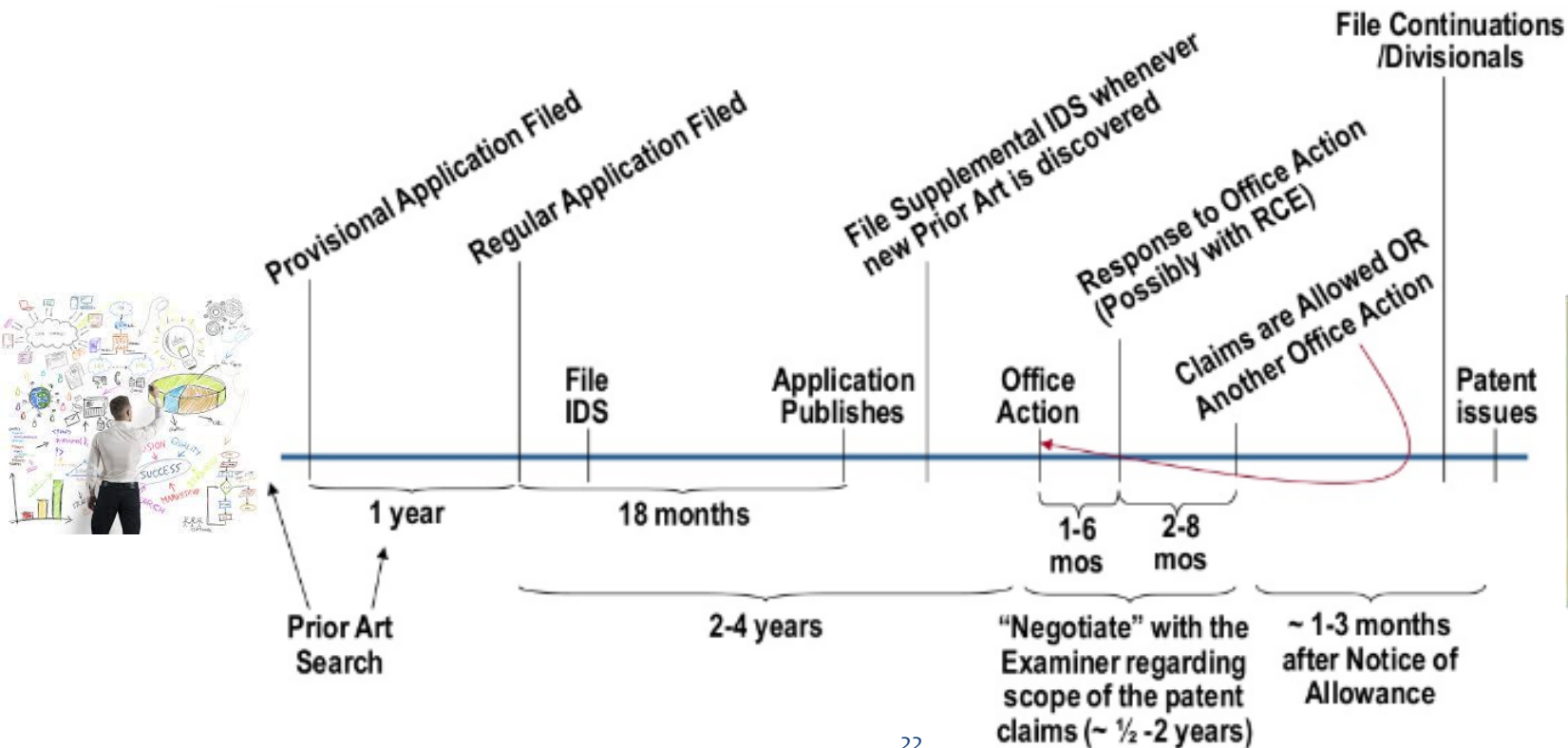


- \* Nonprovisional (regular) application
- \* Provisional application:
  - \* Not examined
  - \* One year grace period for public disclosure
    - \* Early priority date
    - \* Refine concept and test market
    - \* Cost saving
- \* Caveats
  - \* Support in compliance with § 112

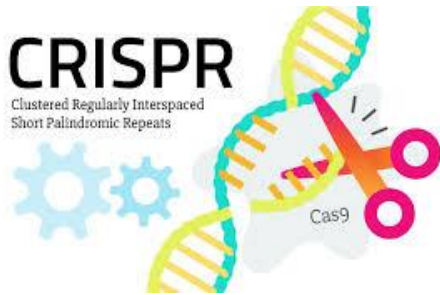




# Patent Prosecution Timeline

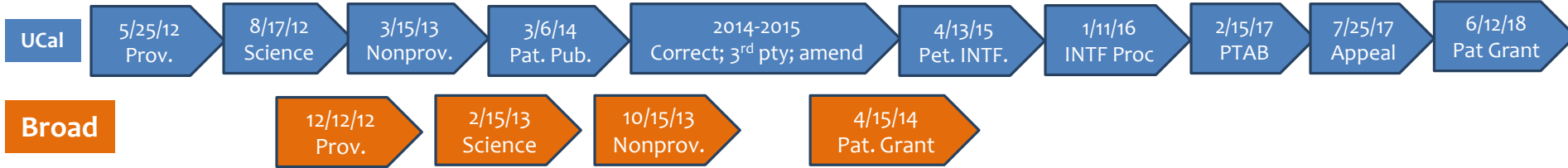


# Case Study: CRISPR



- \* CRISPR : revolutionary gene editing technology
- \* Numerous applications: curing diseases, protecting plants, producing food, creating biofuels, reviving extinct animals, etc.
- \* PRNewswire: *“Global CRISPR market is estimated to grow at a CAGR of 33.26 during the forecast period to reach a total market size of US\$3,087 million by 2023 from US\$551 million in 2017.”*
- \* Who: UCal (Jennifer Doudna et al.) v. Broad Inst. (Feng Zhang)

# Battle of CRISPR Patents



(19) **United States Patent Application Publication**  
**Doudna et al.**  
 (10) Pub. No.: US 2014/0068797 A1  
 (43) Pub. Date: Mar. 6, 2014

(54) **METHODS AND COMPOSITIONS FOR RNA-DIRECTED TARGET DNA MODIFICATION AND FOR RNA-DIRECTED MODULATION OF TRANSCRIPTION**  
 61/757,640, filed on Jan. 28, 2013, provisional application No. 61/765,576, filed on Feb. 15, 2013.

(71) Applicants: **Jennifer A. Doudna**, Berkeley, CA (US); **Martin Jinek**, Berkeley, CA (US); **Emmanuelle Charpentier**, Berkeley, CA (US); **Krzysztof Chylinski**, Berkeley, CA (US); **James Harrison Doudna**, Berkeley, CA (US); **Wendell Lim**, San Francisco, CA (US); **Lei Qi**, Albany, CA (US)

(72) Inventors: **Jennifer A. Doudna**, Berkeley, CA (US); **Martin Jinek**, Berkeley, CA (US); **Emmanuelle Charpentier**, Berkeley, CA (US); **Krzysztof Chylinski**, Berkeley, CA (US); **James Harrison Doudna**, Berkeley, CA (US); **Wendell Lim**, San Francisco, CA (US); **Lei Qi**, Albany, CA (US)

(73) Assignees: **UNIVERSITY OF VIENNA, Vienna (AUT); THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Oakland, CA (US)**

(21) Appl. No.: **13842,859**

(22) Filed: **Jan. 15, 2013**

**Related U.S. Application Data**  
 (60) Provisional application No. 61/652,086, filed on May 25, 2012; provisional application No. 61/716,256, filed on Oct. 19, 2012; provisional application No. 61/757,640, filed on Jan. 28, 2013; provisional application No. 61/765,576, filed on Feb. 15, 2013.

**Publication Classification**  
 (51) **Int. Cl.**  
*C12N 15/90* (2006.01)  
*C12N 15/113* (2006.01)  
*C12N 9/22* (2006.01)  
 (52) **U.S. Cl.**  
 CPC ..... *C12N 15/907* (2013.01), *C12N 9/22* (2013.01), *C12N 15/113* (2013.01)  
 USPC ..... **800/18**, 536/23.1, 435/320.1, 435/199, 435/325, 435/243, 435/252.3, 435/419, 435/257.2, 435/349, 435/352, 435/353, 435/354, 435/363, 435/366, 435/462; 435/91.53, 435/375, 536/24.5, 506/16, 800/298, 800/13, 800/19, 514/44 R, 424/93.21, 424/93.2

(57) **ABSTRACT**  
 The present disclosure provides a DNA-targeting RNA that comprises a targeting sequence and, together with a modifying polypeptide, provides for site-specific modification of a target DNA and/or a polypeptide associated with the target DNA. The present disclosure further provides site-specific modifying polypeptides. The present disclosure further provides methods of site-specific modification of a target DNA and/or a polypeptide associated with the target DNA. The present disclosure provides methods of modulating transcription of a target nucleic acid in a target cell, generally involving contacting the target nucleic acid with an enzymatically inactive Cas9 polypeptide and a DNA-targeting RNA. Kits and compositions for carrying out the methods are also provided. The present disclosure provides genetically modified cells that produce Cas9; and Cas9 transgenic non-human multicellular organisms.

## RESEARCH ARTICLE

### A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity

Martin Jinek,<sup>1,2\*</sup> Krzysztof Chylinski,<sup>3,4\*</sup> Ines Fonfara,<sup>4</sup> Michael Hauer,<sup>2,†</sup> Jennifer A. Doudna,<sup>1,2,5,6,†</sup> Emmanuelle Charpentier<sup>2,†</sup>

Clustered regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated (Cas) systems provide bacteria and archaea with adaptive immunity against viruses and plasmids by using CRISPR RNAs (crRNAs) to guide the silencing of invading nucleic acids. We show here that in a subset of these systems, the mature crRNA that is base-paired to trans-activating crRNA (tracrRNA) forms a two-RNA structure that directs the CRISPR-associated protein Cas9 to introduce double-stranded (ds) breaks in target DNA. At sites complementary to the crRNA-guide sequence, the Cas9 HNH nuclease domain cleaves the complementary strand, whereas the Cas9 RuvC-like domain cleaves the noncomplementary strand. The dual-tracrRNA:crRNA, when engineered as a single RNA chimera, also directs sequence-specific Cas9 dsDNA cleavage. Our study reveals a family of endonucleases that use dual-RNAs for site-specific DNA cleavage and highlights the potential to exploit the system for RNA-programmable genome editing.

(12) **United States Patent**  
**Zhang**  
 (10) Patent No.: **US 8,697,359 B1**  
 (45) Date of Patent: **\*Apr. 15, 2014**

(54) **CRISPR-CAS SYSTEMS AND METHODS FOR ALTERING EXPRESSION OF GENE PRODUCTS**

(68) **References Cited**  
 U.S. PATENT DOCUMENTS  
 2010/0076057 A1 3/2010 Sontheimer et al.  
 2011/0189796 A1 8/2011 Terro et al.  
 2011/0226308 A1 9/2011 Wondolowski et al.  
 2013/0130348 A1 5/2013 Haurwitz et al.

FOREIGN PATENT DOCUMENTS  
 WO WO/2008/108889 9/2008  
 WO WO/2010/054108 5/2010  
 WO WO/2012/164665 12/2012  
 WO WO/2013/098344 7/2013  
 WO WO/2013/176772 11/2013

OTHER PUBLICATIONS  
 Makarova et al., "Evolution and classification of the CRISPR-Cas systems" 96) Nature Reviews Microbiology 467-477 (1-23) (Jan. 2011).  
 Wondolowski et al., "RNA-guided genetic silencing systems in bacteria and archaea" 82) Nature 331-338 (Feb. 16, 2012).  
 Guimaraes et al., "Cas9-crRNA ribonucleoprotein complex mediates specific DNA cleavage for adaptive immunity in bacteria" 109(79) Proceedings of the National Academy of Sciences USA E2579-E2586 (Sep. 4, 2012).  
 Jinek et al., "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity" 337 Science 816-821 (Aug. 17, 2012).  
 Carroll, "A CRISPR Approach to Gene Targeting" 2009) Molecular Therapy 1658-1660 (Sep. 2012).  
 U.S. Appl. No. 61/652,086, filed May 25, 2012, 69 pages.\*  
 Al-Amir et al., "Clustered Regularly Interspaced Short Palindromic Repeats (CRISPRs): The Hallmark of Innate Antiviral Defense Mechanism in Prokaryotes," *Biof. Chem.* (2011) vol. 392, Issue 4, pp. 277-289.  
 Hale et al., "Essential Features and Rational Design of CRISPR RNAs that Function With the Cas RAMP Module Complex to cleave RNAs," *Molecular Cell*, (2012) vol. 45, Issue 3, 292-302.

(69) **Related U.S. Application Data**  
 Provisional application No. 61/842,322, filed on Jul. 2, 2013; provisional application No. 61/736,527, filed on Dec. 12, 2012; provisional application No. 61/788,927, filed on Jan. 2, 2013; provisional application No. 61/791,409, filed on Mar. 15, 2013; provisional application No. 61/835,931, filed on Jan. 17, 2013.

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



# Lessons from CRISPR Patent Fights



- \* Is it obvious?
  - \* Would application of CRISPR-Cas9 in vitro and in bacterial systems have had a “reasonable likelihood of success” in eukaryotic cells?
  - \* Prof. Doudna: The results suggested the “exciting possibility” that CRISPR-Cas9 could be operative in eukaryotic cells; “it was not known whether such a bacterial system would function in eukaryotic cells.” Acknowledging she had experienced “many frustrations” getting CRISPR to work in human cells and that she knew that if she succeeded, CRISPR would be “a profound discovery.”
- \* Publish or non-publish?
  - \* Pre-issuance damage; PCT; scrutiny; design-around; marketing . . .
- \* Build a patent portfolio
  - \* Initial UCal Pat. App. 13/842,859 has 155 claims
- \* Expedite patent prosecution?

# Expedite Patent Prosecution

## Track One Prioritized Examination

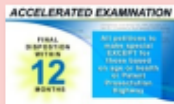


### First Action in less than 5 months and final disposition objective is within 12 months

- Faster time to first action
- Request must be filed via EFS web and fee required at the time of filing
- No additional examination-related support documents
- Application limited to no more than 30 total claims (4 independent claims maximum)
- Prioritization fee: \$4000 (\$2000 small, \$1000 micro)

[http://www.uspto.gov/patents/init\\_events/Track\\_One.jsp](http://www.uspto.gov/patents/init_events/Track_One.jsp)

## Accelerated Examination



### First Action in less than 5 months and final disposition objective is within 12 months

- Faster time to first action
- Petition, petition fee, preexamination search, and an "Examination Support Document" required at the time of filing
- Promotes personal interviews prior to issuance of first Office action
- Application limited to 20 claims (3 independent claims maximum)

<http://www.uspto.gov/patents/process/file/accelerated/index.jsp>

## Patent Prosecution Highway



### Provides accelerated prosecution following favorable results from a participating foreign office

- Entry based upon at least one allowable claim in counterpart foreign application
- First Office action within 2-3 months of petition grant
- Request must be submitted prior to a first action
- No limit on the number of claims

[http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp)

# Costs vs. Benefits



## \* Costs

- \* Government fees (filing fee, search fee, examination fee, issue fee, maintenance fee, etc.)
- \* Attorney fees (hourly fees, flat rate, hybrid model, etc.)

## \* Benefits

- \* Market size
- \* Market competitions
- \* Product life time
- \* Market territories

Stu's Views © 2004 Stu All Rights Reserved www.STUS.com



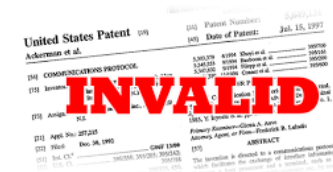
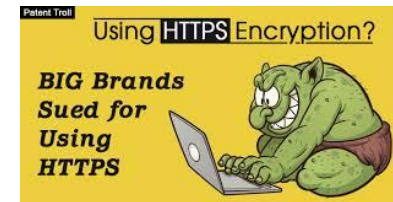
"No, my husband and I never fight. I'm a litigator and, frankly, he can't afford my time."

# Patent Enforcement

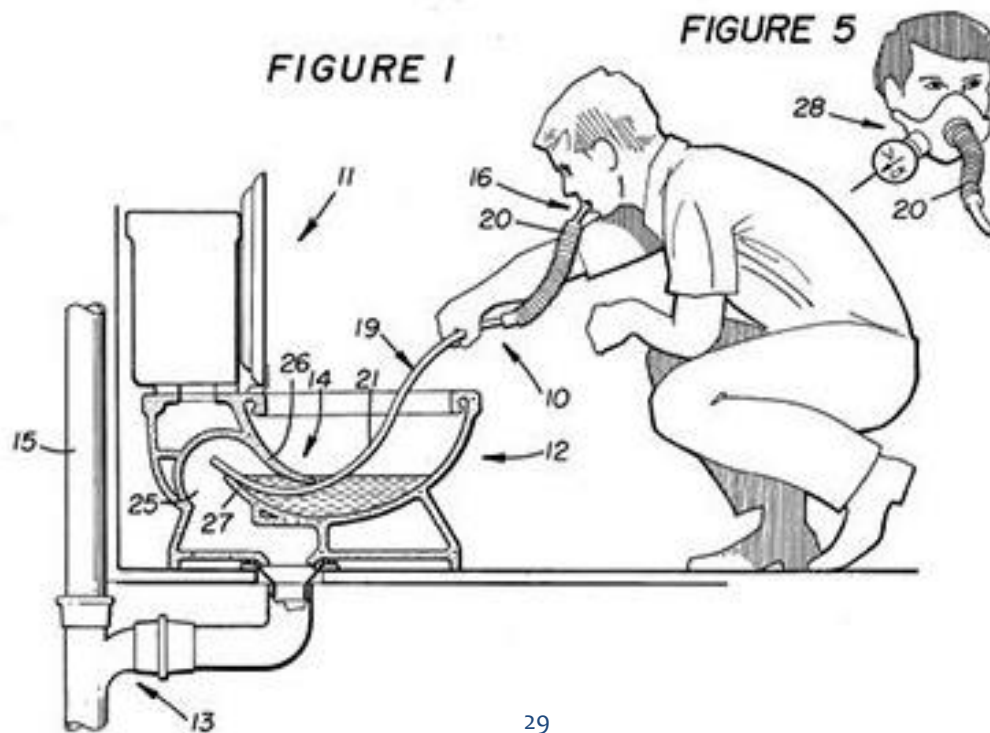
## THE Patent WARS

THE CONVOLUTED BATTLEFIELD OF TECH IP.

- \* Stakes and costs
- \* Patent infringement
- \* Patent work around
- \* Patent enforceability
- \* Patent defensibility



# Questions?



U.S. Patent Mar. 23, 1982

Sheet 1 of 2

4,320,756