Intersections between the FDA & USPTO:

Traditions and New Aspects

NAPP 25th Annual Meeting & Conference,
July 2022

Hibbs Law, LLC
Genna Hibbs & Emily Mosnick

- Intellectual Property boutique firm **founded in 2013**
- **Bar Admissions:** Illinois, US Northern District IL, US Patents & Trade Office
- **Focus Areas:** Patents, Trademarks, Copyrights, Unfair Competition, Trade Secrets, Infringement Enforcement/Litigation, Licensing, Entity Formation, Regulatory Compliance, and Business Transactions.
- **Clientele:** Small business, medium corporations, individuals
- **Technology:** Biotechnology, Genetics, Chemistry, basic devices.
- Substantial dedication to ***pro bono*** legal services (20-30% of time)

Roadmap:

Part One: Traditions

Patent §101 Utility requirements

Hatch-Waxman Act

Patent Prosecution—FDA interactions

- §2107.01—**General principles governing utility rejections**
  - Judicial Rule: FDA approval not necessary for therapeutic utility; expected to get P applications filed prior to full testing (practical with costs/investment)
    - In re Hartop, 311 F.2d 249 (CCPA 1962)
    - Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994)
    - In re Brana, 51 F.3d 1560 (Fed. Cir. 1995)

Patent Prosecution—FDA interactions

- Judicial Rule, Origins:
  - "As previously pointed out, one major public purpose of the patent law is to secure the disclosure of inventions with the least possible delay. In discharging this function, it is entirely proper that *reasonable proof* of an applicant's asserted utility be required by the Patent Office. What I here criticize is the manner in which these requirements have been extended beyond a reasonable compliance with statutory requirements. I find no reason, either in logic, justice, or public policy why the grant of a patent here should be delayed until the pharmacological merits of the disclosed invention are established by clinical tests conducted on humans, when such merits may be evaluated on the basis of other qualified tests."
    - Isenstead v. Watson, 157 F.Supp 7 (D.C.Cir. 1957)

§2107.03—Special considerations for asserted therapeutic or pharmacological utilities

-Human Clinical Data → Presumption

"Thus, as a general rule, if an applicant has initiated human **clinical trials** for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility."

Let's look at the presumption,

§2107.03—Special considerations for asserted therapeutic or pharmacological utilities

-Safety & Efficacy Considerations

- "The Office must confine its review of patent applications to the statutory requirements of the patent law. Other agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs."

  = Full circle to Isenstead.

§2107.03—Special considerations for asserted therapeutic or pharmacological utilities

-Safety & Efficacy Considerations, con't

- The FDA pursues a two-prong test to provide approval for testing. Under that test, a sponsor must show that the investigation does not pose an unreasonable and significant risk of illness or injury and that there is an acceptable rationale for the study.
- If the use reviewed by the FDA **is not** set forth in the specification, FDA review may not satisfy 35 U.S.C.101.

§2107.03—Special considerations for asserted therapeutic or pharmacological utilities

-Safety & Efficacy Considerations, con't

- However, if the reviewed use **is** one set forth in the specification, Office personnel must be extremely hesitant to challenge utility. In such a situation, experts at the FDA have assessed the rationale for the drug or research study upon which an asserted utility is based and found it satisfactory.
- Examiner's Burden to challenge utility: there is no sound rationale for the asserted utility even though experts designated by Congress to decide the issue have come to an opposite conclusion.

§2107.03—Special considerations for asserted therapeutic or pharmacological utilities

-Safety & Efficacy Considerations, con't

Not an Absolute: "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *In re Brana,* 51 F.3d 1560, 34 USPQ2d 1436(Fed. Cir. 1995) (citing *Scott v. Finney,* 34 F.3d1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994)).

"Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See *In re Sichert*, 566 F.2d 1154, 196 USPQ 209(CCPA 1977); *In re Hartop,* 311 F.2d 249, 135USPQ 419 (CCPA 1962); *In re Anthony,* 414 F.2d1383, 162 USPQ 594 (CCPA 1969); *In re Watson*,517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In reKrimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd.Pat. App. & Inter. 1981)."

§2107.03—Special considerations for asserted therapeutic or pharmacological utilities

-Treatment of Specific Disease Conditions

- Claims directed to a method of treating or curing a disease for which there have been no previously successful treatments or cures warrant careful review for compliance with 35 U.S.C. 101.
- In these cases, it is important to note that the Food and Drug Administration has promulgated regulations that enable a party to conduct clinical trials for drugs used to treat life threatening and severely-debilitating illnesses, even where no alternative therapy exists.
- Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible.
- Risk circling into a sec. 103 issue??

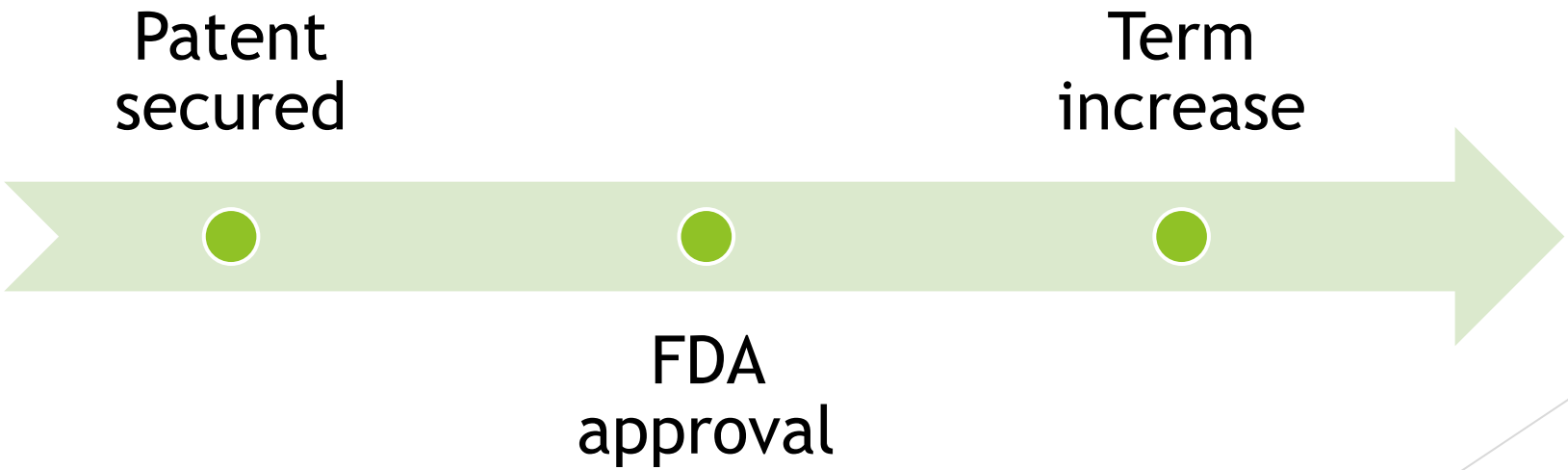
Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act) 1984

Data Exclusivity

FDA Data Exclusivity—keep it secret, keep it safe!

- 5 years for new chemical entity (21 U.S.C. 355(j))
- 3 years for new indications for pharmaceutical drugs (orange book)
- 12 years for biologic products (42 U.S.C. 262(k)(7))

Patent Term Extension



Sec. 156 / MPEP §2750: USPTO's job to evaluate the FDA approval and grant extension

- "An application for the extension of the term of a patent under 35 U.S.C. 156 must be submitted by the owner of record of the patent or its agent within the sixty-day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use."

Part Two:
Patents and Gene Therapies

Familiar framework, new problems?

Biologics/ Gene Therapies: new story, same story?

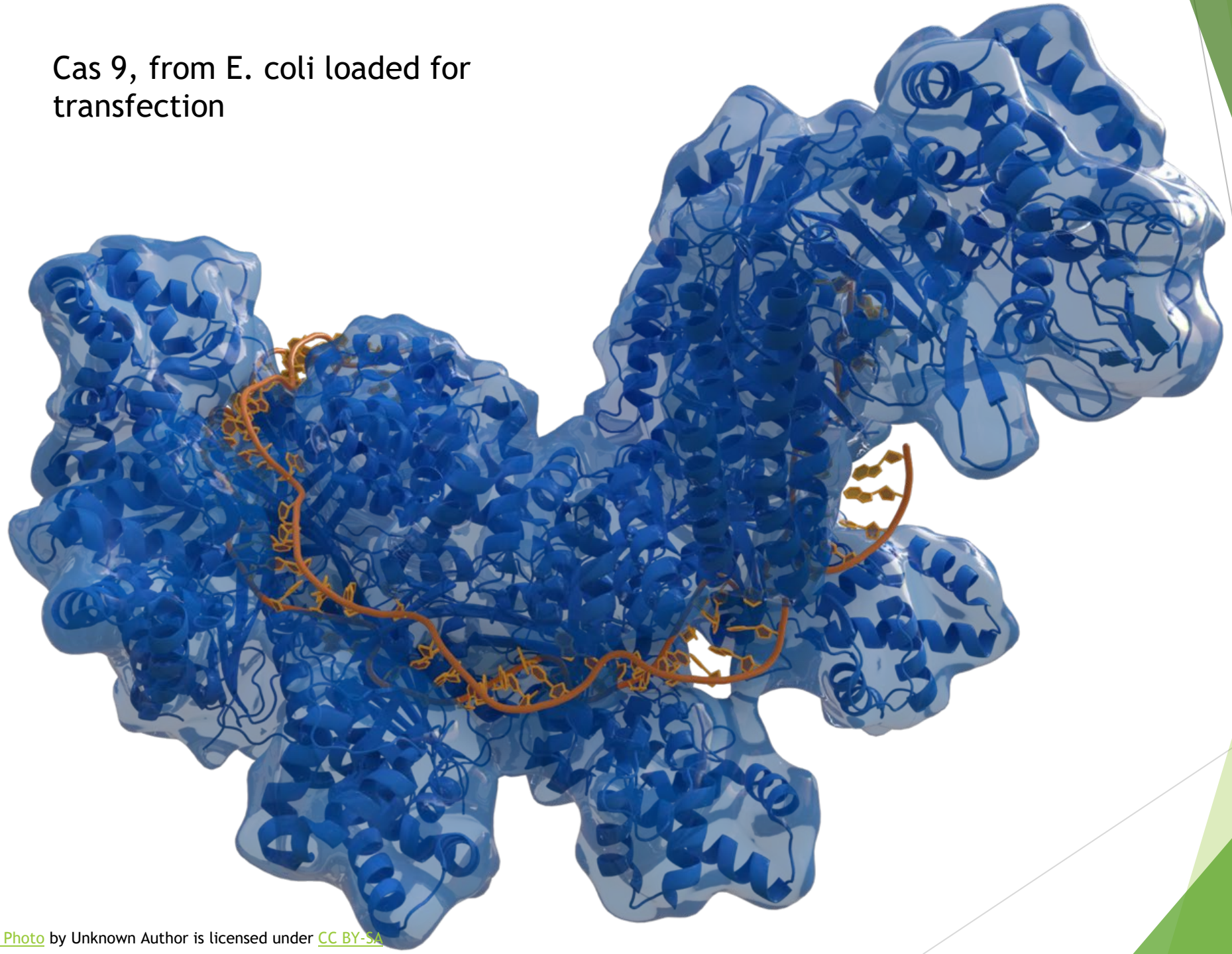
- Biologics Price Competition and Innovation Act (BCPI) of 2009
  - Biosimilar Implementation Committee (BIC) is ‘working’ to implement H-W-style processes for biologics: abbreviated applications like drug generics
    - On the books since 2010, last page update 2016, staffing issues/ administrative priority changes / pandemic = ??
  - What about generic safe harbor/ patent expiration/ “orange book” for biologics?

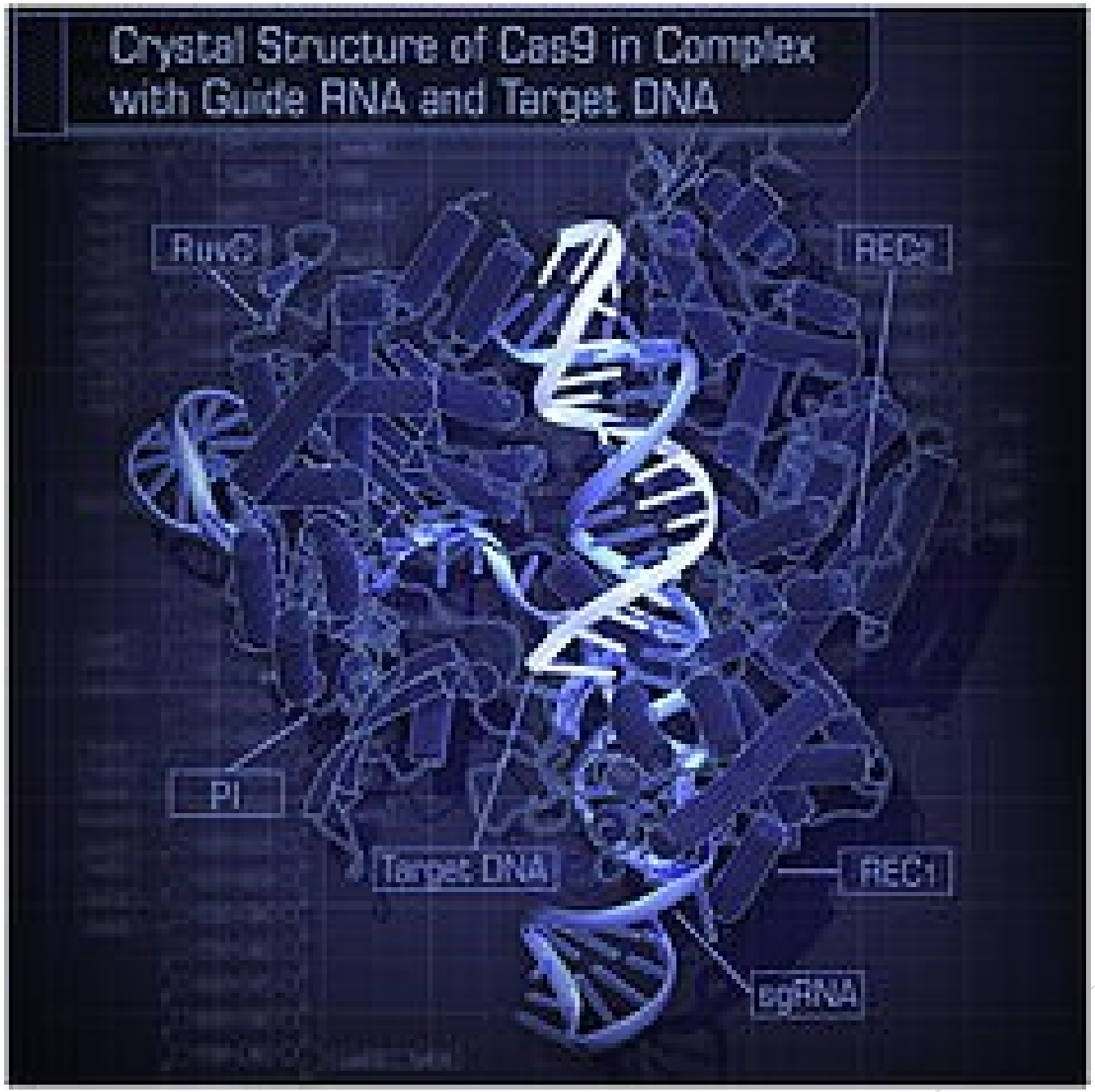
FDA currently has 24 approved gene therapies. 1st was 30Aug17 Kymriah (17 in 2019)

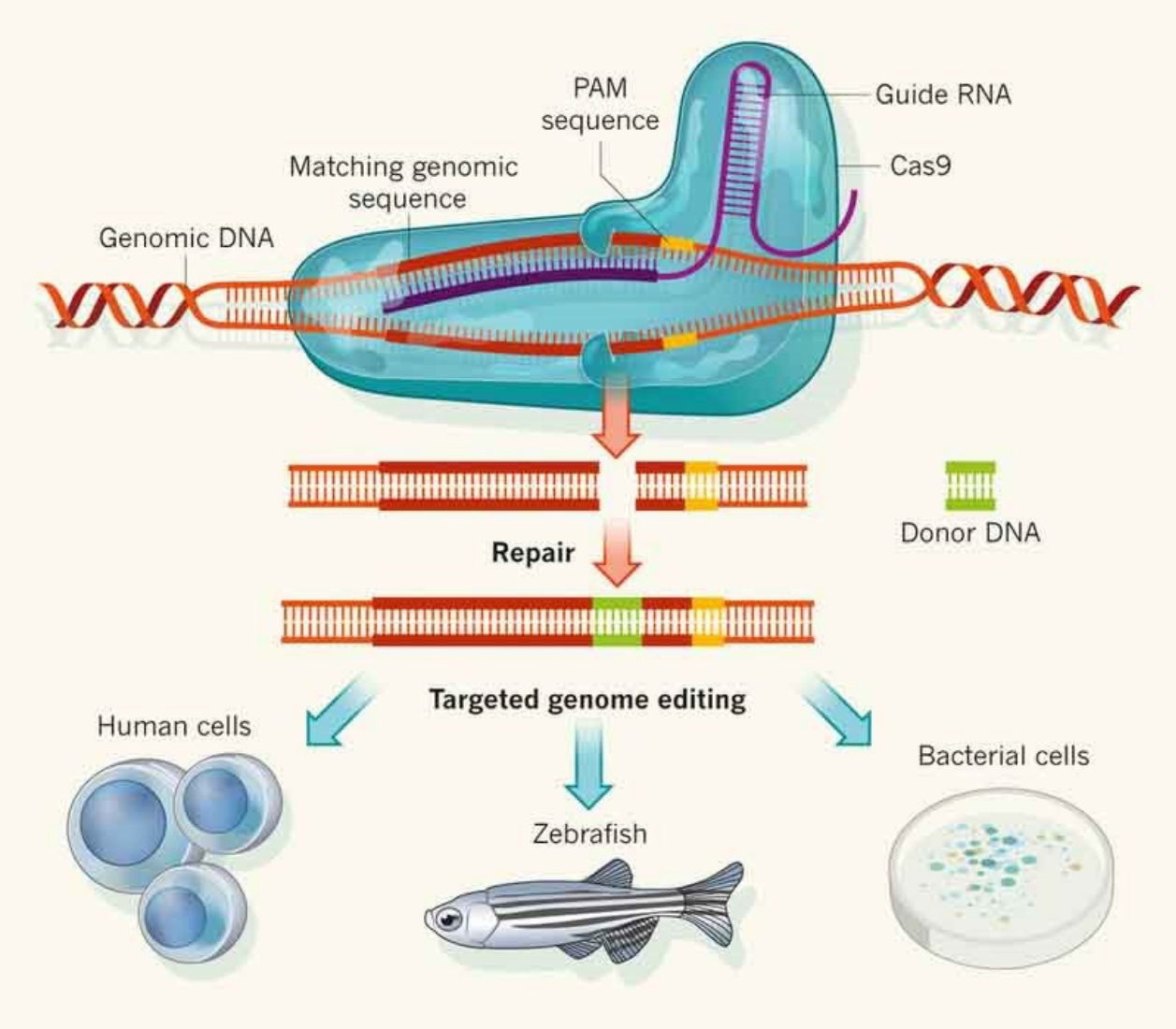
ABECMA (idecabtagene vicleucel)
Celgene Corporation, a Bristol-Myers Squibb Company
ALLOCORD (HPC, Cord Blood)
SSM Cardinal Glennon Children's Medical Center
BREYANZI
Juno Therapeutics, Inc., a Bristol-Myers Squibb Company
CARVYKTI (ciltacabtagene autoleucel)
Janssen Biotech, Inc.
CLEVECORD (HPC Cord Blood)
Cleveland Cord Blood Center
Ducord, HPC Cord Blood
Duke University School of Medicine
GINTUIT (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen)
Organogenesis Incorporated
HEMACORD (HPC, cord blood)
New York Blood Center
HPC, Cord Blood
Clinimmune Labs, University of Colorado Cord Blood Bank
HPC, Cord Blood - MD Anderson Cord Blood Bank
MD Anderson Cord Blood Bank
HPC, Cord Blood - LifeSouth
LifeSouth Community Blood Centers, Inc.
HPC, Cord Blood - Bloodworks
Bloodworks
IMLYGIC (talimogene laherparepvec)
BioVex, Inc., a subsidiary of Amgen Inc.
KYMRIAH (tisagenlecleucel)
Novartis Pharmaceuticals Corporation
LAVIV (Azficel-T)
Fibrocell Technologies
LUXTURNA
Spark Therapeutics, Inc.
MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane)
Vericel Corp.
PROVENGE (sipuleucel-T)
Dendreon Corp.
RETHYMIC
Enzyvant Therapeutics GmbH
STRATAGRAFT
Stratatech Corporation
TECARTUS (brexucabtagene autoleucel)
Kite Pharma, Inc.
YESCARTA (axicabtagene ciloleucel)
Kite Pharma, Incorporated
ZOLGENSMA (onasemnogene abeparvovec-xioi)
Novartis Gene Therapies, Inc.

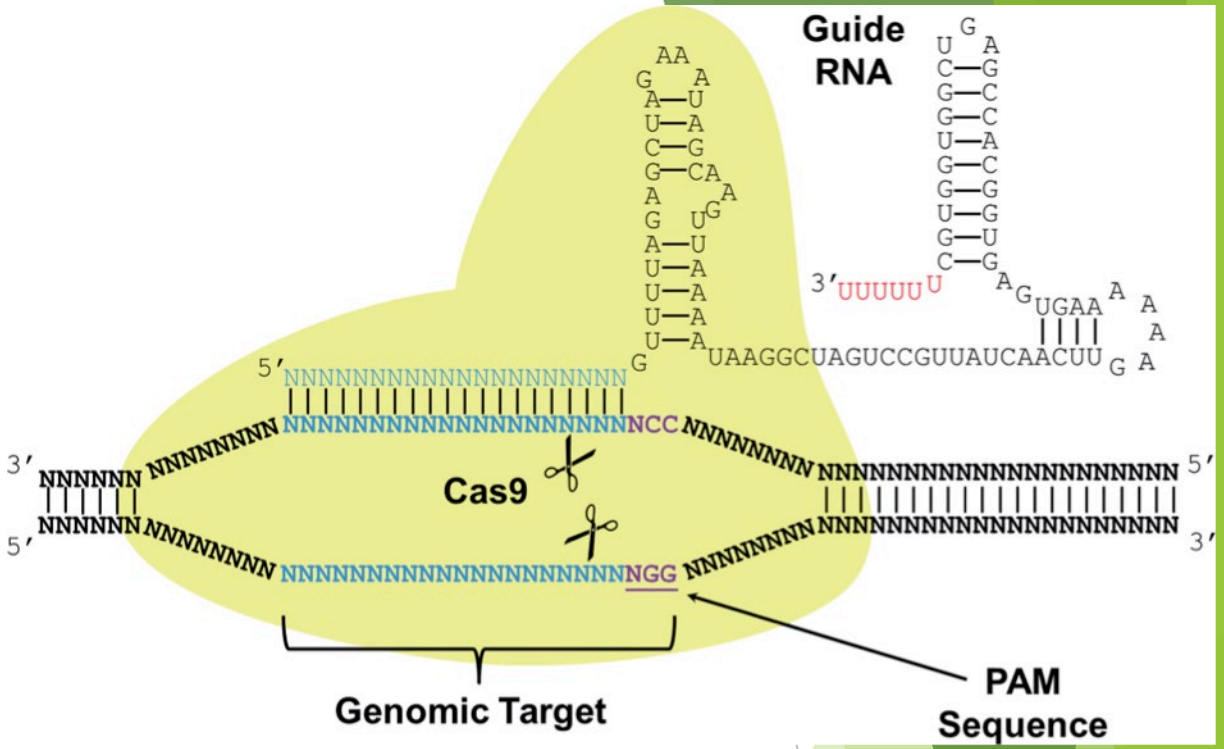
CRISPR-CAS9

Cas 9, from E. coli loaded for transfection




Crystal Structure of Cas9 in Complex
with Guide RNA and Target DNA
RuvC
REC2
PI
Target DNA
REC1
sgRNA





So many options!!
Find specific sequences and:

- Add new material
- Express existing material
- Block material
- Label

Battle of the CRISPR: 11,000 Families
https://www.nature.com/articles/d41586-022-00629-y

- Feng Zhang of **MIT/Cambridge/Harvard** (US Patent for CRISPR-Cas9 in eukaryotes, EPO revoked)
- Doudna of **Caribou & UC Berkley (CVC)** (US interference and EPO opposition)
- Charpentier of UC Berkley and Sigma-Aldrich/**MilliporeSigma and Broad Inst.** (AU issued, EPO appeal lost Jan2020, US interference).
- June 2019: new US patent interference (examine priority on competing inventions) — which was started by the USPTO rather than one of the parties — involves one patent application filed by and 13 patents issued to the Broad in 2014, 2015, and 2017, and 10 patent applications filed by UC Berkeley in 2018, all on the use of CRISPR-Cas9 to edit eukaryotic genomes.
- = 28Feb22 BROAD was first.

July 2021 Competition EO

6Jul2022 USPTO Letter

1. Enhancing collaboration with other agencies, such as the FDA, on key technology areas, including pharmaceuticals and biologics
2. Improving procedures for obtaining a patent to ensure that the USPTO issues robust and reliable patents
3. Improving the process for challenging issued patents before the Patent Trial and Appeal Board (America Invents Act proceedings)
4. Improving public participation in the patent system
5. Considering new proposals for incentivizing and protecting innovation while minimizing unnecessary delays in getting more affordable drugs to market

https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

https://www.uspto.gov/initiatives/drug-pricing-initiatives

Part Three: FDA & CDB Trademarks

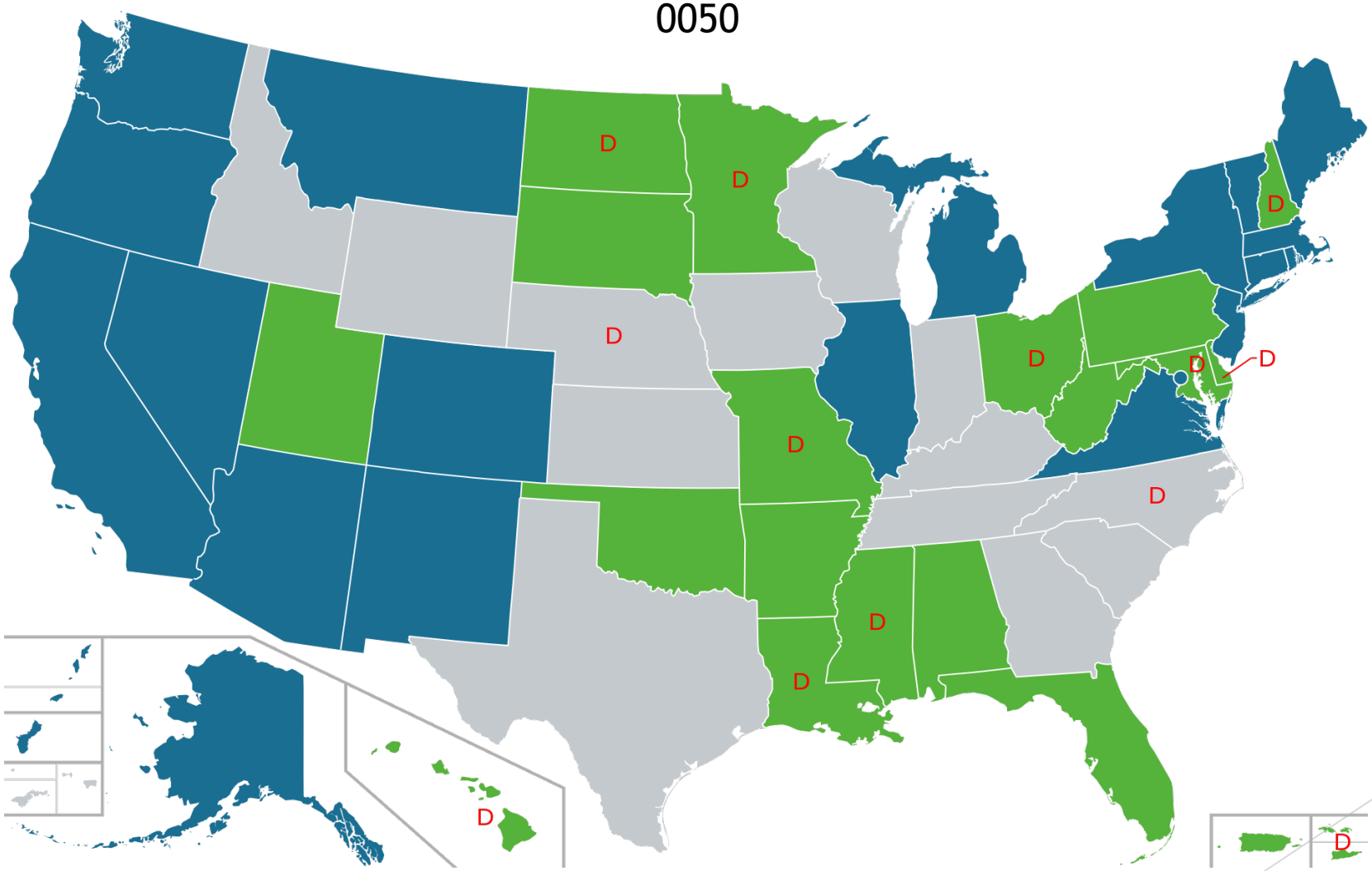
New Frontier!

Human Consumption Cannabinoid Trademarks = IP Landrush

USDA → FDA

- 2018 USDA Farm Bill separated cannabinol/hemp from cannabis/THC.
- Specifically left human-consumption/ animal consumption in FDA's court.
- GRAS approved: hulled hemp seeds, hemp seed protein, and hemp seed oil
- Pharma Company filed IND application for CBD epilepsy treatment, Epidiolex, approved summer 2018 (fast-tracked, orphan treatment, priority review). Also three synthetics approved.
  - Investigational New Drug application
  - (great way to press against/ slow down the GRAS standard).
- FDA held public hearings over Summer 2019.
- Jan 2020 congressional testimony update on status.
- Playing the waiting game for human use.

In the meantime,



CBD Industry: IP protection needed & wanted by these industry players

- 2019 estimates over 3,000 players in the industry
  - https://www.forbes.com/sites/julieweed/2019/11/09/cbd-industry-executives-share-challenges-and-advice/#4da3fdaf688e
- 2018 estimated $600M
  - https://www.forbes.com/sites/irisdorbian/2019/03/12/cbd-market-could-pull-in-16-bln-by-2025-says-study/#3ff15fa53efd
- 2022 estimates $1.9B
  - https://www.statista.com/statistics/760498/total-us-cbd-sales/

USPTO Examination Guide 1-19 Examination of Marks for Cannabis and Cannabis-Related Goods and Services after Enactment of the 2018 Farm Bill May 2, 2019

- For applications filed on or after **December 20, 2018** that identify goods encompassing cannabis or CBD, the 2018 Farm Bill potentially removes the CSA as a ground for refusal of registration, but only if the goods are derived from "hemp." Cannabis and CBD derived from 2 marijuana (i.e., Cannabis sativa L. with more than 0.3% THC on a dry-weight basis) still violate federal law, and applications encompassing such goods will be refused registration regardless of the filing date.
- the identification of goods must specify that they contain less than 0.3% THC (and derived from hemp, not marjiuana).

Trademarks Con't

- The use in foods or dietary supplements of a drug or substance undergoing clinical investigations without approval of the U.S. Food and Drug Administration (FDA) violates the FDCA. 21 U.S.C. §331(ll)
- Registration of marks for foods, beverages, dietary supplements, or pet treats containing CBD will still be refused as unlawful under the FDCA, even if derived from hemp, as such goods may not be introduced lawfully into interstate commerce.
- …the waiting game!
- "CBD" goods/services search in TESS = 4,121 marks as of 18Feb2020.

Trademark Options:

- State registration?
- ITU applications: I year from application to submit specimen of use, with 6mo extensions up to 36mos. But substantive examination still occurs!
- Get in with approved uses, add new G/S designations later?
- International TM filing then use priority (likely amended) for US?
- Hang in there, when FDA allows more uses → amend filing date

Questions?

The End.