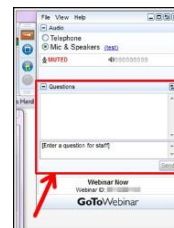




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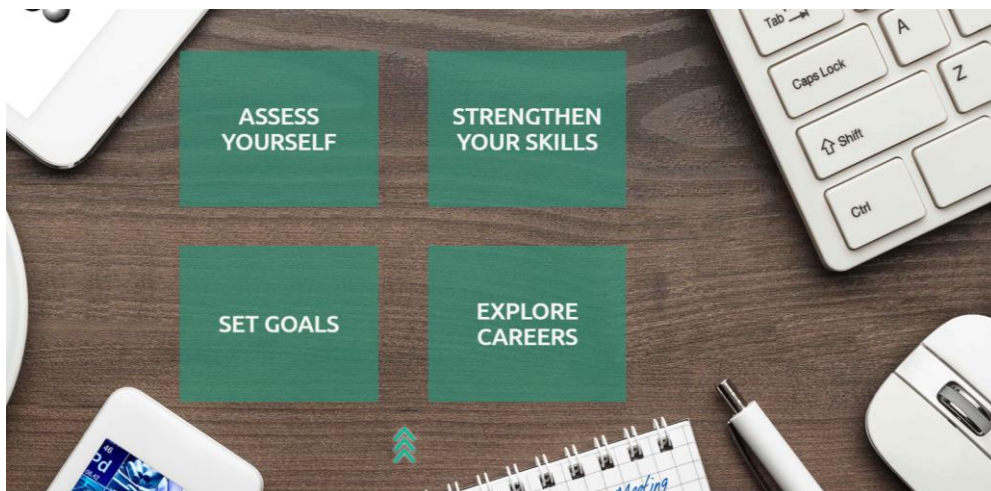
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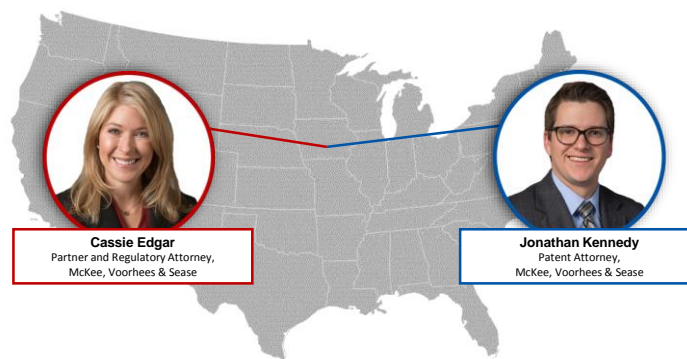


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IP & Regulatory Issues in Gene Editing





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IP AND REGULATORY ISSUES IN GENE EDITING

Cassie Edgar
 McKee, Voorhees & Sease

MVS **McKEE, VOORHEES & SEASE PLC**
WWW.IPMVS.COM

Biotech Attorney (Intellectual Property, Regulatory, Licensing)

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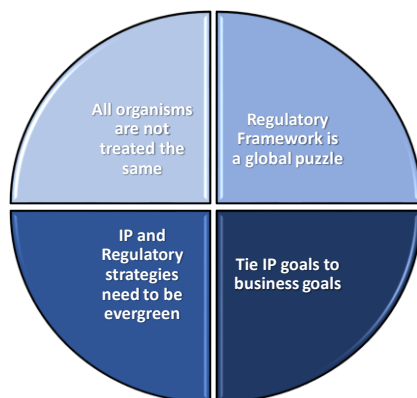


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Overview: Four Key Takeaways

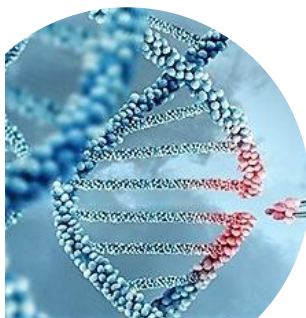


Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



What is your familiarity with gene editing?

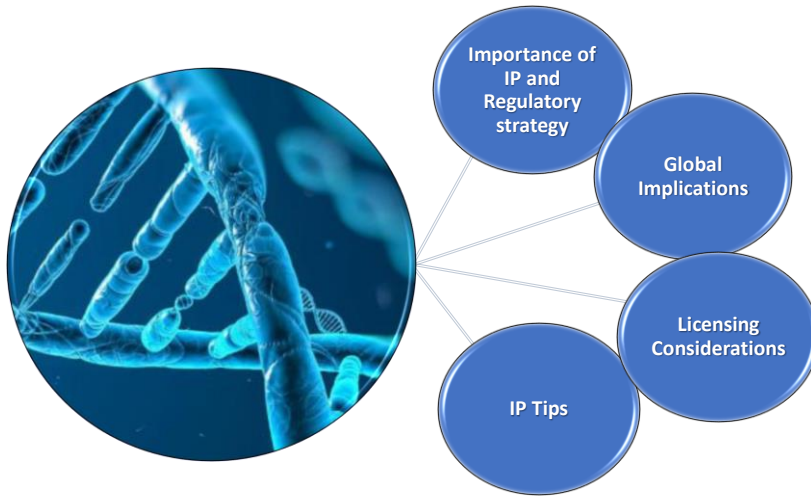


- I am a bench scientist working in gene editing
- My organization is actively engaged with gene editing technology
- I fund/advice companies who utilize gene editing technology
- I've read the news, from babies to bananas
- I've written the news, from babies to bananas

** If your answer differs greatly from the choices above tell us in the chat!*



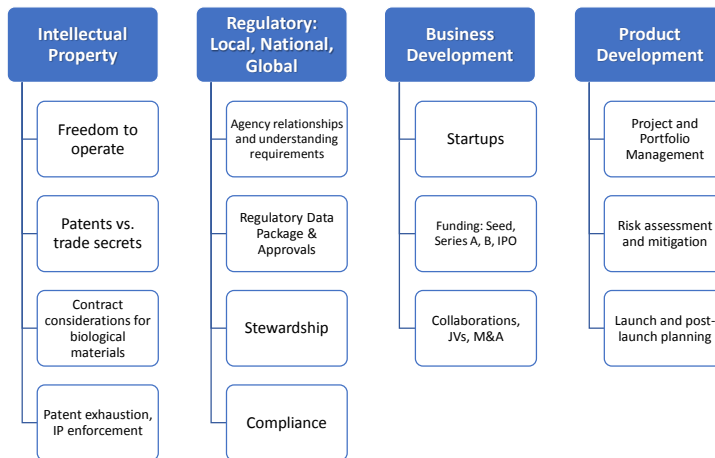
Discussion Topics



Why talk about IP & Regulatory for gene editing?

Appropriate IP & Regulatory counsel is critical

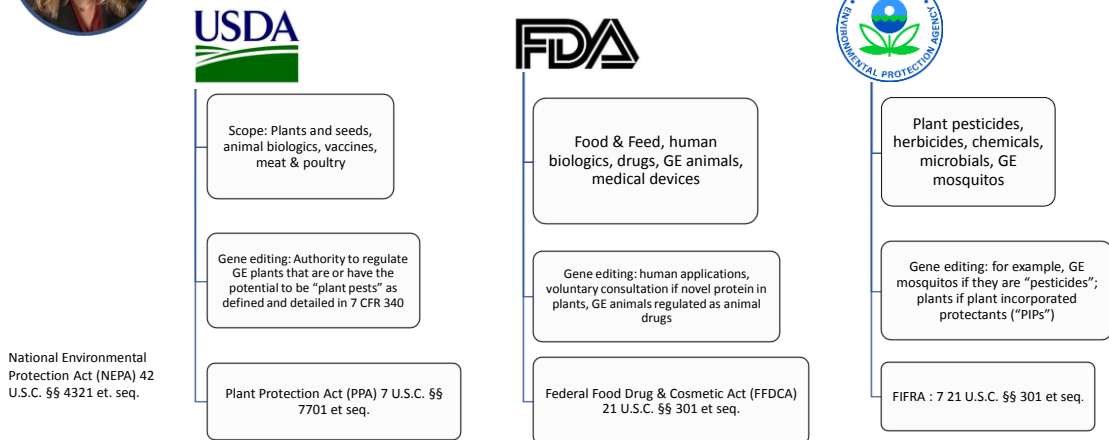
Actions requiring IP & Regulatory input deeply embedded from initiation through post-launch phases





All organisms are not treated the same

Coordinated Framework for Biotechnology



Global Overview: GE Food Regulatory Requirements

Commodity products move!

With GE organisms intended for human consumption, there are a variety of global approvals required:

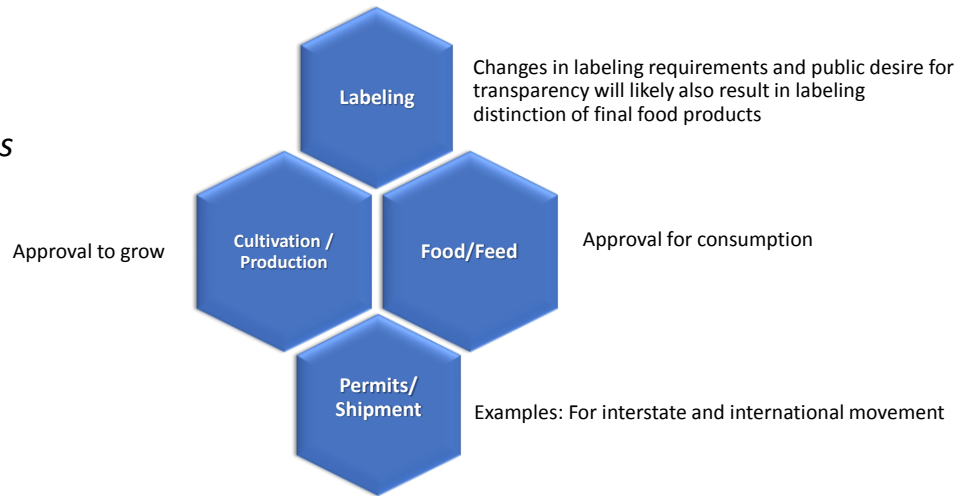
- Data requirements differ per country: there is no global harmonized regulatory system
- Data requirements differ for cultivation and food/feed approvals
 - "Cultivation" (production) approval or approval to grow
 - Specific to country where organism is grown
 - Agency is based on specifics of organism and trait
 - Food/Feed approval or approval for consumption





GE Food Regulatory Requirements

Examples



Stewardship: Gene Editing

- Due to the inconsistent regulatory treatment of gene edited products, implementing a stewardship program is key to mitigate liability from working with gene edited products
- Product catalogs/press releases and regulatory requirements for a detection method mean that products will be able to be identified and traced back to the trait developer/company
- **Avoid this Headline:** “Leaked e-mails show that gene edited octopi were released into the U.S. food supply”
- **Avoid this Outcome:** Global markets refuse to accept U.S. octopi exports, commodity prices tank, class action lawsuits, ruined reputation for gene editing technology for all applications and actors





Stewardship

Due to varied requirements and asynchronous approvals, global product stewardship is important



Responsible management of a product from inception through ultimate use

- Beyond regulatory compliance
- Throughout product lifecycle
- With licensees



Stakeholder confidence (critical for new technologies)

- Regulators
- Consumers
- Value chain partners



Mitigate liability risks



Core Elements of Stewardship Programs

Organizational Structure

Policies and Procedures

- For each stage of lifecycle
- To maintain product integrity
- To avoid material being out of place
- Preventive measures
- Monitoring procedures
- Recordkeeping and documentation

Training Programs

- For employees
- For value chain partners

Requirements in Contracts and Licenses

- With researchers
- With licensees
- With customers and value chain partners

Incident Management Plan



Global Overview: Patent Protection

- **Patent law is *not* global:** what is patentable in the U.S. isn't the same as the standard of patentability in China, Brazil, or EU for example.
- **Germplasm** (actual plants, animals) **is not patentable in every country:** IP strategy will include customizing claim sets to specific needs and current patent law in desired countries.



Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



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Would you eat gene edited (no foreign DNA from other species) food products?

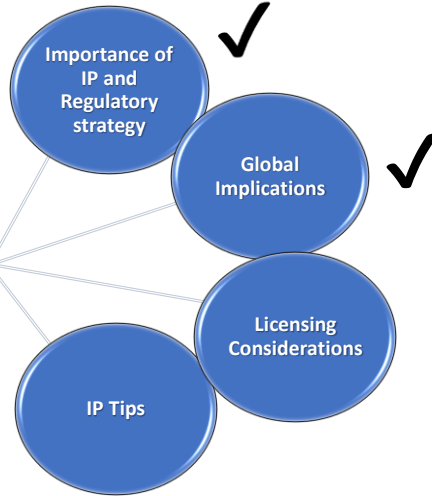
- I would consume microbes/plants/animals without regulatory review
- I would consume microbes/plants/animals after a science-based risk assessment by a government agency
- I would consume microbes/plants only but not animal products
- I would not eat gene edited food products



** If your answer differs greatly from the choices above tell us in the chat!*



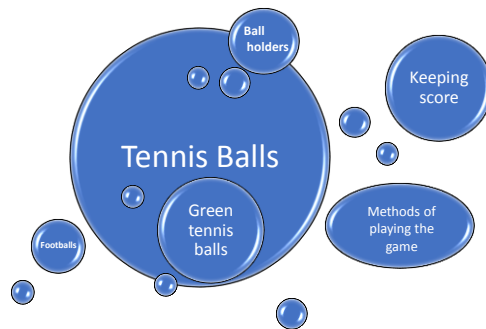
Discussion Topics



Licensing Considerations







Setting and executing against an appropriate licensing strategy starts with...

What are you trying to accomplish?





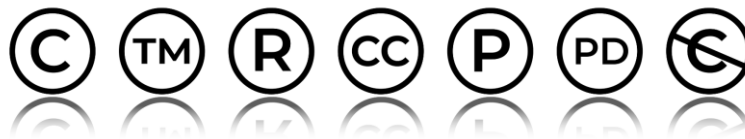
What to expect in a gene editing license

-  Upfront license fee
-  Milestone payments
-  Improvements grant
-  Royalty structure
-  Sublicensee restrictions/stewardship requirements/reporting
-  Termination implications



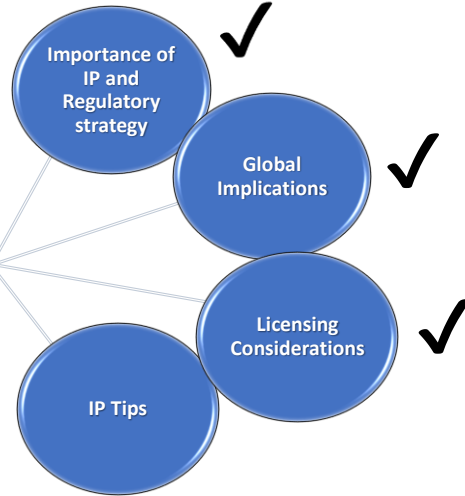
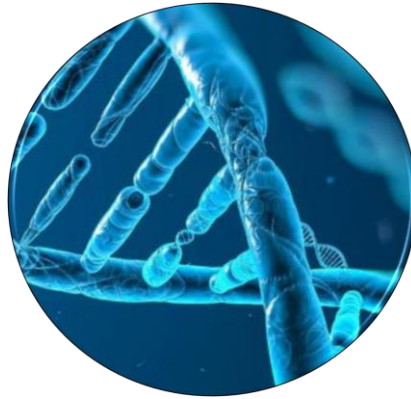
Licensing considerations for gene editing

- **What are you licensing, exactly?** Pay attention to patent family expiration dates in view of your product development timelines.
- Particularly with self-replicating organisms, be mindful of **patent exhaustion issues** within license language and on any packaging/labeling (especially after Lexmark)
- Watch out for **regulatory data** cooperation needs and obligations
- **Post-patent term:** regulatory data can act as a de facto bar for continued commercialization.
- **Stewardship** is critical both for licensors and licensees – draft and comply with care!





Discussion Topics



Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



A Hershey's Kiss is covered by what type of Intellectual Property protection?

- Patent
- Trade Secret
- Copyright
- Trademark
- All of the Above

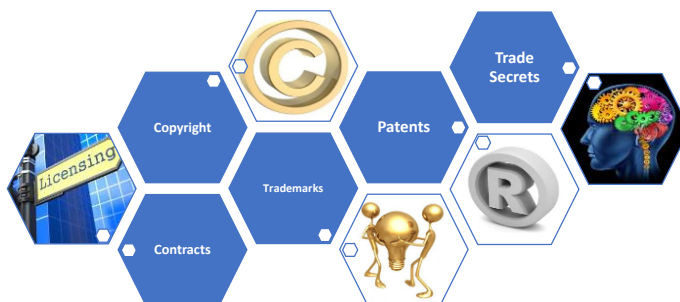


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What is Intellectual Property?

Intangible product of human imagination, creativity and inventiveness that has value in the marketplace¹.

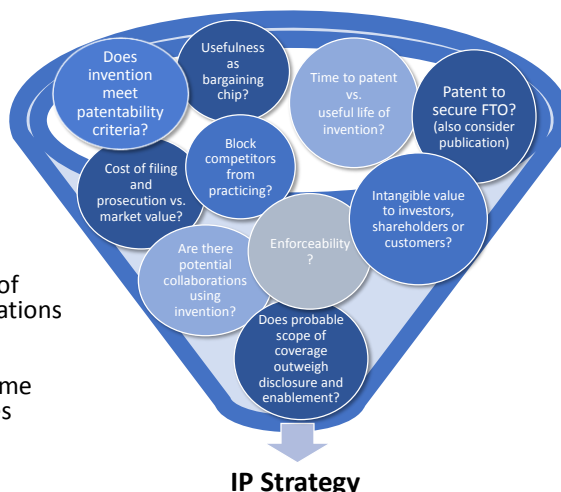


¹Adapted from Bringer, Bruce R. The Importance of Intellectual Property, Prentice Hall, 2010.



IP Strategy

- Many inputs into IP strategy
- Strategic importance to the business and value of financial investment in filing(s) are key considerations
- The answer to “is it patentable” changes over time due to new case law and patent office guidelines





Intellectual Property Tips

Think offensively AND defensively at the start of the game!

- Analyze **FTO issues** based on R&D and commercial plans to focus on specific technologies at issue
- For plants remember additional methods of intellectual property protection such as **plant patents** and **PVP certificates**
- **Remember to broaden patent strategy beyond the immediate invention:** in addition to methods of making current product(s) and product(s) themselves, include biological materials derived therefrom to the extent allowable (e.g. progeny claims)
- This is a (very) rapidly growing area, **file first!**
- Remember to **refresh FTO analyses** on an appropriate cadence for key development projects



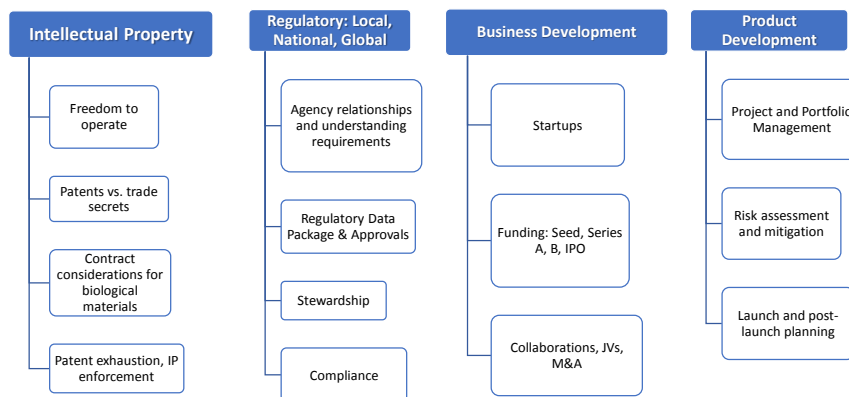
IP & Regulatory Strategies Need to be Evergreen

Appropriate IP & Regulatory counsel is critical

IP & Regulatory decisions need to be refreshed throughout product lifecycle

On any given Tuesday, the world can change...

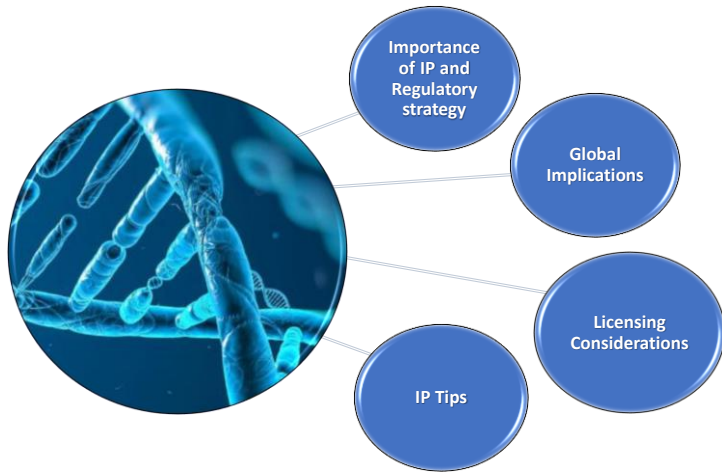
Regulatory & IP law changes on a more rapid cadence than product development timelines for gene edited products...



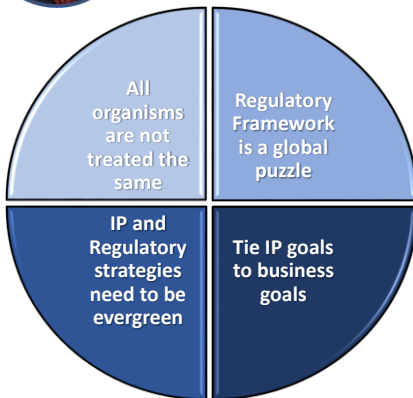


Alignment with business objectives

IP & Regulatory strategy alignment with business goals is critical to advancing and commercializing innovation



Remember: Four Key Takeaways



Thank you! Questions?



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IP & Regulatory Issues in Gene Editing

Cassie Edgar
Partner and Regulatory Attorney,
McKee, Voorhees & Sease

Jonathan Kennedy
Patent Attorney,
McKee, Voorhees & Sease

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