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Genome Editing Deals in Agriculture

Key Issues and Potential Pitfalls

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Genome Editing Deals in Ag

- Licensing and R&D collaborations based on GE tools for applications in plants
- Genome Editing: generation of targeted genetic modifications, including insertion, deletion, replacement, and base editing
- GE tools: methods and materials that pertain to Genome Editing in plants, including CRISPRs, TALENs, meganucleases, zinc fingers, and base editors

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Deal Structures

- Strategic decision for GE tool company:
  - License GE tools (non-exclusive/exclusive)
  - Identify novel product concepts enabled by GE tools; make the edits and license resulting products
  - Collaborate on R&D to identify and edit novel gene targets for products; license GE tools and products
- GE tool license deal reduces operational burden but delivers less value and lower return, and reduces control over GE tools
- Product deals and R&D collaborations require compelling value proposition and operational capability, but offer higher return and greater control over GE tools

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Field of the Deal

- Use in particular crop or crops
  - Plus model organisms for research – *N. benthamiana*, *A. thaliana*
- Use for particular trait concepts
  - Plant architecture (*e.g.* branch angle)
  - Asian soybean rust resistance
  - Corn rootworm resistance
- Use in plant-associated microbiome
- Use for editing particular gene loci

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Exclusions from the Field

- Plant molecular farming
  - Production of biomolecules not endogenous to the plant for extraction/purification
- Exceptions?
  - Pharmaceuticals
  - Nutraceuticals, dietary supplements
  - Food, food ingredients
  - Feed, forage, fiber
  - Industrial enzymes or other industrial products

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Exclusions from the Field

- Gene Drives
  - Systems of biased inheritance that enhance the ability of a genetic element to pass from an organism to its offspring through sexual reproduction
    - *E.g.*, use to eliminate weedy plants or pests
  - Impact on ecosystems unknown
- Exception?
  - Advanced breeding practices

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Exclusions from the Field

- Sterile Seeds
  - U.N. Convention on Biological Diversity recommends global moratorium
- Exceptions?
  - Seedless fruits and vegetables
  - Male sterility for plant breeding
  - Control of pollen-mediated gene flow
  - Prevention of crossing of cultivated plant with wild relative but allowing production of viable seeds or clones from cultivated plant

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Licensor Issue: Use of GE Tools as a Discovery Platform

- Licensee uses GE tool A to determine identity or function of a gene or of one or more genome modifications
- Licensee applies the gained knowledge to create the genome modification using GE tool B, avoiding royalties on GE tool A

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Licensor Issue: Use of GE Tools as a Discovery Platform

- Solution: Define Licensed Product broadly to include genome modifications created *or identified* using GE tool A
- Solution: Restrict use of Editing Data with GE tool B
  - "Editing Data" means data related to the identity or function of a gene or of one or more gene or nucleotide changes, additions, or deletions in a gene or a portion of a gene, wherein such data has been generated, in whole or in part, through the use of GE tool A.

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Licensor Issue: Improvements

- Licensor may be concerned that Licensee will create tool improvement invention:
  - Improvement patent may impede use of Licensor's GE tool and increase likelihood of conflict among multiple licensees
- Solutions:
  - Assignment back
  - Paid-up, non-exclusive, sublicensable grant-back license
  - Agreement by Licensee not to file IP

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Licensee Issues: 3rd Party GE Tools

- CRISPR/Cas9 patent landscape uncertain; Licensee may need additional licenses
  - Solution: Obtain right to offset third party license fees against royalties to Licensor
- New GE tools being discovered – *e.g.*, CRISPR/Cpf1, base editors, genome-writing – may eventually obsolete licensed tools
  - Solution: Obtain right to terminate license (and maintenance fees) but continue to sell existing products subject to royalties

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Licensor Issue: Royalty-Bearing Products

- "Licensed Product" – any product the making, using, selling, offering for sale, exporting, or importing of which in the country in question is Covered by at least one Valid Claim in that country
- "Enabled Product" – any product that is made, in whole or in part, by the use or modification of:
  - any Licensed Patents or any invention covered thereby
  - any Licensed Product
  - any progeny, modification, or derivative of a Licensed Product
  - any plant, plant tissue, or plant seed made or modified through use of a Licensed Product or invention covered by the Licensed Patents, or any progeny, clone, modification, or derivative of such plant, plant tissue, or plant seed

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Licensee Issue: Differentiating Value for Royalties

- Create one or more nucleotide changes, additions, or deletions
- Introduce one or more transgenes into a targeted locus in the genome
- Knock out a gene
- Generate a chromosomal modification (*e.g.*, translocation, inversion, swap) via induction of crossing over at a particular locus in the genome

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R&D Collaboration Issue: Enabling Success

- R&D company concerned with sharing ideas with large partner if only paid where company obtains a patent on the edited gene
  - Typical solution: Isolate all core inventive activities at R&D company
  - Alternative solution: Within defined target list or project scope, R&D company is paid regardless of who obtains the patent

Questions?

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