Role of plant breeders' rights and other forms of IP in promoting plant breeding

Michael Kock, Senior Vice President, Innovation Catalyst
Inari Agriculture Inc., Cambridge, USA

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## Inari - the SEEDesign™ Company

<table>
<thead>
<tr>
<th>Cutting-Edge Technology Platform</th>
<th>Predictive Design</th>
<th>Uncover genes and pathways for critical problems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Multiplex Gene Editing</td>
<td>Broad toolbox incl. proprietary CAS system to edit multiple genes with multiple tools simultaneously</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mission-Driven Product Development</th>
<th>10-20% Yield Increase</th>
<th>Cutting development times and costs across crops and geographies</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>40% Less Water</td>
<td>Creating new seed value while addressing climate change</td>
</tr>
<tr>
<td></td>
<td>40% Less Fertilizer</td>
<td></td>
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<thead>
<tr>
<th>Collaborative Commercial Model</th>
<th>Parent Seed Licensing</th>
<th>Go-to-market model with seed companies.</th>
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<tbody>
<tr>
<td></td>
<td>Co-Development</td>
<td>Out-licensing of parent lines (IP-based !).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In-licensing germplasm from breeding companies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Highly Experienced Team</th>
<th>Deep Biotech, Ag &amp; Technology Experience</th>
<th>Deep knowledge: agriculture, biotech, data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&gt;270 employees (U.S., Belgium)</td>
</tr>
</tbody>
</table>

>270 employees (U.S., Belgium)
The Potential of New Breeding Technologies

<table>
<thead>
<tr>
<th>Potential</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Establish complex traits in accelerated time</strong></td>
<td>• Wheat fungal resistance (6 alleles)</td>
</tr>
<tr>
<td>• Parallel “multiplexing” drastically reduces breeding cycles</td>
<td>• Yield / drought tolerance</td>
</tr>
<tr>
<td>• Only efficient method to establish complex traits in multiple varieties.</td>
<td></td>
</tr>
<tr>
<td><strong>Improvement of vegetatively propagated crops</strong></td>
<td>• Disease resistant sugar cane</td>
</tr>
<tr>
<td>• Multiplexing is the only effective method to achieve breeding progress in vegetatively propagating species.&quot;</td>
<td></td>
</tr>
<tr>
<td><strong>Create new genetic diversity</strong></td>
<td>• Maize improvement</td>
</tr>
<tr>
<td>• Certain loci are not susceptible to natural recombination.</td>
<td></td>
</tr>
<tr>
<td>Editing can unleash new potential.</td>
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</tbody>
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Plant varieties and seeds are high-tech products in an easy-to-copy form. They need IP protection for a sustainable business, especially if licensing-based.
# The IP Tool Kit

<table>
<thead>
<tr>
<th>Tool</th>
<th>Benefits Strengths</th>
<th>Costs Weaknesses</th>
<th>Good For</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patents</strong></td>
<td>• Strong, enforceable right</td>
<td>• Country-by-country differences: Plants / plant varieties not patentable in many countries.</td>
<td>• New processes</td>
</tr>
<tr>
<td></td>
<td>• Limited exemptions</td>
<td>• High threshold: Non-obviousness, written description/enablement (reproducibility)</td>
<td>• New traits defined by specific sequence, plants comprising them</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Moderate allowance rate</td>
<td>• Variety-independent edits (GM-like)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lengthy examination, high costs.</td>
<td>Edits which can be identically created or introgressed in different varieties.</td>
</tr>
<tr>
<td><strong>PBR</strong></td>
<td>• Larger international harmonization</td>
<td>• Difficult enforcement</td>
<td>• New varieties</td>
</tr>
<tr>
<td>Plant Breeders Rights</td>
<td>• Moderate costs, fast grant</td>
<td>• No protection for specific traits or sequences (by design !)</td>
<td>• Complex variety-specific edits (breeding-like)</td>
</tr>
<tr>
<td></td>
<td>• High allowance rate</td>
<td>• EDV provision: Clarity, coupling of dependency and limited scope of protection</td>
<td>Multiplex edits which cannot be identically created</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>or introgressed in different varieties.</td>
</tr>
<tr>
<td><strong>Trade Secrets</strong></td>
<td>• Could be everlasting</td>
<td>• Requires high efforts</td>
<td>• Parent lines of hybrid crops</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Difficult to license</td>
<td></td>
</tr>
</tbody>
</table>

*EDV provision: Clarity, coupling of dependency and limited scope of protection*
IP Protection for Multiplex Editing

- Complex traits require multiplex editing. The innovation is the combination.
- Multiplex edits are established *directly* in each elite variety. Introgression by crossing is practically impossible.
- Edits for a specific target gene vary slightly from variety to variety. The specific combination of edits is limited to each single variety.
- Patents do not provide a reliable global strategy:
  - Plants are not patentable in many countries.
  - DNA claims are suitable for single man-made edits but not for combinations of multiple edits.
  - The exact genetic fingerprint is not reproducible (“enablement”).
  - Method claims usually only extend to the direct product but not to progenies.
- PBRs is the only practical way of protection.
- **But:** If multiplex varieties are always EDVs, they have limited PBR protection: Every variation falls outside the scope. Relying on the initial variety’s PBR is no alternative.
The consequences of a revised EDV definition

**Today**

- **V1**
  - Essential characteristic A
  - PBR Scope of Variety 1
  - The breeder of V2 can enforce a right against V4
  - Expiration of PBR on V1

- **V2**
  - Essential characteristic B
  - PBR Scope of Variety 2

**Draft EXN/EDV**

- **V1**
  - Essential characteristic A
  - PBR Scope of Variety 1

- **V2**
  - Essential characteristic B
  - PBR Scope of Variety 2

- **V2**
  - Predominant derivation
  - Initial Variety (V1)
  - Derived, distinguishable variety (all essential characteristics of V1)
  - Innovative variety V2 derived from V1 (not retaining all essential characteristics of V1)
  - Derived, distinguishable variety (all essential characteristics of V2)

- **V2**
  - The breeder of V2 cannot enforce a right against V2*
  - Nobody can enforce a right against V2*

- **V1**
  - The breeder of V2 can enforce a right against V4

- **V2**
  - Expiration of PBR on V1

- **V2**
  - Expiration of PBR on V1

- **V2**
  - PBR Scope of Variety 2
UPOV & Breeding Innovation
General considerations

- Breeding innovation is measured by **phenotype improvement**.
- Causative genetic changes are limited. Additional changes are a side-effect of the breeding process, not indicative for breeding progress and undesired.
- NBTs enables targeted causative changes without undesired genetic deviation ("precision breeding").
- Breeders should be incentivized to use NBTs and enjoy full PBR protection.
- Genetic similarity as sole criteria for EDVs cannot be reconciled with the wording of the UPOV 1991 act and convert UPOV into a copyright for plant genetics.
- Legal uncertainty for crops with limited genetic diversity (cotton, lettuce).
- Breeders of NBT-derived varieties have no interest to enable “me-too” varieties.

➢ **UPOV needs balance protection for existing varieties and incentive for new breeding innovation agnostic to the method of breeding.**
Clear and fair decision criteria are required:

1. **Is the derived variety clearly distinguishable from the initial variety**
   - YES
   - NO
   - Same Variety

2. **Is there predominant derivation (evidenced by high genetic conformity)?**
   - YES
   - NO
   - No EDV

3. **Is the change based on modifying quantity/quality of an endogenous gene of the initial variety?**
   - YES
   - NO
   - EDV

4. **Does the change create a substantial economic / ecological added-value?**
   - YES
   - NO
   - EDV

- **Art. 14(5)(b)(i) “expression of the essential characteristics that result from the genotype”**
- **Important for differentiation from genetic transformation and trait introgression.**
- **“Breeding” modifies endogenous genes in quantity or quality (protein sequence) of expression.**
- **Important for a balanced solution.**
- **What is the right standard?**
- **“Important technical advance of considerable economic significance […] (TRIPS Art.31(l)(i))**
- **Economic, ecological, and sustainability considerations.**
Conclusions

• New breeding technologies are essential for breeders.
• UPOV must provide balanced protection agnostic to the breeding method.
• A phenotype-based assessment of the added-value is important.
• Guiding principles should be developed for case-by-case assessment.
• Abandoning the current explanatory notes is not a solution.
• If no agreement on guiding principle for added-value can be found, a revision of UPOV might be unavoidable
  • Article 14(5)(i): Uncouple dependency and limited scope of protection. → Enable multiple dependencies.
  • Article 17(i): Enable compulsory (cross-) licensing.
Thank You