



UPOV "Seminar on the interaction between plant variety protection and the use of plant breeding technologies"

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

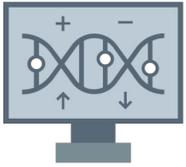
*Michael Kock, Senior Vice President, Innovation Catalyst*

*Inari Agriculture Inc., Cambridge, USA*



March 22, 2023

# Inari - the SEEDesign™ Company



## Cutting-Edge Technology Platform

Predictive Design  
Multiplex Gene Editing

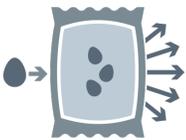
Uncover genes and pathways for critical problems  
Broad toolbox incl. proprietary CAS system **to edit multiple genes with multiple tools simultaneously**



## Mission-Driven Product Development

10-20% Yield Increase  
40% Less Water  
40% Less Fertilizer

Cutting development times and costs across crops and geographies  
Creating new seed value while addressing climate change



## Collaborative Commercial Model

Parent Seed  
Licensing  
Co-Development

Go-to-market model with seed companies.  
**Out-licensing of parent lines (IP-based !).**  
**In-licensing germplasm from breeding companies**



## Highly Experienced Team

Deep Biotech,  
Ag & Technology  
Experience

Deep knowledge: agriculture, biotech, data  
>270 employees (U.S., Belgium)



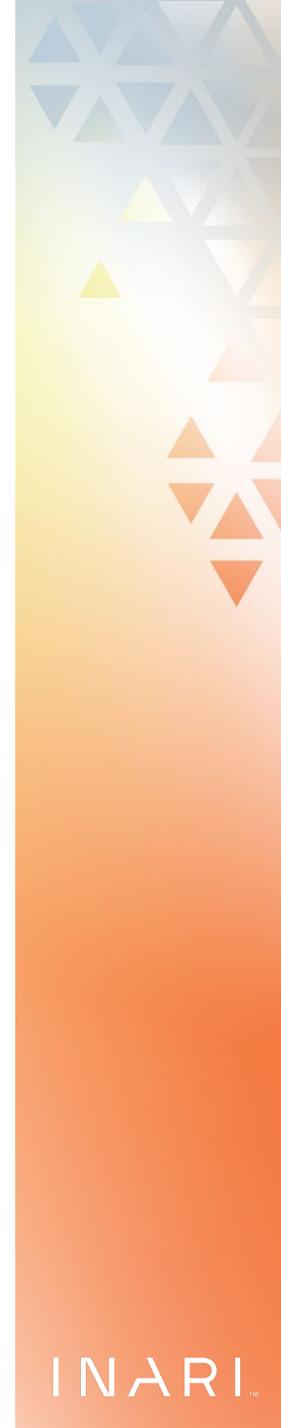
# The Potential of New Breeding Technologies

Potential	Example
<b>Establish complex traits in accelerated time</b> <ul style="list-style-type: none"><li>Parallel "multiplexing" drastically reduces breeding cycles</li><li>Only efficient method to establish complex traits in multiple varieties.</li></ul>	<ul style="list-style-type: none"><li>Wheat fungal resistance (6 alleles)</li><li>Yield / drought tolerance</li></ul>
<b>Improvement of vegetatively propagated crops</b> <ul style="list-style-type: none"><li>Multiplexing is the only effective method to achieve breeding progress in vegetatively propagating species."</li></ul>	<ul style="list-style-type: none"><li>Disease resistant sugar cane</li></ul>
<b>Create new genetic diversity</b> <ul style="list-style-type: none"><li>Certain loci are not susceptible to natural recombination. Editing can unleash new potential.</li></ul>	<ul style="list-style-type: none"><li>Maize improvement</li></ul>

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.

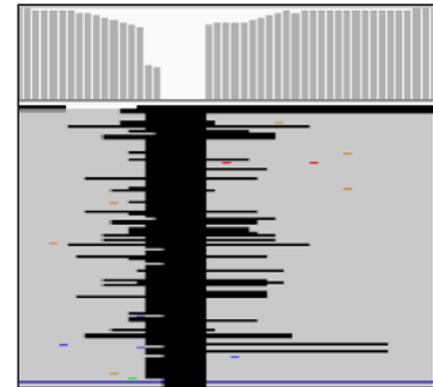
# The IP Tool Kit

Tool	Benefits Strengths	Costs Weaknesses	Good For
<b>Patents</b>	<ul style="list-style-type: none"> <li>• Strong, enforceable right</li> <li>• Limited exemptions</li> </ul>	<ul style="list-style-type: none"> <li>• Country-by-country differences: Plants / plant varieties not patentable in many countries.</li> <li>• High threshold: Non-obviousness, written description/enablement (reproducibility)</li> <li>• Moderate allowance rate</li> <li>• Lengthy examination, high costs.</li> </ul>	<ul style="list-style-type: none"> <li>• New processes</li> <li>• New traits defined by specific sequence, plants comprising them</li> <li>• Variety-independent edits (GM-like) Edits which can be identically created or introgressed in different varieties.</li> <li>• US: Specific varieties</li> </ul>
<b>PBR</b> Plant Breeders Rights	<ul style="list-style-type: none"> <li>• Larger international harmonization</li> <li>• Moderate costs, fast grant</li> <li>• High allowance rate</li> </ul>	<ul style="list-style-type: none"> <li>• Difficult enforcement</li> <li>• No protection for specific traits or sequences (by design !)</li> <li>• EDV provision: Clarity, coupling of dependency and limited scope of protection</li> </ul>	<ul style="list-style-type: none"> <li>• New varieties</li> <li>• Complex variety-specific edits (breeding-like) Multiplex edits which cannot be identically created or introgressed in different varieties.</li> </ul>
<b>Trade Secrets</b>	<ul style="list-style-type: none"> <li>• Could be everlasting</li> </ul>	<ul style="list-style-type: none"> <li>• Requires high efforts</li> <li>• Difficult to license</li> </ul>	<ul style="list-style-type: none"> <li>• Parent lines of hybrid crops</li> </ul>



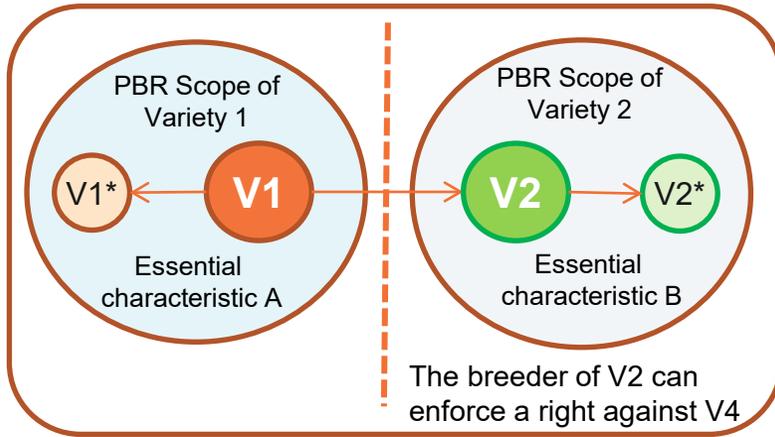
# IP Protection for Multiplex Editing

- 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.

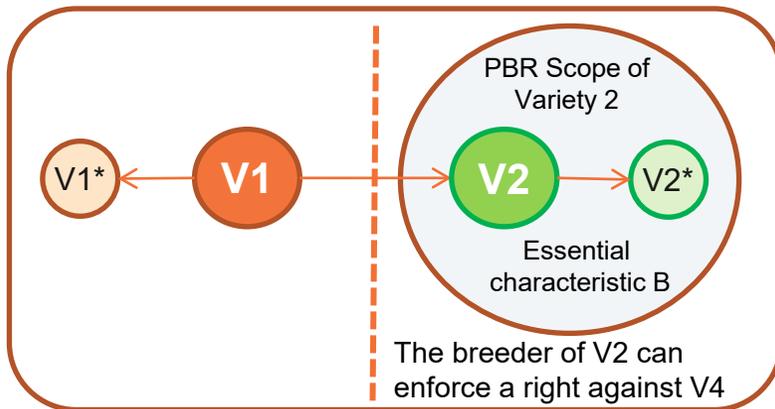


# The consequences of a revised EDV definition

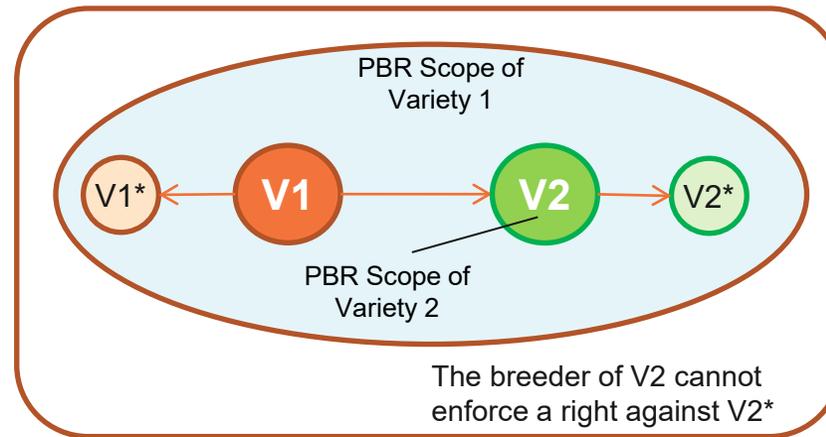
## Today



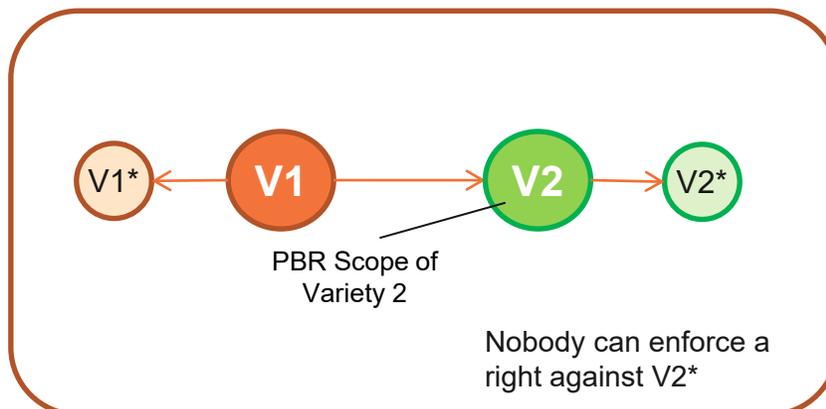
Expiration of PBR on V1



## Draft EXN/EDV



Expiration of PBR on V1



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

# UPOV & Breeding Innovation

## General considerations

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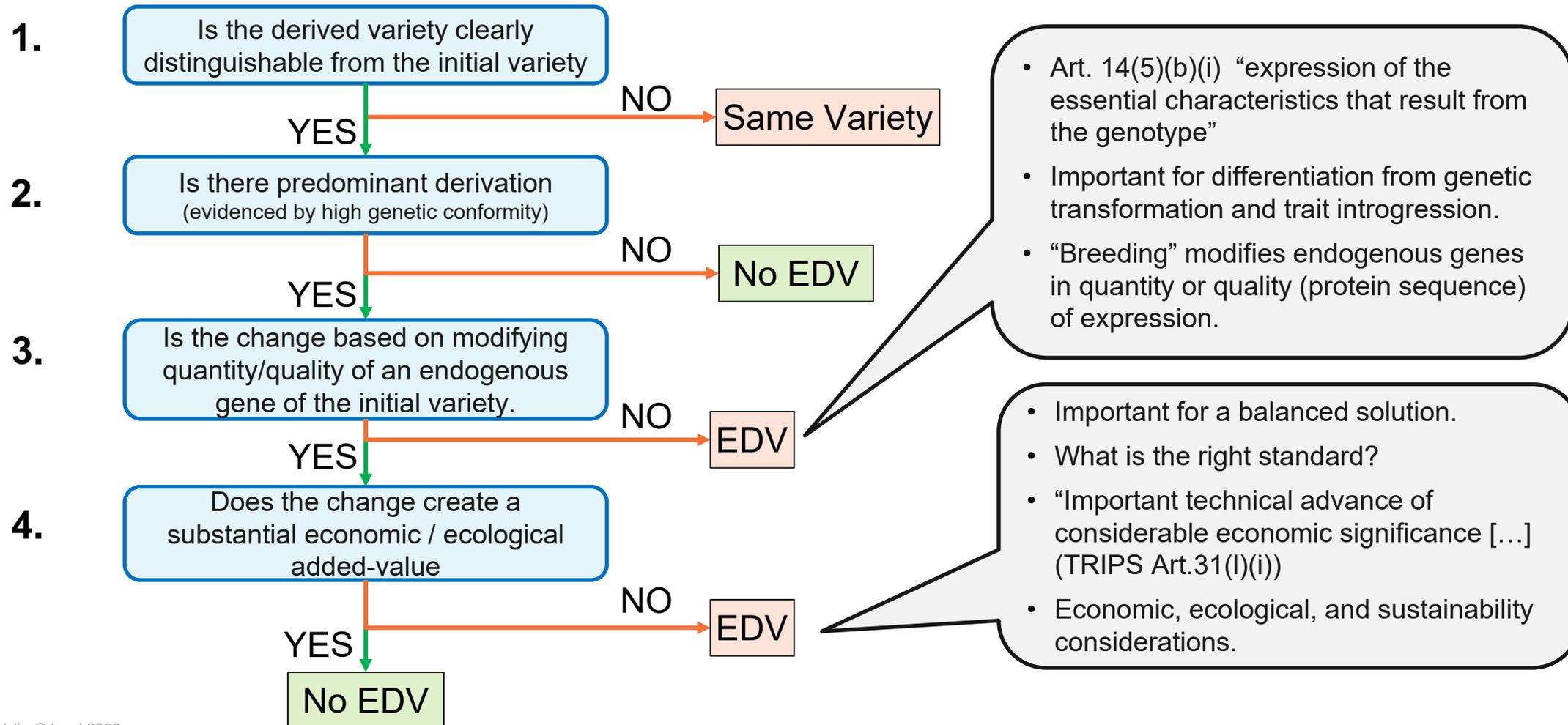
- Breeding innovation is measured by **phenotype improvement**.
  - Causative genetic changes are limited. Additional changes are a side-effect of the breeding process, not indicative for breeding progress and undesired.
  - NBTs enables targeted causative changes without undesired genetic deviation (“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.



# UPOV & Breeding Innovation

## How to find the right balance?

Clear and fair decision criteria are required:



# Conclusions

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- 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

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