



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

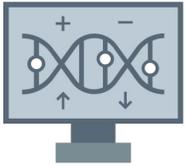
Michael Kock, Senior Vice President, Innovation Catalyst

Inari Agriculture Inc., Cambridge, USA



March 22, 2023

Inari - the SEEDesign™ Company



Cutting-Edge Technology Platform

Predictive Design
Multiplex Gene Editing

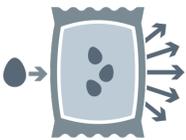
Uncover genes and pathways for critical problems
Broad toolbox incl. proprietary CAS system **to edit multiple genes with multiple tools simultaneously**



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)



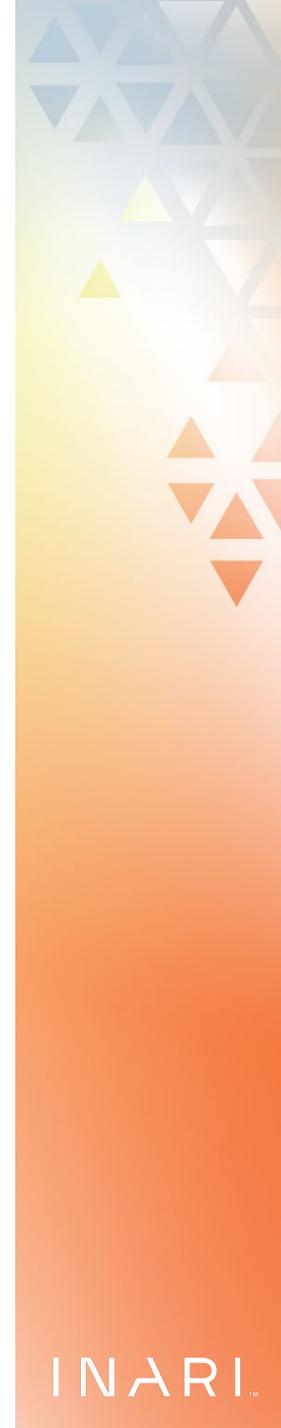
The Potential of New Breeding Technologies

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

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.

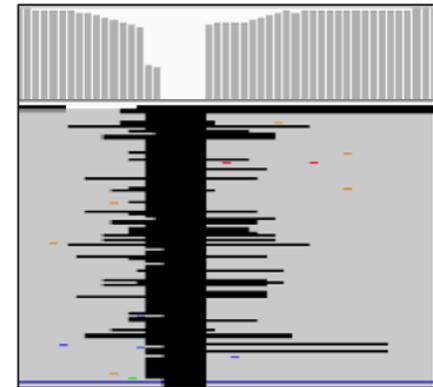
The IP Tool Kit

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



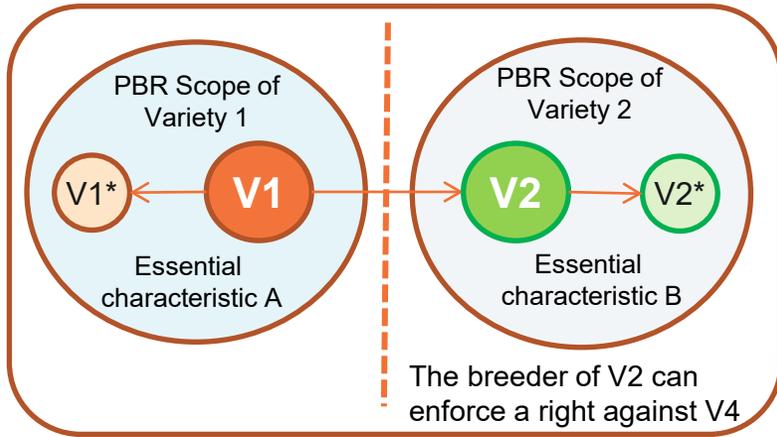
IP Protection for Multiplex Editing

- 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.

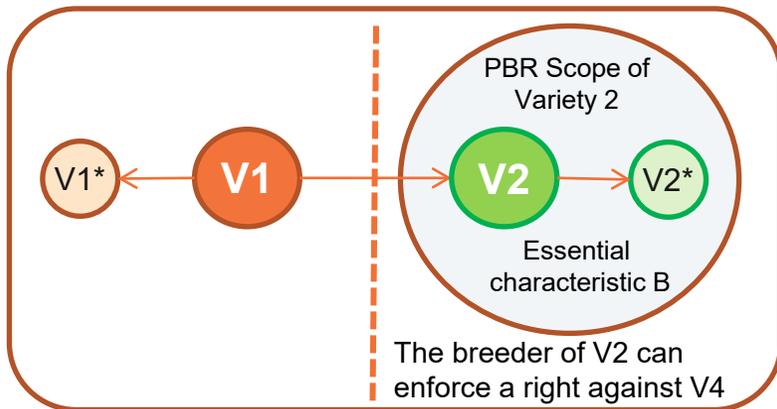


The consequences of a revised EDV definition

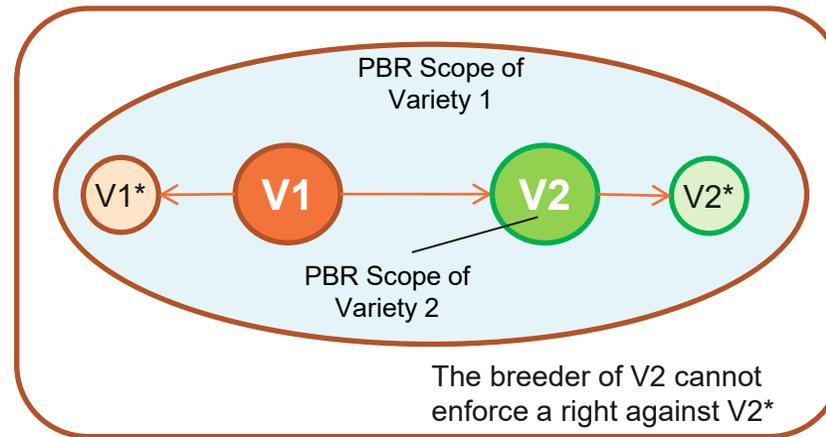
Today



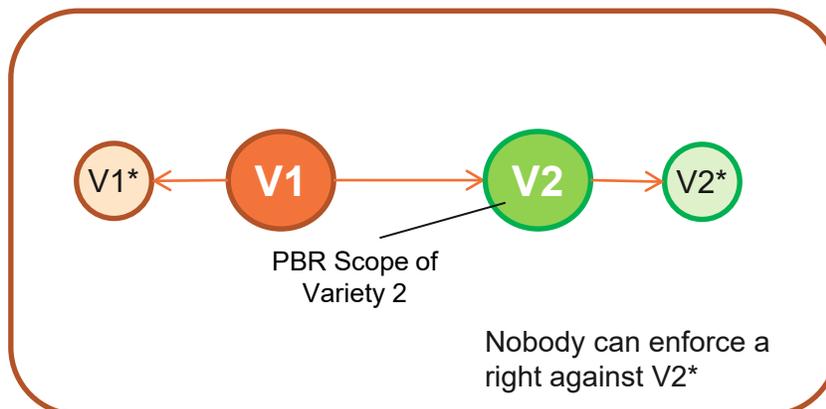
Expiration of PBR on V1



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

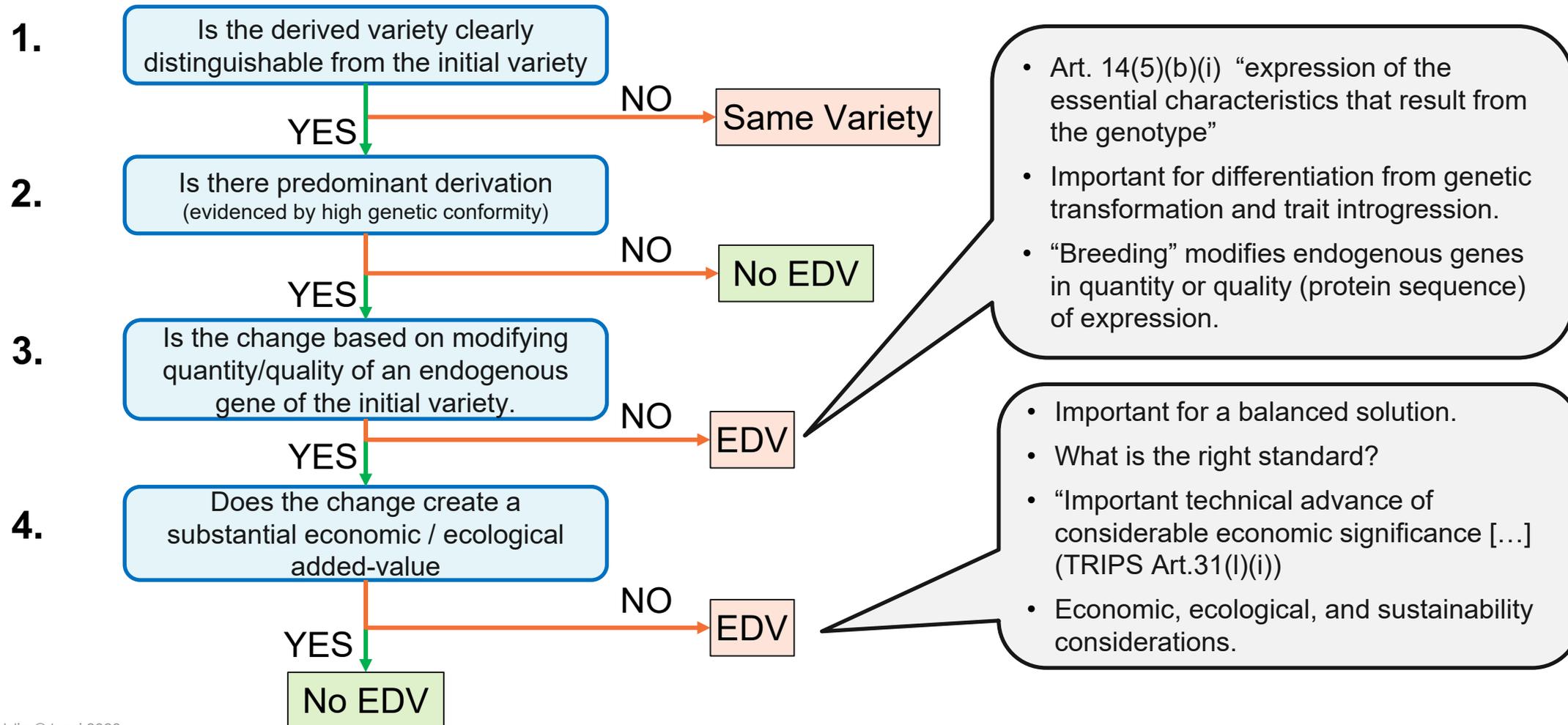
- Breeding innovation is measured by **phenotype improvement**.
 - Causative genetic changes are limited. Additional changes are a side-effect of the breeding process, not indicative for breeding progress and undesired.
 - NBTs enables targeted causative changes without undesired genetic deviation (“precision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

- 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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