New Plant Breeding Innovation and Patents
Emerging Challenges

GRUR 2021 Annual Conference

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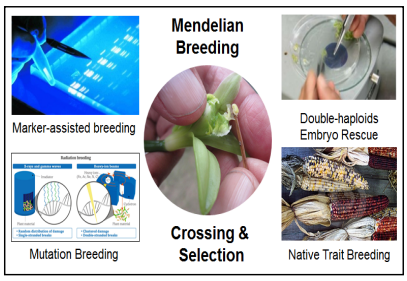
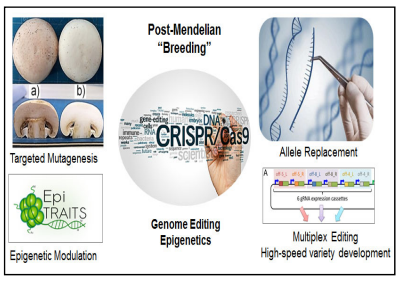
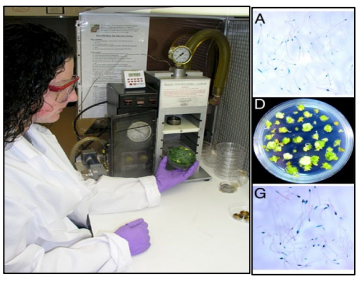
New Breeding Innovation

Conventional Breeding	Breeding-by-Editing	Plant Biotechnology







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OVERVIEW

1. **Something OLD**
   - Things which do not change …
2. **Something NEW**
   - New challenges
3. **Something Borrowed**
   - Scalability of existing solutions?
4. **Something Blue**
   - Blue ocean thinking: New solutions?

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Something OLD

Myth busting

- **Novelty:** A new process does not necessarily lead to a new product
  - Absolute novelty: Re-making of an existing trait by a new process doesn't create novelty.
- **Inventiveness:** Use of genome editing is not necessarily inventive
  - Genome editing is meanwhile part of the tool kit for the skilled person.
- **Enabling disclosure:** Claims need to be supported by the disclosure
  - Need for deposits is reduced → Good news for vegetative propagated plants
  - Claims to (new) knock-out traits may be broad, claims to change-of-function traits should be narrow (unpredictability of the art)
  - **But:** SDN-1 changes are unprecise. How many parallel changes are reproducible? (Undue burden → EPO Guidelines G-II 5.4; T 1957/14).

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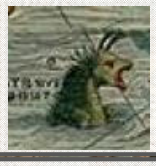
Something New

Patent Complexity
Reach-through claims

Something NEW

The VUCA world of genome editing and patent

HERE ARE MONSTERS !



Monster 1 „Volatility“: The inventorship and validity of key patents is debated. Resolution may take years and may differ from country-to-country

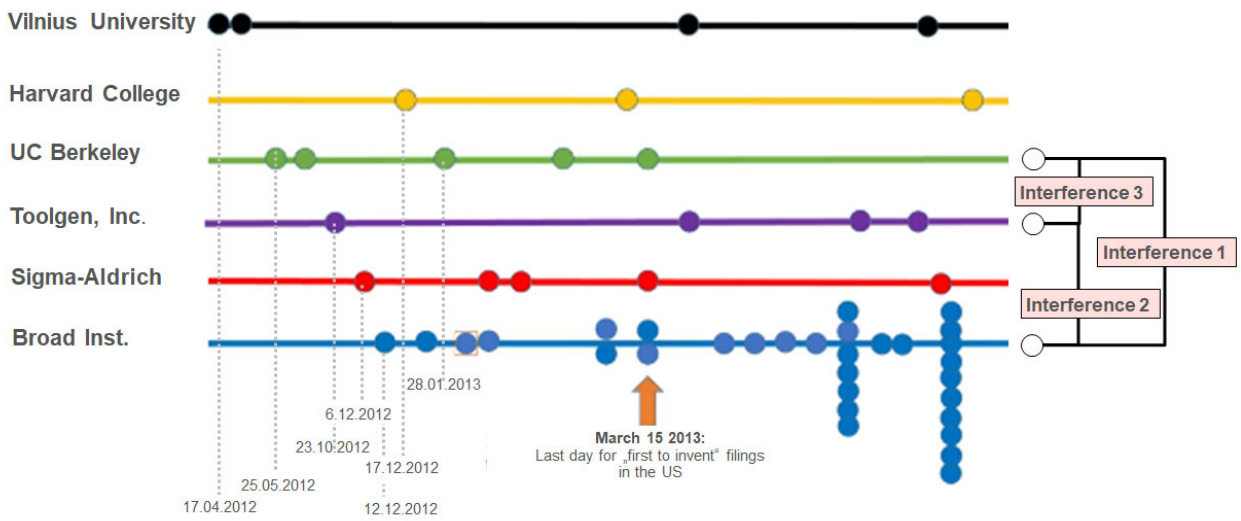
Monster 2 „Uncertainty“: The scope of method claims is unclear in many countries and could create substantial legal uncertainty.

Monster 3 „Complexity“: The patent landscape for technologies and resulting products is highly complex with multiple overlapping rights.

Monster 4 „Ambiguity“: Does a plant with a new combination of native traits escapes Rule 28 if one native trait is introduced by genome editing?

Monster 1: Volatility

Cas9 Landscape



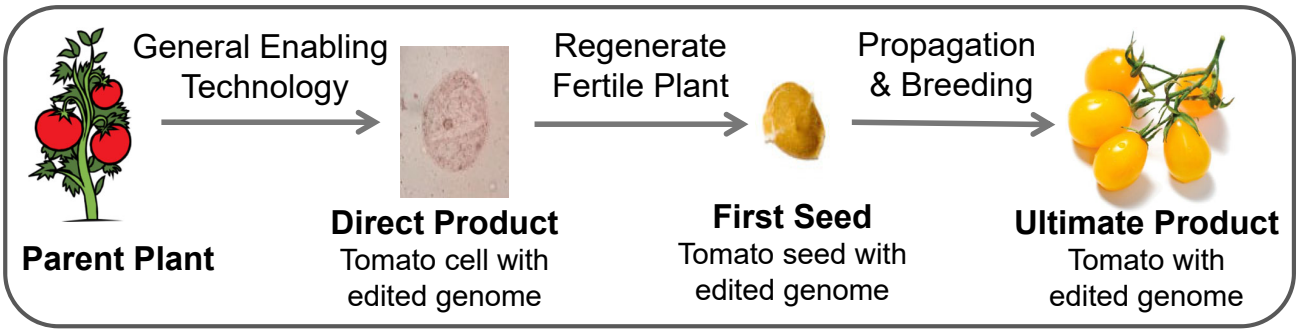
- Disputes in several legislations (>$500m legal costs)
- Different outcome country-by-couantry
- Overlaps and multiple dependencies
- Years to final resolution

- Patent pool failed
- Nobody has FTO
- Stifling innovation

Monster 2: Uncertainty

Scope of Method Claims

Most countries: Method claims only extend to **direct products** of the process



Monsanto Technology LLC v Cargill International SA

UK HIGH COURT OF JUSTICE / 2007 WL 2944762 / 10th October 2007

35. The phrase 'directly obtained by means of the process' means 'the immediate product of the process'.

37. All the RR soybean plants […] can be described as the ultimate product of the original transformation of the parent plant. But I cannot see that it can be properly described as the direct product of that transformation, a phrase I would reserve for the original transformed plant. This aspect of the claim must fail.

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Monster 2: Uncertainty

Scope of Method Claims

US: Method of editing claims likely extend to progenies

- Under 35 USC § 271(g) method claims to make an edited organism likely extend to progenies as long the edit is present. No case law for biological products (yet).

CA, AU: Method claims likely extend broadly to progenies

- Under the **"Saccharine Doctrine"** method claims extend to final products even if the patented process relates to an intermediate. Potentially applicable to all method claims. No case law for biological products (yet).

EU: Some method claims may extend to propagation material

- Art.8.2 Dir.98/44: A method claim to produce biological material with *"specific characteristics as a result of the invention"* extends to progenies with the same characteristics. No case law. Deviating views:
  - Method claims only extend to products if the specific characteristic is essential for the inventiveness of the method. ("Erfindungsgemäße Eigenschaft") → Rare case !
  - Method claims extend to products as long they cause any specific characteristic. (Obiter dictum: MedImmune v Novartis, Case HC09 C04770 [2011] EWHC 1669)

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Monster 2: Uncertainty

Scope of Claims on Enabling Technology Methods

Complexity & Ambiguity

Direct Product	Products with „specific characteristics“	Any Product
• The method claim may be infringed by the party using the method. • The use of the ultimate plant by third party breeders and farmers does not infringe.	• The method claim may be infringed by the party using the method. • The use of the ultimate plant usually does not infringe or the characteristic is clear from the patent.	• The method claim may be infringed by the party using the method. • The use of the plant by third party breeders and farmers may infringe w/o options to obtain legal certainty.

Manageable Complexity

High Complexity
Dozens of method patents may apply to a single product.

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Monster 3: Complexity

Trends & Forecast

Patent Complexity While 4 years ago the number of EU varieties with multiple patented traits was <10, today the number is substantial:

No of patents	Sunflower	Pepper	Brassicas	Melon	Tomato	Lettuce	Cucumber	Maize	Other	Total
1	38	69	54	49	104	178	28	122	131	773
2	5	5	9	4	6	24	8	21	9	91
3			1			1				2
4	15									15
Total	58	74	64	53	110	203	36	143	140	881
% Stack	**34,5**	**6,8**	**15,6**	**7,5**	**5,5**	**12,3**	**22,2**	**14,7**	**6,4**	**12,3**
Mixed ownership			1			19				

(Source: PINTO Database, analysis of 12/2020)

Result of technology progress and shorter innovation lifecycles (even in conventional breeding)

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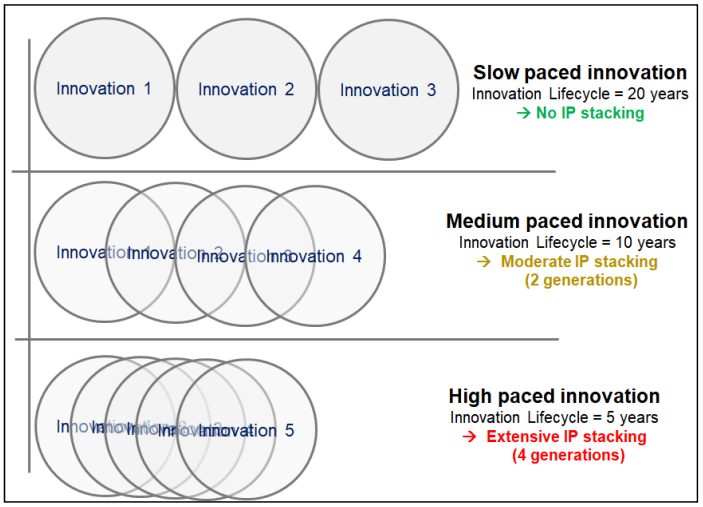
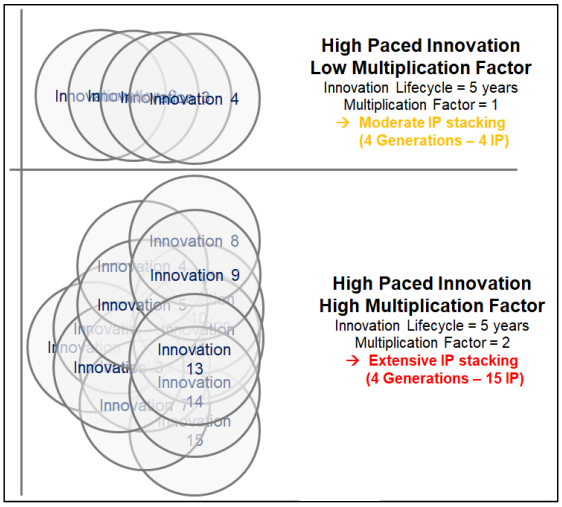
Monster 3: Complexity
Trends & Forecast

Genome Editing and Breeding-by-Editing will lead to

- Faster Development Timelines
- Short Innovation Lifecycles
- Lower Costs

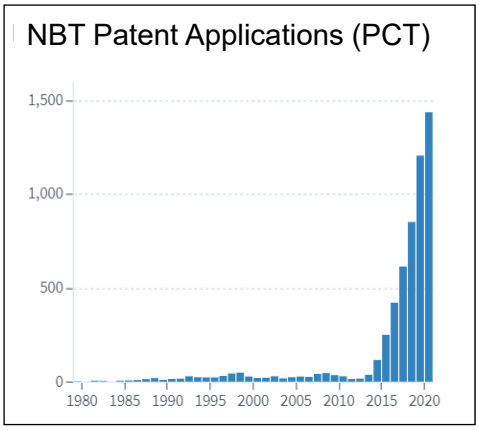




Monster 3: Complexity
Trends & Forecast

NBTs will accelerate the trend:

- Further lifecycle reduction in breeding
- Ability to establish complex traits
- Exponential increase of NBT patents
- Exponential increase of applications for NBT marketing approval ("Am I Regulated" = A.I.R.)



Target	A.I.R Approvals (Jan. 4, 2021)
Grasses	20
Soy	19
Canola	13
Potato	11
Corn	11
Tree	9
Tobacco	7
Tomato	7
Sugarcane	6
Flowers	6
Pennycress	6
Rice	6
Other Plants	35
Total (Plant)	156
Non-plant	13
Total	169

Applicant	No. Plant Approvals
Cibus	14
University Georgia	11
University Florida	10
Ceres	8
Corteva, Pioneer Dow	8
Simplot	8
Living Carbon	8
Calyxt	5
Celectis	4
Illinois State Univ.	4
Scotts	4
Yield10	4
Inari	3
Benson Hill	3
Others	62

Forecast

- **Today** merely 800 out of >80.000 EU varieties are covered by patents (~1%)
- **In 10 years** >10% of the new elite varieties will be covered by patents
- **In 20 years** >50% of the new elite varieties will be covered by patents, usually by 3 - 10.

What does this mean for breeding and farming?

Monster 4: Ambiguity

Breeding-by-editing and Rule 28(2)

Does a claim on plant with a native trait or a new combination of native traits escapes Rule 28 if the native trait is introduced by genome editing?

Introgressing a native trait from a wild-type into an elite variety

By crossing & selection → **Not Patentable**

By using NBTs → **Patentable**

Combining alleles from different lines into a new combination (e.g., removal of deleterious alleles)

By crossing & selection → **Not Patentable**

By using NBTs → **Patentable**

Rule 28(2) "First Glance" Consequence

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Monster 4: Ambiguity

Breeding-by-editing and Rule 28(2)

Does a claim on plant with a native trait or a new combination of native traits escapes Rule 28 if the native trait is introduced by genome editing?

Hn. 3 *If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself* ***introduces a trait into the genome or modifies a trait in the genome*** *of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.*

The decision suggest that "trait" means a **new trait** like GMOs (transgenic organism) and mutants. But the wording could be interpreted broader:

- Does the exception cover the „introduction" of a native trait which could have been introduced by sexual crossing?
- Does the exception cover a „modification" which results in a change which exists already in the gene pool?

Several applications from corn to sugar beet are pending in the „grey space".

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Something Borrowed

Scalability of industry and legal solutions?

Goal	Solution	Challenge(s)	Possible Mitigation
Transparency	PINTO Database	• Voluntary (ESA Members) • Only EU varieties	Obligation to disclose patents on request as requirement for enforcement
Access	ILP – Vegetables	Voluntary	Clarify cross license
		Limited to vegetables	New ILP for field crops
		No stacking mechanism	???
	Art 12 Dir. 98/44: Cross-license	Unclear threshold	Link "technical advantage" to VCU (→ Swiss Patent Law)
		Only for EU	???
FTO for conventional breeders	France Art. L613-2-3: FTO for plants independently developed with an EBP process	Only France	???
Farm-saved-seed	Art 11 Dir. 98/44: FSS exemption	Multiple royalty requests from PBR and patents	???

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Something Blue

Is the current patent system for sustainable for plant innovations?

- **Complexity:** Managing FTO and access may become unmanageable. → Breeders will only improve within their own genetic pool. No exchange of biodiversity. Likely further seed marker concentration.
- **Impact**: Patents will loose impact if the product lifecycles is <5 years but a grant takes >7 years.
- **Exclusivity:** Are exclusivity-based IPR systems sustainable for plants?

Do we need a "UPOV 2030"?

- A holistic incentive system for germplasm improvement and new traits.
- No "free riding": A liability regime for germplasm and new traits.
- Integration of CBD/ITPGRFA.

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THANK YOU VERY MUCH !

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