ESA

European Seed Association

The European seed industry's position on IP protection for plants and seed

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Overview

- Some history
- About PBR and the CPVR evaluation
- About patents and the interface problem
- What comes now?

SOME HISTORY

The starting point

Decision of the ESA Board in September 2009:

- CIPR to review the ESA IP position dating from 2004

Reasons for the IP position review:

- technical as well as political developments in the field of plant breeding and IP protection
- upcoming evaluation of the EU legal framework for plant variety protection

Cornerstones of the work

- CPVR evaluation → priority
- CIPR identified key topics to work on but start with PBR
- IP seminar organized in April 2010 to provide ESA members the possibility for input
- Position papers on PBR aspects adopted and presented in 2010
- Proposal for a position regarding patents from CIPR to ESA Board in March 2011 → parts of it endorsed but further work on some questions
- Final proposal in September 2011 → adopted by ESA Board

ABOUT PBR AND THE CPVR EVALUATION

Phase 1

Topics covered by ESA position

- ✓ Role of the CPVO
- ✓ Use of DNA-based markers in DUS testing
- ✓ Duration of the breeder's right
- ✓ Harvested material and directly obtained products
- ✓ Essentially derived varieties
- ✓ Protection of hybrids and access to parental lines
- ✓ Farm Saved Seed
- ✓ Enforcement of the breeder's right
- ✓ Biodiversity related issues

Presented in details last AM, available at: http://www.euroseeds.org/position-papers/intellectual-property/

The evaluation

Aimed at evaluating:

- System fulfilled its function
- Strengths and weaknesses
- Options for the future

ESA's contribution:

- Detailed input to stakeholder consultation based on existing positions
- Further input to second stakeholder consultation on enforcement and costs + telephone interview
- Comments on report discussed with evaluator and transmitted to Commission
- Participation at EU conference on October 11 in Brussels

Main issues raised by ESA

Scope of CPVR:

- Rights conferred on CPVR holder – should remain
- EDVs – support provision BUT: definition!

  -- thresholds → reversal of burden of proof
- Harvested material – clarify conditions
- Extend scope to directly obtained products

Duration of right:

- If CPVO/COM suggests extension – support
- For potatoes longer protection period

Main issues raised by ESA

Exemptions:

a. Breeder's exemption – one of the core elements – support

b. FSS – no support but if remains:
   - no extension
   - obligatory provision of information on use + NA involvement in collection of information
   - no exception for small farmers
   - clarify 'own holding' concept
   - clarify 'equitable remuneration' - 100% royalty

Main issues raised by ESA

Enforcement:

- Difficult – weak point of the system – need better possibilities
- Better provisions on evidence collection, jurisdiction, expert opinions, execution of judgements in other MSs
- One competent court

Examination/costs:

- One key several doors principle
- DUS should remain based on phenotype
- Possibilities to cut costs (e.g. on-line application)
- Extend role of CPVO (DUS, CC, variety denominations)
- Improve cooperation between NAs, CPVO, applicants

Outcomes of the evaluation

Main recommendations:

- implementation of ‘one key several doors’ approach
- improvement of information on patents
- improvement of interaction with Enforcement Directive
- improvement of adoption of thresholds for EDV determinations
- amendment of CPVR to obligate farmers to report ‘yes’ or ‘no’ whether they have used FSS
- specialized courts on national and EU level
- amendment of CPVR to improve the provisions on protection in respect of harvested material
- extension of CPVR system to EFTA countries
- administrative improvements (access to documents; textual errors; facilitation of hiring procedures)

Outcomes of the evaluation

ESA is:

- very glad about a number of recommendations (such as one key several doors, specialized courts, FSS info obligation)
- supports most of the recommendations

BUT

- regrets that certain issues did not receive enough attention (such as enforcement, definition of EDVs, extension to directly obtained products, symbol, facilitation of communication, interface with patent legislation)

ABOUT PATENTS AND THE INTERFACE PROBLEM

Phase 2

Elements of the position on the interface question

- Free access for further breeding to all genetic material that is commercially available
- Limitation of patentability
- *Material under regulatory requirements*
- Commercialization
- Improving transparency
- ‘Raising the bar’

The guiding principle

<u>Principle laid down by the ESA Board :</u>

The free access to all commercially available genetic material for further breeding should be safeguarded.

Limitation of patentability

1. Breeding processes based on crossing and selection (i.e. essentially biological processes) are excluded from patentability.

2. This principle must also be applied to biological material resulting from the application of such “essentially biological processes”.

3. The effect of any product patent on biological material must not extend to any biological material which has the same properties, but has been produced independently, i.e. without using the patented material, by means of an “essentially biological process”.

1. Patentability of breeding processes

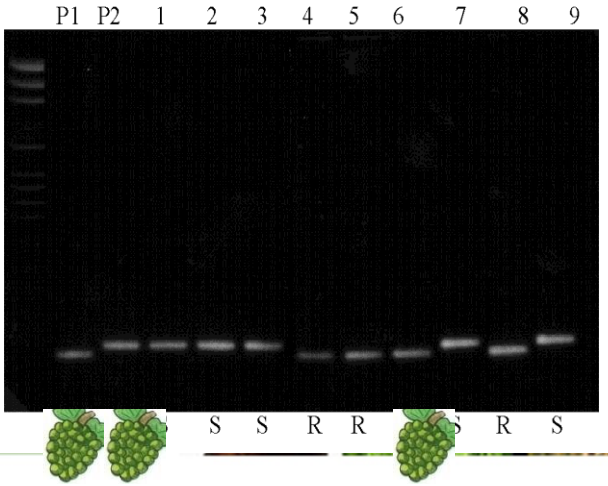
Broccoli decision (G2/07)

X

= sexual crossing & subsequent selection

→ not patentable

\+



= technical step involved

→ not patentable

Limitation of patentability

1. Breeding processes based on crossing and selection (i.e. essentially biological processes) are excluded from patentability.

2. This principle must also be applied to biological material resulting from the application of such “essentially biological processes”.

3. The effect of any product patent on biological material must not extend to any biological material which has the same properties, but has been produced independently, i.e. without using the patented material, by means of an “essentially biological process”.

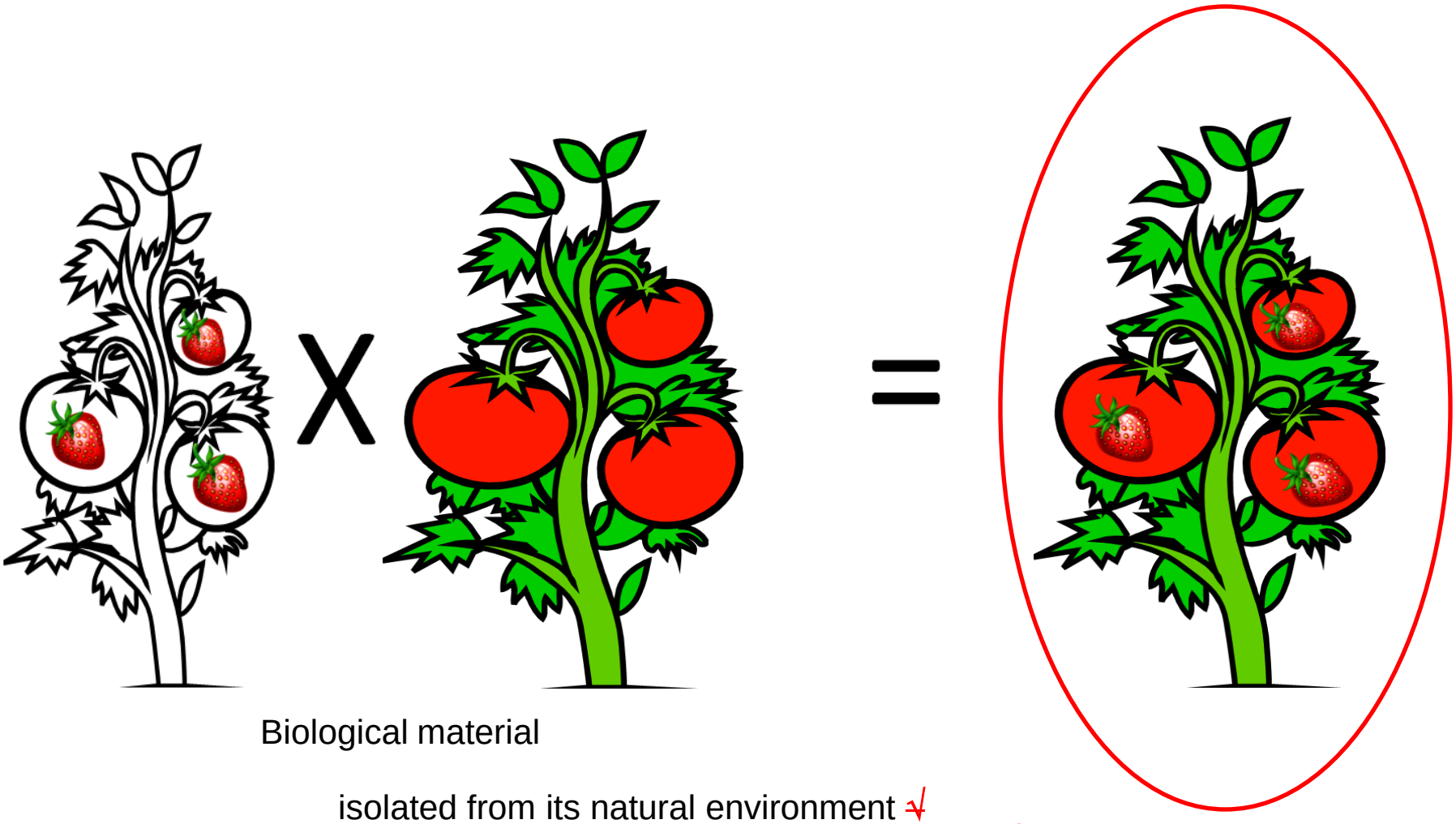
2. Patentability of biological material

- Principle:
  Processes based on crossing and selection and biological material resulting from such processes are not patentable.

- The **process** being used (crossing and selection or any other process) **is decisive** for patentability:

  - crossing and selection: no patentability
  - other processes: patentability

Natural Genetic Traits transferred by crossing

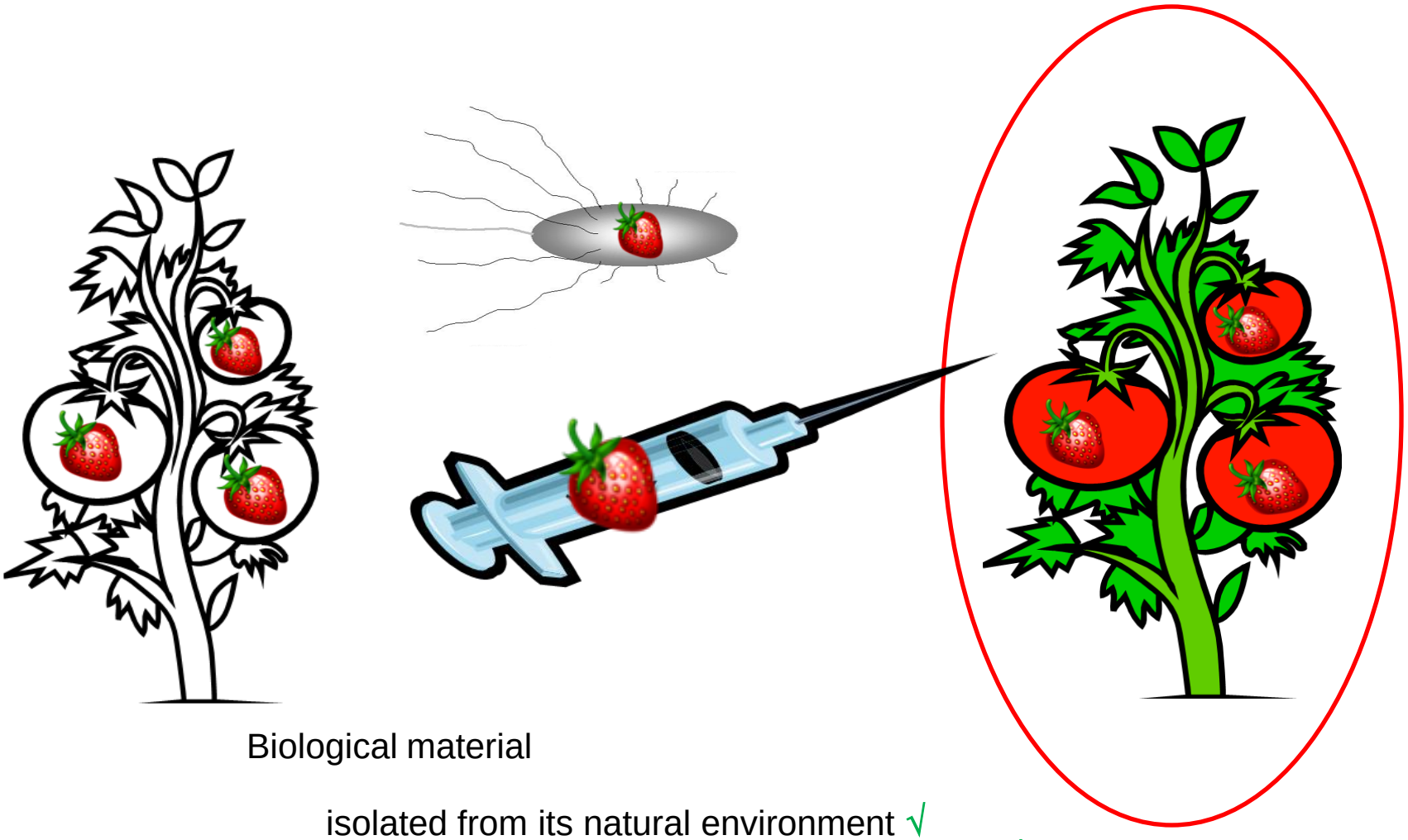


Biological material

isolated from its natural environment √

produced by means of a technical process √

Genetically Modified Organism



Biological material

isolated from its natural environment √
produced by means of a technical process √

Limitation of patentability

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3. Effect of granted patents

Effect of granted patents:

Product patent = absolute protection

Position:

If product produced by another breeder by a process based on crossing and selection independent of the patented material → free, i.e. no patent infringement

Material under regulatory requirements

CRLA and Board conclusion:

Currently, the obligation of compliance with regulatory obligations principally rests with the authorisation holder.

As a matter of principle, the responsibility for compliance with regulatory obligations and provisions must follow the access.

Further, more detailed investigation of the matter is assigned to CRLA.

Commercialization

Current ESA position on this matter remains in place.

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If the breeder of a new variety wishes to commercialize the variety still comprising a patented element → authorization of the patent holder needed.

→ Left up to bilateral agreement of the parties.

BUT: position supplemented with the request that in any case so-called FRAND (fair, reasonable and non-discriminatory) conditions should be applied in such bilateral deals

Improving transparency

To have information on the patent status of biological material:

- Companies owning patents on biological material undertake
  - may set up a public database on their own websites containing information on the patent status of their genetic material
- In addition, a common portal is created which contains links to all the public databases on the company websites
- Breeders regularly monitor the relevant websites
- Practical implementation to be elaborated by CIPR

Raising the bar

- Aimed at regular exchange with patent examiners on questions related to patents on plant-related inventions

- Last ESA/EPO meeting – beginning of June 2011:
  - Good participation from both sides
  - Open and fruitful discussion

- Continue on a regular basis - at least once per year

WHAT COMES NOW?

What comes now?

Is there a phase 3?

YES, there is.

1. Write the position paper:
   CIPR to work on it → to be finalized by end of 2011

2. Work on implementation of position

What comes now?

Work on implementation:

by Secretariat & CIPR

Identify solutions allowing quick and effective implementation

Possible tools may include e.g.: implementing legislation, guidance document, explanatory note, case law, EU patent with unitary effect, targeted amendments etc.

THANK YOU FOR YOUR ATTENTION!

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Back-ups

Patent data

According to data of the EPO (2009):

1400 European patents have been granted for inventions relating to plants

of which:

- 1317 for inventions involving genetic modification of a plant
- 83 for inventions which do not involve genetic modification

Source: EPO

Patent examples

Examples:

1. “A molecular marker selected from the group consisting of SEQ ID NO: 159 to 237.” (EP 2 247 734)

2. “A method of producing a variety capable of bearing seedless fruits, wherein a plant of a male sterile variety having a parthenocarpic trait is **backcrossed** with a plant of a fixed line which is capable of sustaining the parthenocarpic trait and the male sterile trait of the plant, as a pollen parent.” (EP 2 245 922)

3. “A plant capable of bearing seedless fruits, wherein the plant is obtained by **a crossing method** comprising the following steps (a) and (b):

   – a step (a) of selecting a first filial generation plant which is capable of bearing seedless fruits as well as having a male sterile trait and a parthenocarpic trait from the group of first filial generation plants generated by crossing between a plant of a male sterile line and a plant of a parthenocarpic line; and

   – a step (b) of crossing the thus selected first filial generation plant with a plant of a fixed line which is capable of sustaining the parthenocarpic trait and the male sterile trait of the plant, as a pollen parent, to thereby generate a progeny plant having the parthenocarpic trait and the male sterile trait.” (EP 2 245 922)

Broccoli decision

1. A method for the production of .*Brassica oleracea* with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises:
   a) crossing wild *Brassica oleracea species selected* from the group consisting of *Brassica villosa and Brassica drepanensis with broccoli double haploid* breeding lines;
   b) selecting hybrids with levels of 4-methylsulfinylbutyl gluc… or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in b… aploid breeding lines;
   c) backcrossing and selecting plants with the genetic co… the expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-m… glucosinolates, or both; and
   d) selecting a broccoli line with elevated … ylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinlates {sic} … or causing a strong induction of phase II enzymes, wherein molecular mark… eps (b) and (c) to select hybrids with genetic combination encoding expres… evels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucos… pable of causing a strong induction of phase II enzymes."

2. A method according t… the *Brassica oleracea breeding lines are broccoli double haploid* breeding lines co… alleles the presence of which results in self-incompatibility in the *Brassica olerace… comprising crossing* wild *Brassica oleracea with broccoli double haploid* breeding lines con… specific SI alleles to produce plants; and selecting for said plants by screening for said specific SI a… s with molecular probes.

3. The method according to claim 1 or claim 2, wherein only 4-methylsulfinylbutyl glucosinolate is elevated relative to that initially found in the *Brassica oleracea breeding lines.*

4. The method according to claim 1 or claim 2, wherein only 3-methylsulfinyipropyl glucosinolate is elevated relative to that initially found in the *Brassica oleracea breeding lines.*

Broccoli decision

5. An edible *Brassica plant produced according to the* method of any one of claims 1 to 4.

6. An edible portion of a broccoli plant produced according to the method of any one of claims 1 to 4.

7. Seed of a broccoli plant produced according to the method of any one of claims 1 to 4.

8. A broccoli plant having elevated levels of 3 -methylsulfinyipropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, wherein the broccoli plant is a hybrid plant following crossing of broccoli double haploid breeding lines with wild *Brassica oleracea species selected from the group* consisting of *Brassica villosa and .Brassica drepanensis* and the levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, are between 10 and 100 pmoles per gram of dry weight of said plant.

9. A broccoli inflorescence having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, wherein the broccoli inflorescence is obtained from a hybrid plant following crossing of broccoli double haploid breeding lines with wild *Brassica oleracea species* selected from the group consisting of *Brassica viliosa* and *Brassica drepanensis and the levels of* 3-methylsulfinyipropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, are between 10 and 100 pmoles per gram of dry weight of the inflorescence.