



Broccoli and tomatoes ...14 years and counting...

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CROP Innovation & Business - April 2017

EPO - Non Patentability of breeding processes

EP 1 069 819 – the Broccoli patent

METHOD FOR SELECTIVE INCREASE OF THE ANTICARCINOGENIC GLUCOSINOLATES IN BRASSICA SPECIES

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 with *Brassica oleracea* breeding lines; and,
 - (b) **selecting** hybrids with levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in *Brassica oleracea* breeding lines.

Not Patentable

Article 53.b EPC: Exceptions to patentability

European patents shall not be granted in respect of:

- (b) plant or animal varieties or essentially biological processes for the production of plants or animals



EPO - Non Patentability of breeding processes

Enlarged Board of Appeal – Broccoli 1 (G02/07)

Essentially Biological process :

*“Hence, in more general terms, the conclusion to be drawn is that a **process for the production of plants which is based on the sexual crossing of whole genomes** and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, **remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC**”*

G02/07 - Page 69

EPO - Non Patentability of breeding processes

Enlarged Board of Appeal – Broccoli 1 (G02/07)

“...the Enlarged Board is unable to see why the legislator's decision to provide **appropriate patent protection** for "secondary" features such as technical devices or means (today e.g. **markers**) by allowing them to be **patented in themselves...**”

G02/07 - Page 67

“**Processes for selecting** plants or animals **using genetic molecular markers** without crossing the plants or animals are **not excluded** from patentability.

Technical means, such as **genetic molecular markers**, used in such processes **are not excluded**, either”



EPO - Patentability of products

EBA – Broccoli 2 (G02/13)

*“The scope of application of the term “essentially biological processes for the production of plants” Article 53(b) EPC is interpreted to the effect that **product inventions** where the claimed subject-matter is directed to plants or plant material such as a fruit or plant parts other than a plant variety, as such, **are not excluded from being patented**”*

G02/13 – Final Conclusion

Article 53.b : Exceptions to patentability

European patents shall not be granted in respect of:

(b) plant or animal **varieties** or essentially biological **processes** for the production of plants or animals



EPO - Patentability of products

EBA – Broccoli 2 (G02/13)

*“The Enlarged Board is aware of the various ethical, social and economic aspects in the general debate [...] However, considering such general arguments in the present referrals **does not fall under the judicial decision-making powers of the Enlarged Board**”*

*“It has to be borne in mind that the **role of the Enlarged Board of Appeal is to interpret the EPC** using generally accepted principles of interpretation of international treaties. **It is not mandated to engage in legislative policy**”*

G02/13 – Pages 63-64

EU - Non Patentability of products

European Parliament Resolution – May 2012



“The European Parliament

[...]

3. ***Welcomes the decisions of the Enlarged Board of Appeal of the EPO in the so-called ‘broccoli’ (G 2/07) and ‘tomato’ (G 1/08) cases, dealing with the correct interpretation of the term ‘essentially biological processes for the production of plants (or animals)’ used in Directive 98/44/EC and the European Patent Convention to exclude such processes from patentability”***

Resolution 2012/2623

EU - Non Patentability of products

European Commission Notice – Nov. 2016



*“**Essentially biological procedures**’, i.e. crossing and selection of the **whole genome** [...] do not meet the general conditions for patentability, as they are neither inventive nor reproducible. Breeding is a reiterative process, in which a genetically stable end-product with the required characteristics is attained only after much crossing and selection. This process is so strongly marked by the individuality of the initial and intermediate material that an identical result will not be obtained upon its repetition. **Patent protection is not appropriate for such procedures and their products**”*

Explanatory statement to the ROTHLEY report, as found in Notice 2016/C 411/03

EU - Non Patentability of products

European Union Council – Feb. 2017

“THE COUNCIL OF THE EUROPEAN UNION:

*7. **URGES** Member States, in their capacity as members of the European Patent Organisation, to **advocate** that the practice of the European Patent Organisation is aligned with these conclusions”*



Independant



EPO current situation

Proposals and stays

*“EPO intend to submit to its governing bodies, early in 2017, a discussion paper setting out options, **including a proposal for an amendment of the implementing regulations**”*

JURI – Committee on Legal Affairs – Hearing Nov 2016

*“The President of the EPO has decided that, in view of the potential impact of the Commission Notice, **all proceedings before EPO examining and opposition divisions** in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process **will be stayed ex officio**”*

EPO Notice – Nov. 2016

EPO current situation

Last news : March 23rd 2017 - EPO CA/PL 4/17



EPO released a **four options** document for discussion by the Patent Law Committee of April 2017

- *Continue the examination practice based on the interpretation of Article 53(b) EPC established by decisions G 2/12 – G 2/13 (option 1)*
- *Amendment of the Convention (option 2)*
- *Amendment of the Implementing Regulations to the EPC (option 3) or*
- *Change of practice by the first instance based on modified administrative instructions (EPO notice, Guidelines) issued under Article 10(2)(a) EPC (option 4)*

EPO current situation

Last news : March 23rd 2017 - EPO CA/PL 4/14



Continue the examination practice based on the interpretation of Article 53(b) EPC established by decisions G 2/12 – G 2/13 (option 1)

The European Notice is not the law. Only CJEU could be “binding”

The situation is **inconsistent** and even **in conflict** with the European Notice which has been endorsed by both the Council of the EU and the EP Parliament

Amendment of the Convention (option 2)

This would require **unanimity** of the 38 EPC states which will have **one year** to declare they do not want to be bound by the amendment, leading to uncertainty

EPO current situation

Last news : March 23rd 2017 - EPO CA/PL 4/14



Amendment of the Implementing Regulations (option 3)

Favored by the Office (?) and some member states - not requiring unanimity

New Rule 28 (2) EPC : *Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process*

Achievable by summer 2017

Change of practice by modified administrative instructions (option 4)

Non legislative approach, quick to implement

EPO Future situation



The EPO Patent Law Committee of April 2017 and the EPO Administrative Council of June 2017 may lead to the implementation of one of the four solutions (or alternative ones?)

*Under any option, **ultimate legal certainty** for the EPO's legal framework and practice will be **established by a decision of the Enlarged Board of Appeal** which, if available, **takes into account a decision of the CJEU***

EPO Document CA/PL 4/17 Point 60

At this occasion, the Enlarged Board of Appeal could **take into account the European Commission Notice** that did not exist at the time of the second broccoli decision

EPO Future situation



Patentability of Products from essentially biological processes **could be ruled out of European Patent Office practice** in the coming months

BUT

Getting a **new Enlarged Board of Appeal** decision confirming the solution implemented by the European Patent Office governing bodies **could take about 5 years**



Thank you
for your attention

...and see you in 5 years ?!?