



Seminar on the interface between PVP and patents

**Jean-Luc GAL,
European Commission, GROWTH F5
Brussels, 24 June 2015**

Plant variety protection

- **Council Regulation No 2100/94 – Community plant variety rights**
- ***sui generis* system**
- **protectable plant varieties:**
 - **D**istinct
 - **U**niform
 - **S**table
 - new

Plant-related legislation

- **1961** – UPOV Convention
- **1963** – **Strasbourg Patent Convention** – first harmonization of national patent laws in Europe
- **1973** – **European Patent Convention**
- **1994** – **TRIPS Agreement**
- **1994** – **Regulation No 2100/94** on Community Plant Variety Rights
- **1998** – **Directive 98/44/EC** – protection of the biotechnological inventions

Biotech Directive

- **1988** – first COM proposal
- **1995** – rejected by the EP
- **1995** – second COM proposal
- **1998** – adopted → Directive **98/44/EC**

Patent protection

- **Requirements of patentability:**
 - New
 - Inventive
 - Industrially applicable
- **Subject-matter patentable**
 - the technical feasibility of the invention is not confined to a particular plant variety
- **Excluded subject-matter**
 - Plant varieties,
 - Essentially biological processes for the production of plants (EBPs)

Decision of the Enlarged Board of Appeal 20 December 1999 G 1/98

A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it **may embrace plant varieties**.

Essential Biological Processes (EBPs)

- **Article 4(1)(b) only excludes from the patentability essential biological processes for the production of plants.**
- **Quid of the product obtained through EBPs?**
- **National legislations remain silent on this issue except NL and DE laws which exclude such a product from the patentable subject matter.**

EBPs – new developments

- **EBPs consist entirely of natural phenomena (crossing or selection)**
- **EPO's Enlarged Board of Appeal clarified the limits of patentability of plants, plant material and related methods of producing plants**
- **G 2/07 and G 1/08** – clarification of the definition of EBPs in terms of their patentability:
- Process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plant and subsequently selecting plants is excluded from patentability

EBPs – cont'd

- It does not matter whether a technical device such as a marker, serves or assists the performance of crossing and of the selection of the plants
- It is not relevant whether a step of a technical nature is new or a known measure, whether it is trivial or a fundamental alteration of the known process, whether it does or could occur in nature, whether the essence of the invention lies in it
- However, methods for the production of plants **based on engineering** of one or more specific genetic traits into a target plant's genome are patentable

EBPs – New developments – cont.

- **G 2/12 and G 2/13 clarified the patentability of plant products derived from EBPs:**
 - plant materials (plants, plant parts, or fruits) are patentable
 - may be claimed as product per se or as product-by-process
 - regardless of their method of production
 - compliance with standard requirements for the product claims

Cross licensing regime –art 12 Dir 98/44

- **Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.**

Article 12(3) Dir. 98/44

- **Applicants for a cross- licence must demonstrate that:**
- **(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;**
- **(b) the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety**

Breeders' exemption

- a tool allowing breeders to freely use patented biological material for breeding, or discovering and developing other plant varieties => **the limited breeders' exemption**
- **not included in the Biotech Directive**
- **provided by several national patent laws (NL, FR, DE)**
- **UPC Agreement – Article 27(c)**
- **UPOV – the full breeders' exemption** – in addition allowing the commercialization of products stemming from the breeding activities

Biotech Expert Group

- 15 experts in patent law and biotechnologies providing the COM with expertise, analysis and comments *inter alia* on the patentability of plant related materials
- mandated for 2 years – started in DEC 2013
- active work – 12 meetings - in two sub-groups: plant and stem cell
- towards the finalizing the Group's report advising the COM

'Plant' sub-group

- **8 experts with different expertise** (ESA, No patents on seeds, EPO, academy, scientific and industry views included)
- **issues covered in the sub-group's report:**
 - technological developments on the field of plant breeding
 - EBPs for the production of plants
 - products obtained by EBPs
 - patents for plants v plant varieties
 - breeders' exemption
 - compulsory cross-licensing

16c Report

- COM's obligation to report annually to the Council and the EP
 - *on the development and implications of patent law in the field of biotechnology and genetic engineering*
- issued only twice – in 2002 and 2005
- 2012 - EP resolution (reminder of our task)

Perspectives and conclusions

- **EP resolution (B7-0228/2012)**
- **Written questions (E006045 and 006066/2015)**
- **Transmission of the analyses/reports by the expert group to the Commission**
- **The Commission will assess the works done by the experts and will consider the possible next steps**

***Thanks
for
your attention!***

Any further questions:

Jean-Luc.Gal@ec.europa.eu

Lucie.Zamykalova@ec.europa.eu