Intellectual property and GMOs

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GMOs

- GMOs are animals, plants, or microorganisms

- Microorganisms and their uses are patentable, so this presentation is about plants and animals only

The European Patent Convention (EPC) and the European Patent Office (EPO)

- Patent law in Europe is dominated by the EPC and the decisions of the Technical and Enlarged Boards of Appeal of the EPO (TBoAs and EBoA)

- National patent offices, national courts, and national laws tend to follow the EPO and the EPC – so I'll only talk about the EPO and the EPC

EPC

- This was agreed in 1973 after negotiations which began in the late 1940s
- It came into force in 1979, and has had had one major revision, agreed in 2000
- It contains Articles and Rules, the Rules cannot override the Articles. The Articles must be agreed by all member states, the Rules can be pushed through by the Administrative Council without ratification

Plants and animals

- It seems clear *on a surface level* and from a review of the negotiations which led to the EPC being agreed (i) that plants and animals were NOT to be patentable, (ii) that routine plant/animal breeding processes and farming processes were NOT to be patentable, and (iii) that microbiological/irradiation processes for producing new types of plants/animals WERE to be

Art. 53 EPC

- European patents shall not be granted in respect of ... plant or animal varieties or essentially biological processes for the production of plants or animals ...

- Clear, surely?

G-1/98 Transgenic plant/NOVARTIS II

- BUT, in 1998, under pressure from the European Commission, the European Parliament enacted the ‘European Biotech Directive’ (Directive 98/44/EC)

- This stipulated that certain things were to be patentable in the EU, stipulations that were at odds with the EPC

G-1/98 Transgenic plant/NOVARTIS II

- In particular, the EBD said:
- 2(2). A process for the production of plants or animals is essentially biological if it consists **entirely** of natural phenomena such as crossing or selection.
- 4(2). Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

G-1/98 Transgenic plant/NOVARTIS II

- Fearing that the EPO might lose business if the EPC was more restrictive than the EBD, the President of the EPO in September 1999 pushed through new Rules for the EPC which mirrored those provisions of the EBD

- At the time, a decision was pending before the EBoA (G-1/98) on a case relating to claims to a transgenic plant

G-1/98 Transgenic plant/NOVARTIS II

- The referring TBoA had offered the EBoA TWO ways of interpreting the exclusion of plant and animal varieties:
- (1) Novelty – the claim should be rejected if it encompassed excluded subject-matter, i.e. if it covered plant or animal varieties
- (2) Higher taxonomic level – the claim should be accepted if it was worded at a higher taxonomic level than ‘variety’

G-1/98 Transgenic plant/NOVARTIS II

- The Novelty approach doesn’t make sense, the EBoA did not consider any other approaches, and the Higher taxonomic level approach is consistent with the EBD
- So the EBoA gave its blessing to that approach and G-1/98 is sacred territory, not to be challenged
- A plant or animal ‘variety’ falling within the scope of such claims, though not patentable in itself, will infringe

G-2/07 Broccoli/PLANT BIOSCIENCE and G-1/08 Tomatoes/STATE OF ISRAEL

- Fast forward a few years and we have two European patents, one for ‘healthy broccoli’ and the other for ‘wrinkly tomatoes’, both containing claims to conventional breeding processes for producing the plants. These were opposed and in due course were consolidated before the EBoA

G-2/07 Broccoli/PLANT BIOSCIENCE and G-1/08 Tomatoes/STATE OF ISRAEL

- Since the processes involved some technical steps, the patentees argued that they were patentable since the were not *entirely* biological (i.e. as in the EBD)

- The EBoA decided otherwise, and to agribusiness' despair said that claims must not cover the sexual reproduction step. Remember that GM seed as sold is the product of a GM step followed by many sexual reproduction steps – the permissible claims would not cover the product as sold

G-2/12 Tomatoes II/STATE OF ISRAEL and G-2/13 Broccoli II/PLANT BIOSCIENCE

- The patentees retaliated by limiting their claims to the plants produced by the conventional breeding processes, defined at the Higher taxonomic level, and argued that the exclusion of ‘essentially biological processes’ could not be read to exclude the products of such processes.

G-2/12 Tomatoes II/STATE OF ISRAEL and G-2/13 Broccoli II/PLANT BIOSCIENCE

- The EPO was on its way to accepting this when Opponent Unilever and *amici* such as my wife and I pointed out that this would leave the exclusion toothless since the product claims would be infringed by performing the unpatentable process

- So the cases went back to the EBoA – BUT with any consideration of the sacred case G-1/98 NOVARTIS II excluded from consideration

G-2/12 Tomatoes II/STATE OF ISRAEL and G-2/13 Broccoli II/PLANT BIOSCIENCE

- Under its new chairman, the EBoA allowed the product claims

Melons

- Since then, the ‘seedless melons’ case, opposed by many interested parties, has been heard at Opposition level, and has been revoked

- BUT NOT on the grounds of Art 53 EPC

Is the situation hopeless?

- My belief is that it is NOT, in view of the operative language of Art 53 EPC

- “ European patents shall not be granted in respect of … plant or animal varieties…”

- To my mind, a straightforward reading of this is that there is an implicit disclaimer to the excluded subject matter, i.e. the claim may encompass a plant or animal variety but it is not infringed by one.

Summary

- Plants and animals are patentable if claimed generically, and the variety/species actually used will infringe, as will all methods of growing or producing them
- GM processes are patentable and the direct product will infringe
- The EPO’s G-1/98 NOVARTIS II decision MUST be challenged

THE END

- Thanks for listening

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