Patenting life: Where does Europe stand?

Geertrui Van Overwalle

Centre for Intellectual Property Rights, K.U.Leuven, (Belgium)
Tilburg Institute for Law, Technology and Society, Tilburg University (Netherlands)

Outline

Plant varieties – Gene patents

• Achievements
  Describing and assessing the current system

• New perspectives
  Constructing [Optimizing] the current system

1. Plants

• European Patent Convention, 1973
  – Patentability: Exclusion plant varieties (art. 53b)

• EU Biotechnology Directive, 1998
  – Patentability: Exclusion essentially biological processes for the production of plants or animals (art. 4 1b)
  – Scope: The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, … in which the product in incorporated and in which the genetic information is contained and performs its function (art. 9)
The broccoli case – method MAS

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.

9. An edible Brassica plant produced according to the method of any one of claims 1 to 6.

10. An edible portion of a broccoli plant produced according to the method of any one of claims 1 to 6.
A method for breeding tomatoes with reduced water content and on products of that method

Claims

1. A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of:

   crossing at least one Lycopersicon esculentum plant with a Lycopersicon esculentum plant to produce hybrid seeds;
   collecting the first generation of hybrid seeds;
   growing plants from the first generation of hybrid seeds;
   collecting the seeds of the most recent hybrid generation;
   growing plants from the seeds of the most recent hybrid generation;
   allowing plants to remain on the vine past the point of normal ripening and screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.
“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.

However, if a process of sexual crossing and selection includes within it 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 that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability. Therefore, such a process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.”

The soybean case – scope

6. A DNA sequence encoding a Class II EPSPS enzyme selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:5.
Gerechtshof 's Gravenhage
"scope protection
DNA sequences in
biological material"

European
Court of
Justice
Restricted
6 July 2010

Achievements

Patentability

• Plants per se
  – genetically modified plants (whole genomes) (rDNAt)
    e.g. claims to end products (modified plant cells, plants, seeds)
    intermediate products: vectors, plasmids, etc. = settled

• Plant methods
  – transformation techniques (rDNAt) e.g. claims to Agrobacterium
    mediated gene transfer = settled
  – (mix) conventional breeding (and molecular breeding) techniques
    "marker assisted selection" (e.g. broccoli patent, tomato patent) = settled

• Plant traits
  – Single native traits - introduced traits = problematic
Assessment

• Restricted access to genetic variation
  [genetic variation = most important source of innovation = condition to safeguard food security]
  – License structure: no/restrictive licensing at high cost
  – Patent thickets: high transaction costs resulting from many patents

2. Gene patents

• EU Biotechnology Directive, 1998
  – Patentability
    “1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

    2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element (art. 5)
BRCA case

The Breast Cancer Linkage Consortium
UK, US, CA, FR, NL

Linkage of early-onset familial breast cancer to chromosome 17q21
JM Hall, MK Lee, B Newman, JE Morrow, LA Anderson, B Huey, and MC King
Science, Vol 250, Issue 4988, 1684-1689

EP699754 10 jan 2001

1. 'A method for diagnosing a predisposition for breast and ovarian cancer in a human subject which comprises determining whether there is a germline alteration in the sequence of the BRCA1 gene or a BRCA1 gene regulatory sequence in a tissue sample of said subject, said alteration being indicative of a predisposition to said cancer.'

EP705902

1. An isolated nucleic acid coding for the BRCA1 polypeptide having the amino acid sequence set forth in SEQ.ID.NO:2, or a modified form of said polypeptide which is functionally equivalent or associated with a predisposition to breast or ovarian cancer.
Genae Girard, 39, is suing Myriad Genetics and the Patent Office over the granting of a patent on a gene. Myriad also has patented the only test that measures the risk of breast and ovarian cancer.

Assessment


Secretary’s Advisory Committee on Genetics, Health, and Society

- Restricted access to health care
  - License structure: no/restrictive licensing at high cost
  - Patent thickets: high transaction costs resulting from many patents
Constructing a better balance

From 'old' to 'new' IP

• Existence of rights
  – Strict(er) interpretation patentability requirements and scope
    • visible in plant jurisprudence in EPO, CJEU
    • not visible yet in human gene patent discourse EPO

• Exercise of rights
  – Need for reconceptualisation of patents
    • “Duty bearing privileges”
    • Social responsibility
  – Instruments