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LEUVEN

12th EIPIN Congress 2011
CONSTRUCTING EUROPEAN IP: ACHIEVEMENTS AND NEW PERSPECTIVES
Strasbourg, February 24-25 2011



Patenting life: Where does Europe stand?

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Ceci n'est pas une pomme



Ceci n'est pas un brevet

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Outline

Plant varieties – Gene patents

- **Achievements**
Describing and assessing the current system
- **New perspectives**
Constructing [Optimizing] the current system

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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 is incorporated and in which the genetic information is contained and *performs its function* (art. 9)

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The broccoli case – method MAS

(19)	 Europäisches Patentamt European Patent Office Office européen des brevets	
		(11) EP 1 069 819 B1
(12)	EUROPEAN PATENT SPECIFICATION	
(45)	Date of publication and mention of the grant of the patent: 24.07.2002 Bulletin 2002/30	(51) Int Cl.: A01H 5/10
(21)	Application number: 99915886.8	(86) International application number: PCT/GB99/01079
(22)	Date of filing: 08.04.1999	(87) International publication number: WO 99/52345 (21.10.1999 Gazette 1999/42)
(54)	METHOD FOR SELECTIVE INCREASE OF THE ANTICARCINOGENIC GLUCOSINOLATES IN BRASSICA SPECIES VERFAHREN ZUR SELEKTIVEN ERHÖHUNG DES ANTICARCINOGENEN GLUCOSINOLATE BEI BRASSICA SORTEN PROCEDE PAR SELECTION D'ACCROISSEMENT DES GLUCOSINOLATES ANTICARCINOGENES DE LA BRASSICA	
(84)	Designated Contracting States: AT BE CH CY DE DK ES FI GB GR IE LI LU MC NL PT SE Designated Extension States: AL LT LV MK RO SI	(56) References cited:
(30)	Priority: 09.04.1998 US 81169 P	<ul style="list-style-type: none"> • MITHEN, R.F. ET AL.: "Glucosinolates of wild and cultivated brassica species" PHYTOCHEMISTRY, vol. 26, no. 7, 1987, pages 1969-1973, XP002110359 cited in the application • CARLSON, D.G. ET AL.: "Glucosinolates in Crucifer Vegetables: Broccoli, Brussels Sprouts, Cauliflower, Collards, Kale, Mustard Greens and Kohlrabi" JOURNAL OF THE AMERICAN SOCIETY OF HORTICULTURAL SCIENCE, vol. 112, no. 1, 1987, pages 173-178, XP002110360 cited in the application • FAHEY J W ET AL.: "Broccoli sprouts: an
(43)	Date of publication of application: 24.01.2001 Bulletin 2001/04	
(73)	Proprietor: Plant Bioscience Limited Norwich, Norfolk NR4 7UH (GB)	



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Claims

having elevated levels of glucosinolates, a class of compounds with anti-cancer potential.

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.

Opposition
 "essentially
 biological
 process for the
 production of plants"

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The tomato patent

		Europäisches Patentamt European Patent Office Office européen des brevets			
(19)				(11) EP 1 211 926 B1	
(12) EUROPEAN PATENT SPECIFICATION					
(45) Date of publication and mention of the grant of the patent: 26.11.2003 Bulletin 2003/48		(51) Int Cl ⁷ : A01H 5/10, A01H 1/04			
(21) Application number: 00940724.8		(86) International application number: PCT/IL00/00389			
(22) Date of filing: 04.07.2000		(87) International publication number: WO 01/013708 (01.03.2001 Gazette 2001/09)			
(54) METHOD FOR BREEDING TOMATOES HAVING REDUCED WATER CONTENT AND PRODUCT OF THE METHOD VERFAHREN ZUR ZUCHT VON TOMATEN MIT NIEDRIGEM WASSERGEHALT UND PRODUKT DIESES VERFAHRENS PROCEDE PERMETTANT DE CULTIVER DES TOMATES AYANT UNE TENEUR EN EAU REDUITE ET PRODUIT OBTENU AU MOYEN DE CE PROCEDE					
(64) Designated Contracting States: AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE		(56) References cited: • DATABASE CAB [Online] CAB INTERNATIONAL, WALLINGFORD, OXON, GB; an 88 88394, 1984 GOLAS, J.; "Resistance of tomato cultivars to fruit cracking." XP002149829 • DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; August 1998 (1998-08) BERINACCHI D ET AL.; "Advanced backcross QTL analysis in tomato. I. Identification of QTLs for traits of agronomic importance from <i>Lycopersicon hirsutum</i> ." Database accession no. PREV198603480216			
(30) Priority: 19.08.1999 IL 13150999					
(43) Date of publication of application: 12.06.2002 Bulletin 2002/24					
(72) Proprietor: STATE OF ISRAEL-MINISTRY OF AGRICULTURE IL-50 290 Beit Dagan (IL)					

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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* spp. to produce hybrid seed;
collecting the first generation of hybrid seeds;
growing plants from the first generation of hybrid seeds;
pollinating the plants of the most recent hybrid generation;
collecting the seeds produced by 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.

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Enlarged Board of Appeal

"marker assisted selection **not** patentable
9 December 2010

"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."

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The soybean case – scope



(19) Europäisches Patentamt European Patent Office Office européen des brevets			
		(11) EP 0 546 090 B2	
(12) NEW EUROPEAN PATENT SPECIFICATION			
(45) Date of publication and mention of the opposition decision: 19.07.2006 Bulletin 2006/29	(51) Int Cl.: C12N 15/64 (2006.01) C12N 5/10 (2006.01)	C12N 15/62 (2006.01) A01H 5/00 (2006.01)	
(45) Mention of the grant of the patent: 19.06.1996 Bulletin 1996/25	(86) International application number: PCT/US1991/006148	(87) International publication number: WO 1992/004449 (19.03.1992 Gazette 1992/07)	
(21) Application number: 91917090.2	(22) Date of filing: 28.08.1991		
(54) GLYPHOSATE TOLERANT 5-ENOLPYRUVYL-SHIKIMATE-3-PHOSPHATE SYNTHASES GLYPHOSATTOLERANTE 5-ENOLPYRUVYL-3-PHOSPHOSHIKIMAT-SYNTHASEN SYNTHASES DE 5-ENOLPYRUVYL-SHIKIMATE-3-PHOSPHATE TOLERANT LE GLYPHOSATE			
(84) Designated Contracting States: AT BE CH DE DK ES FR GB GR IT LI LU NL SE	(56) References cited: EP-A- 0 218 571 EP-A- 0 428 641 US-A- 4 769 061	EP-A- 0 293 358 WO-A-91/04323	
(30) Priority: 31.08.1990 US 576537	(43) Date of publication of application: 16.06.1993 Bulletin 1993/24	• PLANT PHYSIOLOGY vol. 89, no.4, April 1989, ROCKVILLE, MD, USA, page 47; EICHHOLTZ, D., ET AL.: "Glyphosate tolerant variants of petunia EPSP synthase" • CHEMICAL ABSTRACTS, vol. 103, 1985	
(7) Proprietor: Monsanto Company St. Louis, Missouri 63167 (US)			

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.

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**Gerechtshof 's
Gravenhage**

*"scope protection
DNA sequences in
biological material"*

**European
Court of
Justice**

Restricted
6 July 2010

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Achievements

Patentability**• Plants *per se***

- genetically modified plants (*whole* genomes) (rDNA) e.g. claims to end products (modified plant cells, plants, seeds) intermediate products: vectors, plasmids, etc. = **settled**

• Plant methods

- transformation techniques (rDNA) 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**

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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

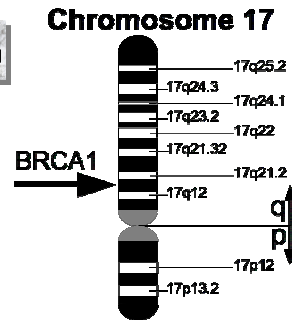
2. Gene patents

- 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

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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 alternation 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.

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The New York Times



US
EPO



Today's drug target discoveries will lead to new therapies that treat the underlying cause of the disease, not just its symptoms.

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		Lab Certification		Contact Us
				Site Map

GENETIC TESTING

Myriad Genetic Laboratories offers the most accurate genetic test available for:

- **BRCAAnalysis®** genetic testing for hereditary breast and ovarian cancer



Assessment

Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests
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



Giuseppe Arcimboldo

Impact “Old IP”



Giuseppe Arcimboldo

Impact “New IP”