

To
European Patent Office
Munich
Erhardtstraße 27

D-80469 München
Germany

Opposition to Patent EP 1 962 578

Title: CLOSTEROVIRUS-RESISTANT MELON PLANTS

Proprietor: Monsanto Invest N.V., Amstelveen (NL)
Date of publication and mention of the grant of the patent: 04.05.2011
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Application number: 06835672.4
Date of opposition: 3.2. 2012

The fee for the opposition of 705 € was transferred to the bank account Commerzbank München, BLZ 700 800 00, KtNr. 3 338 80000 of the EPO

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Reasons for opposition:

The opponents request the patent to be revoked entirely. The opposition is filed on the ground that the subject matter of the European patent is not patentable under Article 100, EPC.

- Especially relevant is Article 53b, EPC which excludes patents on plant varieties and on essentially biological processes for the breeding of plants.
- The patent is not inventive according to Article 56, EPC.
- The invention is not disclosed in a manner sufficiently clear and complete as required by Art 83, EPC
- The patent is contrary to morality and public order, Art 53a, EPC.

A public hearing is requested in case the opposition division does not revoke the patent entirely.

Introduction:

In May 2011, the US corporation Monsanto was awarded a European patent on conventionally bred melons (EP1962578). Melons have a natural resistance to certain plant viruses. It was known in the case of Cucurbit yellow stunting disorder virus (CYSDV) that certain melons are known to occur in nature being resistant to this disease. Using conventional breeding methods, this type of resistance was introduced from an Indian melon to other melons and has now been patented as a Monsanto “invention”.

The opponents regard this patent an abuse of patent law because it contravenes European law excluding patents on conventional breeding. Further it is a case of biopiracy, since the original plants come from India and are registered in international seed banks. Patents like this are blocking

access to the genetic resources necessary for further breeding, and basic resources needed for daily life are subordinated to monopolisation and financial speculation.

A precedent was set by the European Patent Office in December 2010. It decided that conventional breeding could not be patented (G2/07 and G1/08). However, in the Monsanto patent case, the EPO excluded the process for melon breeding. The plants and all parts of the plant, such as the seeds and the melon fruit, have been patented as an invention. Therefore, the patent was only changed cosmetically but not in substance.

The plant disease, Cucurbit yellow stunting disorder virus (CYSDV), has been spreading through North America, Europe and North Africa for several years. Monsanto can now block access to breeding material which inherits genetic conditions that confer resistance. DeRuiter, a well known seed company in the Netherlands, originally developed the melons. DeRuiter used plants designated PI 313970 - a non-sweet melon from India. Monsanto acquired the seed company in 2008, and now also owns the patent.

Detailed reasoning of the opposition:

(1) Art 53b, EPC, essentially biological breeding:

In claim 1 the term “introgression” is used to describe the process to produce the plants as expected. In addition the word introgression is defined in the description of the patent as “crossing” (page 5, para 27): *“As used herein, the terms “introgression”, “introgressed” and “introgressing” refer to both a natural and artificial process whereby genes of one species, variety or cultivar are moved into the genome of another species, variety or cultivar, by crossing those species. The process may optionally be completed by backcrossing to the recurrent parent.”*

This understanding of the word “introgression” is underlined by further passages of the patent description such as the exemplification on page 11, para 72 which describes the process of breeding by crossing and selection. Thus claim 1 falls under the exemption of Art 53b, EPC and the ruling of G1/08 which excludes patents on breeding that are based on crossing and selection.

The patent also mentions ways to introduce the desired trait from one trait to another by protoplast fusion and genetic engineering. However these technical variants to achieve the plants as described do not overcome the exclusion of Art. 53 b for the following reasons:

1. the patent does not enable a skilled person to perform genetic engineering to achieve CYSDV resistant plants. The DNA that would enable the resistance is not described in the patent. The method of genetic engineering is also not supported by the wording of the claims.
2. The plants as described in claim 1 are homozygous. However if protoplast fusion is used, it only can be applied as additional technical step to achieve these plants, but it can not replace crossing and selection. As it is described in the patent (page 12, para 73): *“As indicated, the last backcross generation may be selfed in order to provide for homozygous pure breeding (inbred) progeny for closterovirus-resistance. Thus, the result of recurrent selection, backcrossing and selfing is the production of lines that are genetically homogenous for the genes associated with closterovirus-resistance as well as other genes associated with traits of commercial interest.”* Thus in it is a process of crossing and selecting that renders the plants as claimed. In result, the breeding of these melons can not patented.
3. Protoplast fusion as combination of the whole genomes being excluded by G1/08. Protoplast fusion does not add any new or specific genetic information to the plants genome but just combines the whole genome of the donor plant with the ones of the recipient plant. If it were possible to overcome the exclusion of Art 53b by using protoplast fusion, this technical variant could be included into the wording of any patent that is based on crossing and selection just to escape Art 53b.
4. The fact that claim 1 is directed to products and not to the process of breeding can also not be used as an excuse to escape the prohibition of Art 53b. If the EPO would permit such a wording as being patentable, the Art. 53b could no longer be applied in accordance with G1/08 and would become meaningless.

(2) Art 53b, EPC, plant varieties:

To render the plants as described in claim 1 (“a CYSDV resistant plant”), it is not sufficient only to introduce the relevant marker gene. To achieve potential resistance against CYSDV, further breeding

steps have to be included. This follows from the description of the patent on page 12, para 74-82. By reading this description it becomes evident that these melon plants, “cultivars” and breeding lines which render resistance against CYSDV meet the characteristics of plant varieties as described in Rule 26 (4) EPC. Thus these CYSDV resistant melons as described in claim 1 and especially in claim 3, are excluded from patentability. This conclusion is also in accordance with G1/98.

The opponents are aware that the EPO has so far established a quite narrow interpretation for the exclusion of plant varieties (T1854/07). This legal practice was used by many applicants which choose the wording of their claims in a way to escape the prohibitions even if the overall content of the patent falls within the exclusion of Art. 53b. However, as the recent decisions G2/06, G1/08 and the judgement C-34/10 of the European Court of Justice show, an interpretation of existing exemptions that can be qualified as “whole content approach” should be applied in the area of biotechnology. Thus the wording of the claims alone no longer can be regarded as being decisive for the questions if the exclusion has to be applied. By reading carefully the patent description it has to be acknowledged that the plants as described in the patent indeed fulfill the definition of plant varieties as provided by the EPC. Thus the subject matter of the patent has to be regarded as being not patentable.

(3) Art. 56

The applicant did not investigate the mechanisms that underly the resistance against CYSDV nor was he able to identify the DNA that is directly involved in the biological mechanisms of the resistance. It did not even show that it was able to breed indeed new melon plants that indeed show resistance against CYSDV. The detection of marker genes useful in plant breeding can not be regarded as being inventive. Any skilled person that has access to standard technologies is able to identify marker genes that can be useful for breeding. The possibility to spare costs and time in a breeding program (page 2, line 9-10) does in itself not qualify inventiveness.

(4) Art. 83

The applicant did only provide a marker gene, but did not show how to breed resistance against CYSDV successfully. Which of the other markers as mentioned are necessary? Which other genetic elements / background are necessary to successfully establish resistance? Since the resistance is

known to be based on a quantitative trait locus, it is essential not only to introduce a certain marker into a plant but also to elaborate on other genetic elements that contribute to the resistance to larger or smaller degree. The technical details as described in the patent are not sufficient to enable a skilled person to breed a CYSDV resistant melon with a predictable rate of success. As it is explained vaguely in the patent description: “A *QTL* may for instance comprise one or more genes of which the products confer the genetic resistance. Alternatively, a *QTL* may for instance comprise regulatory genes or sequences of which the products influence the expression of genes on other loci in the genome of the plant thereby conferring the CYSDV-resistance. The *QTL* as disclosed herein (*QTL-1*) may be defined by indicating its genetic location in the genome of the respective wild *Cucumis* accession using one or more molecular genomic markers.”

McCreight, J.D. & Wintermantel, W.M. (2010) discovered that in the case of CYSDV-resistance further crossings with melons like TGR-1551 be necessary to achieve the necessary level of resistance in melons. They show that the use of PI313970 material as described in the patent does not render sufficiently strong resistance against CYSDV in California, but only to certain strains of the virus abundant in Spain (McCreight J.D. & Wintermantel W.M. (2008).

So in conclusion the patent does not describe successfully how to breed a new melon which is resistant to CYSDV as it is claimed by the applicant. The only thing which is provided is a tool that might be helpful in selecting some relevant material that might contribute to a resistance. In conclusion, the invention is not disclosed in a manner sufficiently clear and complete as required.

(5) Art 53 a

PI313970 originates from India and is registered in the Germplasm Resources Information Network (see D3). The international seed banks are following a general policy that their genetic material should be available for plant breeding. Patents as EP 1 962 578 are restricting this availability (see International Treaty on Plant Genetic Resources for Food and Agriculture, IT PGRFA). While the plant material as such is not claimed in the patent, any usage of the relevant markers for commercial breeding of other melons with potential resistance of CYSDV can be blocked by the patent holder. In conclusion the patent is a misappropriation of genetic material as provided by seed banks and originally stemming from India. This is also stated in a letter of support by the organisation Navdanya from India which accuses the patent to violate the Biodiversity Act and the Plant Variety

Protection and Farmers Rights Act (attached). Navdanya is a network of 500,000 seed keepers and organic farmers in India.

It is important to note that Indian Biodiversity Act is the national implementation of the Convention on Biological Diversity – signed by 193 Parties, including the member states of the European Patent Organisation. As specified in the Nagoya Protocol, it is the duty of Parties to the CBD “*that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.*” Although the Nagoya Protocol is not in force now, the duty to implement such measures is already part of the Convention itself (Art. 15.7). Therefore the granting of the patent is against the *ordre public*.

Access to material which is useful for breeding melons with a sufficiently high level of resistance against CYSDV as described by McCreight, J.D. & Wintermantel, W.M. (2010) can be hampered or even blocked. The main purpose of this patent is not to protect an invention, but to monopolize and control resources necessary for plant breeding. Given the so called Millenium goal of reducing the number of those suffering from hunger by the year 2015, this kind of patenting is not only hampering plant breeding but has to be regarded as being contrary to public order and morality (see Then & Tippe, 2011).

Documents attached:

D1 McCreight, J.D. & Wintermantel, W.M., 2010, Resistance in Melon PI 313970 to Cucurbit yellow stunting disorder virus, HortScience, published August 1, 2010 (abstract)

D2 McCreight J.D. & Wintermantel W.M., Potential new sources of genetic resistance in melon to Cucurbit yellow stunting disorder virus, Cucurbitaceae 2008, Proceedings of the IXth EUCARPIA meeting on genetics and breeding of Cucurbitaceae (Pitrat M, ed), INRA, Avignon (France), May 21-24th, 2008

D3 data sheet concerning registration of PI 313970,
source: <http://www.ars-grin.gov/cgi-bin/npgs/acc/display.pl?1234456>

D4 Then C. & Tippe R., 2011, Patents on melon, ham and broccoli? Change of paradigm in patent law: From protection of inventions to control of genetic resources, Environmental Law Network International, elni review, 2/2011, pages 53-57.

Further attachments:

letter from Navdanya, India

signatures of opponents