Facts and Submissions

1 European Patent EP1962578, entitled Closterovirus-resistant melon plants, has been granted to Monsanto Invest N.V.(NL). The mention of the grant was published on 04.05.2011 (Bulletin 2011/18).

2 An opposition has been filed on 2.2.2012 by Nunhems B.V. (NL).
The grounds for opposition are Art. 100 (a) EPC in combination with Art. 54 and Art. 56 EPC and Art. 100(b) EPC. The Opponent (O1) filed Documents D1-D13 and arguments in support of the opposition. He requests revocation of the patent in its entirety or oral proceedings as an auxiliary measure.

3 A further opposition has been filed on 3.2.2012 by Christoph Then, Ruth Tippe, Arbeitsgemeinschaft Bäuerliche Landwirtschaft, Bund Naturschutz in Bayern, Erklärung von Bern, Gesellschaft für Ökologische Forschung, Greenpeace Deutschland, Verband Katholisches Landvolk and Zukunftsstiftung Landwirtschaft.
The joint opposition is represented by Christoph Then.
The grounds for opposition are Art. 100 (a) EPC in combination with Art. 53 and Art. 56 EPC and Art. 100(b) EPC. The Opponent (O2) filed Documents D1-D4 and arguments in support of the opposition. He requested revocation of the patent in its entirety or oral proceedings as an auxiliary measure.

4 With letter of 29.10.2012 the Patentee (P) submitted his response together with a consolidated list of documents. He requests maintenance of the patent as granted. He has further submitted Auxiliary Requests I and II and has requested oral proceedings as an auxiliary measure.

5 With letter of 7.2.2013 Christoph Then submitted that he was opposing the patent-in-suit as a natural person and that he was representing the joint opposition.

6 With letter of 14.10.2013 the parties were informed of the preliminary opinion of the opposition division and furthermore that the proceedings were stayed in accordance with Article 112(1) EPC until issuance of the decision of the Enlarged Board of appeal in G2/12 and G2/13.

7 With letter of 10.05.2015 the parties were informed of the outcome of the referrals G2/12 and G2/13 and were invited to Oral Proceedings.

8 With letter of 3.11.2015 O1 informed the parties that he will not attend the Oral proceedings.

9 With letter of 18.11.2015 O2 submitted further arguments in reply to the Summons.

10 With letter of 20.11.2015 P submitted further arguments in reply to the Summons and Auxiliary Requests II-V, replacing Auxiliary Request II on file.

11 Oral Proceedings took place on the 20.1.2016.
At the end of the proceedings, the chairman declared the decision of the Opposition Division to revoke the patent since it does not conform with the requirements of Art. 83 EPC.

12 A list of documents cited during the opposition procedure is attached to this decision (Annex I).

Reasons for the decision

1 **Admissibility / Joint opposition** (Rule 151(1) EPC and G3/99)

1.1 In view of the joint opposition represented by Christoph Then, P submitted that there is a lack of clarity regarding as to who belongs to the group of opponents, in particular with respect to Vandana Shiva, and pointed to G3/99.

P furthermore argued that it is not clear which of the Opponents is a natural person and which is an organisation, and pointed to the inconsistency between p. 2 of the opposition brief, first line, where "Arbeitsgemeinschaft Bäuerliche Landwirtschaft" is listed as opponent, and p.12, where Georg Janssen signs for said organisation.

1.2 O2 replied that on pages 1-2 it can clearly be seen which opponent is a natural person and which is an organisation. Furthermore, Vandana Shiva is not listed as opponent.

1.3 Joint oppositions are accepted at the EPO. The joint opponents are obliged to act through a common representative. This need not be a professional representative **if all opponents have their residence or principal place of business within an EPC state.**
It is current practice of the EPO to regard as the common representative the opponent first mentioned in the list of opponents.
In the present case, Christoph Then is first mentioned as opponent, it is indicated that he will represent the opposition, and signatures of all opponents have been provided on the notice of opposition.
It is, however, pointed out that in the European patent system there is no such role as "supporter of an opposition". It follows that Vandana Shiva has no role in these proceedings exceeding that of a member of the public.
If her role were to be interpreted as a joint opponent, Ch.Then would not be in a position to act as representative for said joint opposition.

With respect to the second argument, the OD considers the list of opponents on p.1-2 of the opposition brief as clear for a mind willing to understand with respect to the distinction between natural persons and organisations.
The signature in the back does not throw doubt on that distinction. It is, as in the following pages, merely interpreted as a representative of the organisation who has signing rights for the organisation as a whole.
In summary, it is clear who belongs to the joint opponents as well as who is going to represent them. The provisions of Rule 151(1) EPC as interpreted by G3/99 are met.

The requirements of Art. 99(1) and Art. and R. 76 EPC are also met. It follows that the Opposition is admissible.

2 **Admissibility of late filed documents D20 and D21**

On the evening of the 19.1.2016, the day before the oral proceedings, a letter by the Indian National Biodiversity Authority was submitted (D20). At the same time, the same text was submitted using the online form for submission of third party observations (D21).

O2 requested to admit these documents into the proceedings as he regarded them as relevant for the objections under Art.53 (a) EPC on file.

P requested not to admit these documents as they are late filed and he did not have an opportunity to analyse their content and prepare a response.

Documents D19 and D20 are not admitted into the proceedings since they are clearly late filed and do not prima facie contribute new and relevant facts or arguments.

3 **Content of the patent in suit**

The patent in suit relates to a plant of the species Cucumis melo (melon) in which a resistance gene against CYSDV (Cucurbit yellow stunting disorder virus, a closterovirus transmitted by whitefly) has been introgressed from a wild melon cultivar (PI313979).

Claim 1 as granted reads: A CYSDV-resistant plant of the species Cucumis melo, said plant comprising an introgression from a plant of melon accession PI313970, which introgression comprises a CYSDV-resistance conferring QTL or a CYSDV-resistance conferring part thereof linked to at least one marker located on chromosome equivalent to linkage group (LG) 6 of melon accession PI313970, wherein said marker is E11/M49-239, and wherein said QTL or said part thereof is present in homozygous form.

The Main Request

4 **Exceptions to Patentability** (Art. 100 (a) EPC in combination with Art. 53(a) EPC).

4.1 O2 submitted that when assessing the compliance of the claimed subject matter with the EPC, in particular with Art. 53(a), the "whole content" approach needs to be taken, as was recently done by the EPO with claims regarding embryonic stem cells. Furthermore a contemporary interpretation of the provisions of the EPC is needed.
The claimed subject matter according to O2 contravenes the provisions of Art. 53(a) in that it would block use of the patented markers in breeding of other melons with potential resistance to CYSDV.
He stressed that this was not a general objection to patents on living organisms, but that in the present case a genetic resource which was placed in a public library had been used to isolate a novel resistance. The purpose of such a public library is clearly to provide access for all to genetic resources.

The patenting of a trait from such a public resource thus according to O2 contravenes morality, since the unhindered access to genetic resources is relevant for the future sustainable agriculture in a growing world population.

4.2 P replied that the patenting of plants is common practice in the EPO and not in itself violating Art. 53(a) EPC and pointed to case law on patenting of plants and animals per se.
In particular the Case Law of the Boards of Appeal of the EPO, 7th edition, elucidates on p. 45 that a ban of patenting of natural substances or living matter cannot be derived from the provisions of the EPC.

4.3 Article 52(1) EPC reads European patents shall be granted for any inventions, in **all fields of technology**.
Article 53 (b) EPC goes on to exclude plant and animal **varieties**.
These provisions have repeatedly been discussed in front of the EBoA, and have been interpreted in G1/98 and G 2/13 in that not all plants and animals are to be excluded, but explicitly varieties.
Rule 27 EPC explicitly states that plants and animals are patentable, if the invention is not limited to a variety.
Thus the EPC explicitly allows for the patenting of plants. No barrier to patenting due to moral reasons can be derived from the simple fact that the patented material will be limited in access, which is the very purpose of a patent.
It is furthermore pointed out that neither the Nagoya protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits which entered into force in 2014, nor the EU regulation on its implementation EU No 511/2014, adopted 16.4.1014, mention patents or foresees a role for the patent offices.
It thus appears that the legislator did until very recently not see a contradiction per se in Benefit Sharing and patenting of plants. The approach taken by the EPO therefore constitutes a contemporary interpretation of the law.
The EPO has further not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and of restricting the field of patentable subject-matter accordingly (see G1/98, Reasons for the decision, point 3.9).

Thus the patenting of plants, even if the traits were isolated from publicly available sources remains compatible with morality and ordre public.
The claimed subject matter conforms with the requirements of Art. 53 (a) EPC.

5 **Exceptions to Patentability** (Art. 100 (a) EPC in combination with Art. 53(b) EPC).

5.1 O2 argued that the claimed subject-matter contravenes Art. 53(b) EPC since G1/08, which prohibits the patenting of methods of producing plants by crossing and selection should be extended by analogy to product claims.

5.2 P replied that the recent decisions of the Enlarged Board of Appeal make it clear that the prohibition of essentially biological methods is not to be extended to products of these methods.

5.3 By decisions of 25 March 2015 the Enlarged Board of Appeal answered the questions referred in that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit or plant parts.

According to him, this applies even if the only method available at the filing date for generating the claimed plants or plant material is an essentially biological process for the production of plants, and also if the claimed product is defined in terms of such a process (product-by-process claim).
Product claims or product-by-process claims directed to plants or plant material other than a plant variety thus are not excluded from patentability under Article 53(b) EPC and are allowable if they fulfil the formal and substantive requirements of the EPC.

Thus the claimed subject matter does not fall under the prohibition of essentially biological methods for the production of plants.

5.4 O2 further argued that the claimed subject matter would necessarily be a variety and thus contravene Art. 53(b) EPC. The claimed resistance is a QTL (qualitative trait locus) which intrinsically means that the claimed resistance is only qualitative. It is one of several loci which together are responsible for a given phenotype.
He stressed that the claimed resistance is not defined in terms of a sequence, but just in terms of a trait cosegregating with a marker, and furthermore the extent of the resistance derived from said trait is not clear as can be seen in D1 and D2.
In this respect he pointed to several passages of the description (especially

paragraphs 71-78) which according to O2 indicate that the final product of the claimed process is necessarily a variety,
O2 moreover argued that any reference to G1/98 which allows for varieties to fall under the scope of a patent is not correct, since G1/98 as well as the EU directive 98/44 is directed only to **biotechnological** inventions, i.e. the result of genetic engineering. In contrast, the claimed subject matter was obtained by conventional breeding.

5.5 P argued that G2/12 and G2/13, like the patent, concern plants which are obtained as the result of marker assisted breeding. It has been decided by the EBoA that such products remain patentable. P added regarding the objection that the claimed subject matter would lack "biotechnological" features that the molecular marker used for the breeding process is in fact such a biotechnological feature.

5.6 The OD agrees that the claimed resistance trait is a qualitative feature. Thus the claimed plants are more resistant to Closterovirus infection than a completely susceptible plant. Said plants, however, are not completely resistant. This is acknowledged by the proprietor as well as in the prior art. This feature of **qualitative** resistance, however, does not appear to be connected to the **heredity** of the resistance gene, which is, according to the patent-in-suit, in a simple Mendelian manner (see disclosure in the application as filed of the patent-in-suit, p. 11, l.13-19).
The opponents have not submitted any evidence to the contrary.
Thus the resistance gene can be transferred into any melon background with conventional breeding methods. It follows that even if the end product of such a breeding step were varieties, the invention is not confined to one or a few varieties but is generally applicable to all melon plants fertile with the donor line.
Moreover, using the marker provided by the inventors, it is easily possible to obtain already in the F2 of a cross of a donor line for the resistance with any melon line plants that are homozygous for the resistance. At this point the plants will necessarily be heterozygous for many other genetic loci, thus not constitute varieties.

Regarding the relevance of G1/98, the OD is of the opinion that G2/13 and G2/13 have unambiguously clarified that the products of essentially biological processes are regarded as patentable, irrespective of any specific technical step used to obtain them.

Thus the OD finds that firstly the claimed plants are not varieties in the sense of Art. 53 (b) EPC and that secondly the exclusion of essentially biological processes does not have any bearing on the patentability of the claimed products.

6 **Novelty** (Art. 100 (a) EPC in combination with Art. 54 EPC)

6.1 Pointing to D1, O1 submitted that claims 1 and 3-5 of the patent as granted lack novelty over the known plant lines from which the introgression segment was originally introduced,
O1 further contested the novelty of the claims based on the disclosure of D8 and D13, where crosses of PI313970 with other melon cultivars are disclosed.
O1 argued that although no specific line is shown as carrying the introgression segment and the Closterovirus resistance, there must have been such plants amongst the various crosses.

6.2 O2 agreed that the subject matter of the claims as granted comprises the parent accession PI313970.

6.3 P argued that the Case Law of the European Patent Office is very clear on the burden of proof in assessing novelty in opposition, and compared the situation to the one in T301/87 where is was found that a library containing a specific substance is not prejudicial to the novelty of the isolated substance.
Furthermore he argued that lack of novelty should not be decided on a balance of probabilities, but the lack of novelty must be shown beyond reasonable doubt.
In the present case, while the relevant resistance trait was clearly present in (part of) the heterogenous seed cataloged as PI313970, there is no proof at all that said seed contained any individuals homozygous for the trait of the invention (see P's submission dated 20.11.2015, p.7, 3rd paragraph).
P pointed out that a heterozygous gene is not necessarily maintained in a population if not selected for.
P added that due to the terminology of claim 1 "comprising an introgression

from a plant of melon accession PI313970" it is clear that PI313970 itself is not being claimed, but that it is necessarily a plant derived from this variety by crossing.

6.4 It is pointed out that D13 is published after the date of filing of the patent-in-suit. However, a variety of documents are available, for example D1, that point to an earlier availability of PI313970.
O1 and P agree that (progeny of) the line PI313970 is publicly available and was so at the time of filing.
The plants of claim 1 are defined solely by the **homozygous** presence of an resistance-conferring introgression from PI313970 defined by a single molecular marker (E11/M49-239).
There is evidence on file from a variety of sources that the original accession PI313970 was not in fact a variety, but that it segregated for several traits (see D1, p. 237 and table 1; D13,abstract; Patentees submission dated 20.22.2015, page 5).
Thus while seed of the original line PI313970 must have contained the resistance trait and marker at least in heterozygous form, the opponents have not shown beyond reasonable doubt that the publicly available line PI313970 contains the claimed resistance trait in homozygous form.

Regarding D8 it is possible that there might have been plants in the population that carry the introgression segment in homozygous form since said plants were backcrossed, also to the parent PI313970 (see table 1, line 9). It appears, however, that this cannot be unambiguously proven from the data presented in D8

Thus, the OD considers the claimed plants to be new in view of the prior art on file, especially D1, D8 and the deposit of PI313970.

6.5 **Sufficiency** (Art. 100 (b) EPC)

6.5.1 O1 pointed out that any level of CYSDV resistance falls under the proviso of claim 1 and that the patent does not teach how to measure CYSDV resistance.

O1 further argued using the data in D2 that the patent-in-suit does not prove that the claimed marker is tightly linked to the QTL in which the resistance resides and that a string of markers would be necessary to reliably define the region in which the QTL resides.

O1 moreover objected that the exact method with which the marker is obtained is not taught in the patent-in-suit. It, however, points out that the length of the marker fragment may vary depending on the method used. Thus O1 argues that a skilled person cannot reliably identify whether a given AFLP fragment constitutes the marker or not.

O1 submitted that no biological material has been deposited. According to O1, this is problematic, since the publicly available accession PI313970 is heterogenous and shows a wide variation in phenotypes including CYSDV resistance as shown in D1 and D13.
Thus the desirable genetic element might be lost during seed multiplication and seed distribution (see D5 and D11 as discussed in O1's opposition brief, point 3.2)

6.5.2 O2 submitted that the data presented by D4 and D14 shows that the resistance from accession PI313970 does not confer resistance to all strains of CYSDV.
Furthermore there is no teaching in the patent-in-suit which additional markers or genetic elements might ne necessary to achieve a functional CYSDV resistance. Thus O2 follows that the invention is not disclosed in a manner sufficiently clear and complete.

6.5.3 P argued that CYSDV resistance can be measured by a skilled person since there is ample literature available how to do so. Furthermore it is not necessary to check for the presence of several markers to ascertain the presence of a QTL since the claimed QTL shows a close linkage.
P points to D2 and D19 as further evidence that the marker E11/M49-239 is in fact tightly linked to the desired resistance trait and thus is a sufficient teaching to work the claimed invention.

Concerning the marker size, P argued that the exact size of the marker is not relevant. The teaching of the patent is sufficiently clear to be worked by a skilled person even if the marker size may vary by 1-2 base pairs as stated in the description.

With regard to the deposit P pointed to D13, D4 and D14 which show that a resistance can be isolated from the publicly available line. D2 according to P shows that the CYSDV resistance can be isolated from PI313970. Thus the

marker provided by the patent in suit is according to O the decisive feature which enables the invention to be worked on the basis of publicly available biological material.

6.5.4 With respect to D2, O2 replied that this cannot be used as a document to support the availability of the line, since the document is silent on where the genetic material used is taken from.

6.5.5 The OD considers that the exact size of the marker is of no relevance for the workability of the invention. A skilled person faced with plants carrying the desired resistance trait could without undue burden select for those plants in which the resistance is cosegregating with the claimed marker even if the marker exhibits slightly different size.

6.5.6 Regarding O1's second argument, the markers on the left and right side of the claimed genetic element conferring the resistance, D2 shows that the claimed marker segregates well with the claimed trait.
The opponents have not submitted any facts showing the opposite, so the single marker is regarded as sufficient to assist in breeding for the desired resistance trait.

6.5.7 The rationale for deposits of biological material is to ensure availability of the biological material to the public.
The requirement for a deposit to satisfy the requirements of Art. 83 can solely be circumvented if the material is available to the public **without restriction** (Guidelines for Examination, F-III 6.2 and 6.3).
The question at hand is thus whether the claimed resistance trait was and is available to the public without restriction over the whole term of the patent.

It appears helpful to look at the history of line PI313970:
It was originally isolated in India in 1961. Seeds of this accession were subsequently brought to the Russian Federation, from where they were imported to the US in 1966.
Subsequently, several seed increases were performed (see D1, p. 235, 3rd paragraph). It was noted in D1 that the melons from the later seed increases differed from the earlier ones in phenotype, thus confirming that PI313970 is not a variety in sense that it is not uniform and stable.

All parties, in particular the patentee when establishing the novelty of the claimed plants in view of the publicly available material, have acknowledged on the basis of D1, D13 and the patent itself that PI313970 is not a variety in the sense of being uniform and stable but that it is heterogenous material segregating for many traits (see patentees' argumentation under 6.3 above).

Even under perfect conditions, it cannot be assumed that the original deposited seed is still viable. Thus a skilled person, attempting to work the invention, would have to acquire seed that is derived from one of above-mentioned seed increases.
It is a known problem in the maintenance of melon lines that traits get lost, as also acknowledged by O1 as well as the patentee (see opposition brief O1, point 3.2.; point 6.3 above).
A seed increase is necessarily a bottleneck in which genetic drift occurs. Since 1961 when the accession was originally deposited, several such seed increases have taken place without applying any selection pressure on the claimed trait.
It thus appears in no way certain that a skilled person would today and over the whole term of the patent be in a position to obtain seed of PI313970 which carries the desired trait without undue burden.

In opposition, the opponent carries the burden of proof to establish that an invention is not workable. If a distinct, uniform and stable variety would have been the starting material, it would have been the role of the opponent to prove any lack of disclosure.
In this case, by showing that firstly the parent accession was heterogenous and might well not have contained the relevant gene in homozygous form at all, and secondly by showing that loss of heterozygous traits is a known problem in melon breeding, the opponents have submitted sufficient facts and arguments to justify an shift in the burden of proof (see Guidelines for Examination, F-III, 4.)

It is not contested that the authors of D13 managed to isolate the claimed resistance from material termed PI313970.
It is, however, pointed out that the authors of D13 did not specify the source of the plant material further than "PI313970", the reader is not informed which seed increase or supplier the plants were obtained from. D4 and D14 are publications from the same authors as D13 referring to the same resistance isolation event, so they cannot be counted as independent verification of the availability of the biological material.

Thus the OD finds that while a resistance was at two time points isolated from heterogenous material termed PI313970, this does not serve as adequate assurance that the claimed trait will be available to the public over the whole term of the patent without restrictions or undue burden.

This problem appears to be aggravated by the fact that the exact conditions for performing the resistance test are not known: It can be seen in D4, table 2 that the same material did in one pathogenicity test show the resistance trait, and in another pathogenicity test did not.

The OD has therefore come to the conclusion the Main Request does not meet the requirements of Art. 83 EPC, since it is not credibly proven beyond reasonable doubt that the claimed biological material is available to the public over the whole term of the patent without restrictions.

The Auxiliary Requests I-V

7 The Opponents raised no formal objections against the Auxiliary Requests. The Auxiliary Requests conform with the requirements of Rule 80 EPC, Art. 123(2) and (3) EPC and Art. 84 EPC.

8 The non compliance with Art.83 is of a fundamental nature and cannot be overcome by restricting the claimed subject matter.
For each of the Auxiliary Requests the skilled person would need access to plants derived from PI313970 which carry the resistance trait in order to work the invention.
The Auxiliary Requests thus contravene the provisions of Art. 83 EPC for the same reasons as detailed above under 6.5.7

9 The patent is revoked since it does not conform with the requirements of Art. 83 EPC.