Report Q114

Biotechnology (including plant varieties)

by Claire Baldock, Chairwoman and
Thomas Bouvet, Co-Chairman

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Introduction

The last report from Special Committee Q114 was prepared for the AIPPI Paris Congress and dated 30th September 2010. Since that report there has been an Avocate General's opinion in CJEU case C-34/10 concerning the patenting of human embryonic stem cells and the Enlarged Board of Appeal of the EPO has handed down a decision in the consolidated referrals G02/07 and G01/08 regarding the exclusion from patentability of essentially biological processes for producing plants and animals. There have also been developments relating to biotechnology patents in France and the US. A report on each of these is set forth below.

In addition a separate section is included in this report, specifically related to developments in relation to Plant Variety Rights. This includes a discussion of case law developments in Europe and comments on harmonization of European laws on breeders' rights and the UPOV

explanatory note of harvested materials. The possibility of a resolution on this issue is suggested for the 2012 Congress.

Biotechnology

1) G01/07 and G02/08

On 9 December 2010 the Enlarged Board of Appeal of the European Patent Office handed down its decision in consolidated proceedings based upon referrals G2/07 and G1/08. The referrals were made in an attempt to clarify the correct interpretation of Article 53(b) EPC relating to the exclusion from patentability of essentially biological processes for the production of plants (and animals).

Each of the two referred cases concerned claims to methods for the production of plants involving crossing and subsequent selection steps. The issue to be resolved was whether technical steps included in a crossing and selection process, or steps which were "non-natural" and thus required human intervention, when included in a claim, were sufficient to take that claim outside the exclusion from patentability under article 53(b) EPC. The Technical Board of Appeal referred two questions in each case, all of which were answered by the Enlarged Board.

The questions were as follows:

G2/07

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?

2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

G1/08

1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the

exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

The Enlarged Board received observations from all parties to the proceedings and also from the President of the European Patent Office together with a number of *amicus curiae* briefs. One of the difficult issues for the Enlarged Board to resolve was the apparent contradiction between the wording of Article 53(b) EPC and Rule 26(5) EPC, which serves to define the term *"essentially biological process".* The definition of Rule 26(5) EPC suggests that *"a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection".* The Enlarged Board immediately appreciated the difficulty with this definition, namely that the terms *"crossing"* and *"selection"* refer to acts performed by a breeder and therefore rely upon an intervention which can not be considered a natural phenomenon. They reviewed the relevant legislative history and concluded that *"regrettably, Rule 26(5) EPC does not give any useful guidance on how to interpret the term "essentially biological process for the production of plants"".*

The Enlarged Board also confirmed that the exception from patentability of an essentially biological process for the production of plants could not be read as only applying where the result of the process was a plant variety. Thus, the exclusion applies to production of plants generally.

The Enlarged Board also placed emphasis on the clear intention of the legislator behind including the term *"essentially"* in the statute. On this basis, they indicated that the provision of a technical step, whether explicit or implicit, in a process which is based on sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape the exclusion if that technical step only serves to perform the process steps of the breeding process. Thus, the term *"essentially"* appears much broader than the originally proposed term *"purely"* and inclusion of a technical step which simply assists with or enhances the biological steps of crossing and selecting will not suffice to avoid the exclusion under Article 53(b) EPC.

The answers given by the Enlarged Board were thus as follows:

1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.

2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

3. If, however, such a process contains within the steps of sexually crossing and selecting 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 the process is not excluded from patentability under Article 53(b) EPC.

4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

Thus, it appears that the exclusion from patentability under Article 53(b) EPC will be interpreted broadly in cases where the invention aims at the production of plants through crossing or selection procedures. Whilst the decision focuses solely on plant production, it is assumed the decision will be applied *mutatis mutandis* to processes for the production of animals. The only clear manner in which to avoid the exclusion lies in the inclusion of additional steps of a technical nature which somehow create a trait in the progeny which are not a direct result of the crossing, for example inclusion of a heterologous gene by recombinant DNA. For all other technical steps, it would appear to be necessary to direct claims to those steps *per se*, without reference to any crossing and selection steps in order to avoid the exclusion.

2) CJEU Referral C-34/10 – Advocate General's Opinion

On 10 March 2011 Advocate General Bot delivered his Opinion in the case of *Oliver Brüstle v Greenpeace eV*, a reference to the European Union's Court of Justice (CJ) from the German Federal Court. The appeal case before the Bundesgerichtshof concerns the validity of Mr Brüstle's national patent, which relates to technology based on the use of human embryonic stem cells. In particular, the claimed invention concerns the isolation and purification of neural precursor cells used for the treatment of neural defects.

Greenpeace challenged the validity of the patent for the reason that it requires the neural precursor cells to be obtained from human embryonic stem cells. In reaching their decision, the Bundesgerichtshof considered it necessary to refer questions to the CJ relating to the interpretation of Directive 98/44/EC of 6 July 1998, (the Biotech Directive) on the legal protection of biotechnological inventions.

The present reference to the CJ concerns in particular, Article 6 of the Biotech directive, which excludes from patentability inventions that are contrary to *"public order"* or morality, and specifically excludes *inter alia "uses of human embryos for industrial or commercial purposes"*. Since Mr Brüstle's invention involves obtaining pluripotent stem cells from few-day old "blastocysts", the German court felt it necessary to seek clarification regarding the following:-

- What is meant by the term "human embryos" in Art. 6(2)(c) of Directive 98/44/EC?

- What is meant by the expression “uses of human embryos for industrial or commercial purposes”?
- Is technical teaching to be considered unpatentable pursuant to Art. 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching,

    (a) because the patent concerns a product whose production necessitates the prior destruction of human embryos, or
    (b) because the patent concerns a process for which such a product is needed as a base material.

The Advocate General’s (AG’s) opinion regarding the definition that should be used in relation to a “human embryo” is relatively clear. In particular, the AG concludes at paragraph 119 that

> *“the concept of a human embryo applies from the fertilisation state to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body. That includes the blastocyst.”*

Moreover, the AG categorises “totipotent cells” as embryos on the basis that they have the capacity to develop into a complete human being. The AG would also classify human embryos generated by artificial cloning techniques, and embryos generated by parthogenesis as entities falling within the legal definition of “human embryos”.

The AG went on to conclude that pluripotent embryonic stem cells do **not** fall within the concept of “human embryos” because they do not have the capacity to develop into a human being. However, the issue of whether inventions relating to these cells are patentable or not, appears to rest with the AG’s opinion regarding the third question of the reference.

In this regard, the AG said that it was not possible to ignore the origin of the pluripotent cell, and noted that in this case, the pluripotent stem cell was removed from a blastocyst, which itself constitutes an embryo. The AG went on to conclude at paragraph 119 that

> *“An invention must be excluded from patentability where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos.”*

Unfortunately, it remains unclear from the AG’s Opinion what is meant by a technical process *“necessitating the prior destruction of human embryos or their use as base material”*. However, many European Attorneys are concerned by the conclusions reached. In particular, it is feared that, if the CJ follow this Opinion, it could prevent patenting in Europe of all technologies relating to human embryonic stem cell technology, as all human embryonic stem cells ultimately derive from human blastocysts. Others believe that the AG’s words do still allow for the possibility of

patenting human embryonic stem cell technologies wherein the stem cells can be derived or obtained from established stem cell banks.

It will be noted that the AGs opinion is apparently contrary to the Resolution adopted by the AIPPI at the Berlin ExCo in 2005 concerning the patentability of human embryonic stem cell lines. Unfortunately, non-governmental organisations such as AIPPI are not permitted to file a*micus curiae* briefs at the CJ. This is an option available only to Governments. However, CIPA has been lobbying the UK Government heavily to file observations following the release of the AG' opinion in the hope of directing the final decision of the CJ to a more favourable outcome for the biotech sector.

3) **Institut Pasteur v. Chiron, Cass. Com., 23 November 2010 (French cour de cassation)**

Institut Pasteur alleged that Chiron would have committed acts of contributory infringement of the French designation of its European patent No. 0 178 978 regarding "*cloned DNA sequences, hybridizable with genomic ARN of lymphadenopathy-associated virus* (LAV)" by selling certain kits for the detection of HIV in blood samples.

The *Cour d'appel* of Paris, on 4 March 2009, dismissed Institut Pasteur's claims on the ground that the detection kits of the Chiron companies did not fall within the scope of the patent and that their sale did not amount to contributory infringement.

From a legal standpoint, it is interesting for several reasons (non of them are specific to biotechnology matters):

- it reminds that the extent of protection conferred by a patent shall be determined by the terms of the claims and that this rule applies even in relation to a pioneer patent; the *Cour d'appel* accepts that the claims of a pioneer patent be drafted in general terms but it specifies that, if the claims are drafted narrowly (here they refer to specific DNA fragments characterized by their size and position on the genome), the patent, even a pioneer one, has a limited scope;
- it indicates that the patent claims which have been amended during prosecution or opposition proceedings before the European patent office can not, under the pretext of interpretation, be given the extent of claims to which the patentee renounced, as this would prejudice to the security of third parties; in this case the patent initially claimed any DNA fragment of the HIV genome but has been amended so as to claim only specific DNA fragments characterized by their size and position on the genome; similarly, the claim covering the detection method initially covered hybridizing viral RNA with a probe consisting of any DNA fragment of the HIV genome have been amended to cover only the use of specific probes.
- it reminds the provisions regarding contributory infringement by indicating that:
  - a means must be considered as essential if it contributes to the result of the invention;

- the means supplied must be suited for putting the invention into effect; in this specific matter, the *Cour d'appel* dismissed the action on the ground that the use of the accused detection kits was not suited to obtain the RNA subject matter of claim 11.

On 23 November 2010, the Cour de cassation, which studies only issues of law dismissed the appeal lodged by Institut Pasteur against the decision of the *Cour d'appel* of Paris of 4 March 2009:

- the main criticism of Institut Pasteur was that the scope of protection must be appraised pursuant to the rule defined in Article 69 EPC, and that the history of the grant should not be taken into account;
- but the *Cour de Cassation* considered that the *Cour d'Appel* did not use the "*file wrapper estoppel"* but took into account the amendments made to the patent in order to determine the scope of the amended claims:
  - "*Secondly, although pursuant to Articles 69 of the Munich Convention in its version applicable to this case and L. 613-2 of the French Intellectual Property Code, the scope of the protection conferred by a patent is determined by the claims as amended following the opposition procedure and the drawings and the description shall be used to interpret the claims, the Cour d'Appel, by pointing out that the patent application had been initially filed with 24 claims but that, following the opposition procedure, it had been granted with 11 claims of a limited scope, simply appraised the scope of the claims in their final drafting" (…)*
  - *"However, firstly, the Cour d'Appel, which did not base its decision on the granting procedure to appraise the scope of claim 8 only pointed out that amendments had been made to it during this procedure and appraised it in its final version, did not have to proceed to the allegedly omitted research, targeted by the second branch of the argument, in order to determine this scope."*

4) Association of Molecular Pathology v. USPTO and Myriad Genetics

In a July 29, 2011 decision in Amp v Myriad Genetics the Court of Appeals for the Federal Circuit considered the patent eligibility (under 35 USC § 101 of the Patent Law) ,of claims drawn to "isolated" DNA molecules and method claims directed to "analyzing" or "comparing" DNA sequences. The court found that "isolated" DNA molecules were patentable subject matter under § 101 of the Patent Law. The Federal Circuit also ruled that a method claim that calls for solely mental "comparing" or "analyzing" steps is not patentable subject matter under §101.

In considering whether "isolated" DNA sequences were patentable subject matter, the court distinguished between a product of nature and an invention made by humans. The court stated that there is a change in the identity of an "isolated DNA molecule" compared with what is found in nature. The Federal Circuit found that the claims to isolated DNA are drawn to patentable subject matter because they embrace molecules that are markedly different (have a distinctive chemical identity and nature) as compared to molecules that exist in nature. The Federal Circuit also distinguished between "isolated" molecules and molecules that are simply

purified. The Court concluded that “isolated” DNA must be chemically cleaved from its chemical combination with other genetic materials. The Court of Appeals pointed out that when it is cleaved from a longer stretch of DNA, an isolated DNA molecule is a distinct chemical entity.

Reviewing the method claims, the court began with the machine-or-transformation test (Bilski v Kappos -US Supreme Court June 2010) to determine whether the claims include transformative steps. Claims that call only for “comparing” or “analyzing” two gene sequences were found to fall outside the scope of § 101 because they claim only abstract mental processes. In contrast, when the claims included the step of “growing” transformed cells in the presence or absence of a potential cancer therapeutic, the presence of mental steps within the claim did not make the claims ineligible for patent protection, because the steps involved physical manipulation of the cells and these steps were central to the purpose of the claimed process.

The long awaited decision by the Federal Circuit reversed a lower court finding that gene sequence and method claims are drawn to non-patentable subject matter under § 101 of the Patent Law.

Plant Variety Rights
Case Law

1) Pirotais et fils SARL, v. SCA Agrico BA, Court of appel Rennes, 30 November 2010

The facts of this matter can be summarized as follows:

- Agrico is the holder of a French PVR covering the potato variety ‘Agata’ and sells certified propagating material of this variety for growing potatoes;
- Pirotais is in the business of:
  - selling potatoes for consumption;
  - selling propagating material for growing potatoes;
- it appears that Pirotais has been selling as propagating material of ‘Agata’, some material not purchased from Agrico but rather some potatoes that should have been sold for consumption.

The interesting aspect of the matter is the indirect evidence on which the court relied to find the infringement, namely:

- that Pirotais sold the potatoes as propagating material, of a size usually used for propagating purposes, to a company involved in the business of growing potatoes;
- a statement from the company which purchased the material, stating that it did use it for growing purposes;
- the absence of purchase, by Pirotais, of propagating material from Agrico or its retailers.

However no direct evidence of the infringement was available because the action had been initiated after Pirotais had stopped infringing.

2) CJEU Referral C-140/10 – *Greenstar-Kanzi Europe NV v Jean Hustin and Jo Goossens*

A procedure is currently pending before the CJEU regarding the exhaustion of Community plant variety rights:

The questions referred by the *Hof van Cassatie van België* (Belgium) on 17 March 2010 are:

> *Should Article 94 of Council Regulation (EC) No 2100/94 [1] of 27 July 1994 on Community plant variety rights, as amended by Council Regulation (EC) No 873/2004 [2] of 29 April 2004, read in conjunction with Articles 11(1), 13(1) to 13(3), 16, 27 and 104 of the aforementioned Regulation (EC) No 2100/94, be interpreted in such a way that the holder or the person enjoying the right of exploitation may bring an action for infringement against anyone who effects acts in respect of material which was sold or disposed of to him by a licensee of the right of exploitation if the limitations in the licensing contract between the licensee and the holder of the Community plant variety right that were stipulated to apply in the event of the sale of that material were not respected?*
> *If so, is it of significance for the assessment of the infringement that the person effecting the aforementioned act is aware or is deemed to be aware of the limitations thus imposed in the said licensing contract?*

The facts can be summarized as follows:

- the PVR holder granted a licence, to multiply the protected apple tree variety, with authorisation to grant sublicenses provided that any sublicensed apple grower signs a “grower undertaking” and that any sublicensed apple retailer signs a “retailer undertaking”;
- the licensee sold trees of the protected variety to a grower, without having the latter sign the “grower undertaking”;
- the grower sold apples to a retailer;
- the PVR holder sued the apple grower and the apple retailer for PVR infringement;
- the apple grower and the apple retailer argue that the apple trees have been purchased from the licensee and thus that the holder’s rights are exhausted.

It should be stressed that the licensee, which obviously breached its contractual obligation, does not seem to be a party to the proceedings.

One of the main issues is whether the breach of the license agreement, by the licensee, can be invoked against third parties which obtained the accused material from the licensee.

The advocate general filed his conclusions on 7 July 2011. He mentions the previous decision Copad of ECJ (23 April 2009 C-59/08) which decided, in a similar factual situation, but in a trademark matter, that the trademark holder’s rights should not be considered as exhausted. Howevera, in this case, the advocate general mentions that he disagrees with this decision.

In the specific PVR matter, he suggests to reply negatively to the first question, namely that:

> *Article 94 of Council Regulation (EC) No 2100/94 [1] of 27 July 1994 on Community plant variety rights, as amended by Council Regulation (EC) No 873/2004 [2] of 29 April 2004, read in conjunction with Articles 11(1), 13(1) to 13(3), 16, 27 and 104 of the aforementioned Regulation (EC) No 2100/94, should be interpreted in such a way that* ***the holder or the person enjoying the right of exploitation cannot bring an action for infringement*** *against anyone who effects acts in respect of material which was sold or disposed of to him by a licensee of the right of exploitation and that the limitations in the licensing contract between the licensee and the holder of the Community plant variety right that were stipulated to apply in the event of the sale of that material were not respected.*

He bases his reasoning on:

- the provisions of Regulation EC No 2100/94 regarding exhaustion of rights, which differ from those of the trademark Directive;
- but implicitly probably also on the fact that he disagrees with the Copad decision.

Developing plant variety law

1) Need for harmonization regarding the breeder's privilege in patent law

Our committee would suggest the AIPPI consider whether there is a need to harmonize the breeder's privilege in patent law.

As a background, it is reminded that the 1991 version of the UPOV Convention has created the breeder's exception which provides that a breeder may always use a protected variety for the purpose of creating new varieties.

Article 15-1 of UPOV 1991 thus provides:

> *"[Compulsory exceptions] The breeder's right shall not extend to:*
> *(…)*
> *iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to Article 14(4) in respect of such other varieties."*

This privilege does not mean that the variety newly created may be grown freely; in particular, the new variety could be covered by the plant breeder's right protecting the variety used to obtain it, in particular if it is:

- not sufficiently distinct from this other variety;
- essentially derived from this other variety.

But breeders cannot be liable for infringement when they are in the process of creating new varieties, even if they are using a protected variety to do so.

However, patent law provisions do not always provide for a similar exception. Directive 98/44/EC does not provide for an exception for acts intended to discover or develop new varieties (such exception could even be viewed as contrary to TRIPS)

But such specific exceptions are however present in several countries:

- France: Article L. 613-5-3 IPC which states "*Rights conferred by the Articles L. 613-2-2 and L. 613-2-3 shall not extend to the deeds performed in order to create or discover and develop other plant varieties*";
- Germany contains a similar provision: Art 11(2)(a) of the German Patentgesetz;
- Swiss contains similar provisions;
- Netherlands DOES NOT provide for such a privilege, but a bill should be presented in fall 2011 to try and introduce this exception in the Dutch law;
- UK law DOES NOT provide for such a privilege.

And in the countries which do not contain specific exception, it is likely that the experimental use exception is not appropriate to cover the breeding process.

AIPPI could consider whether there is an interest in harmonizing this issue.

2) UPOV explanatory note on harvested material

Our Committee also reports on an issue of plant breeders' rights which could be of interest to the AIPPI and on which the AIPPI could issue a resolution in due course.

This issue relates to the scope of protection given to the plant variety right holder, on harvested material, and more particularly to a draft explanatory note prepared by UPOV which we think is open to criticism.

2.1 Law governing plant breeders' rights

Innovation in the field of plant variety is governed in most European countries by a *sui generis* right named plant variety right or plant breeders' rights. Plant varieties, as such, are excluded from patent protection in many countries. The UPOV convention signed by 68 countries is setting rules that the members states should comply with.

Two versions of the UPOV convention are currently in force:

- the version of 2 December 1961 revised on 10 November 1972 and on 23 October 1978;
- the version revised on 19 March 1991 which differs on several points.

The 1991 Act of UPOV convention is of particular interest for the following discussion.

Article 14 of the 1991 Act of the UPOV Convention relates to the scope of breeders' rights, both on the propagation material and on harvested material.

It reads as follows:

> *"(1) [Acts in respect of the propagating material] (a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:*
> *(i) production or reproduction (multiplication),*
> *(ii) conditioning for the purpose of propagation,*
> *(iii) offering for sale,*
> *(iv) selling or other marketing,*
> *(v) exporting,*
> *(vi) importing,*
> *(vii) stocking for any of the purposes mentioned in (i) to (vi), above.*
> *(b) The breeder may make his authorization subject to conditions and limitations.*
> ***(2) [Acts in respect of the harvested material] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.***
> ***[…]*"**

The European Union signed the 1991 Act of UPOV convention on 29 June 2005.

The provisions of Council Regulation No. 2001/94 of 27 July 1994 creating a community plant variety right thus containing provisions similar to those provided in the UPOV convention.

In particular, Articles 13 (1) to 13 (3) of Council Regulation No. 2001/94 of 27 July 1994, read as follows:

> *"1. A Community plant variety right shall have the effect that the holder or holders of the Community plant variety right, hereinafter referred to as 'the holder', shall be entitled to effect the acts set out in paragraph 2.*
> *2. Without prejudice to the provisions of Articles 15 and 16, the following acts in respect of variety constituents, or harvested material of the protected variety, both referred to hereinafter as 'material', shall require the authorization of the holder:*
> *(a) production or reproduction (multiplication);*
> *(b) conditioning for the purpose of propagation;*
> *(c) offering for sale;*

(d) selling or other marketing;
(e) exporting from the Community;
(f) ***importing to the Community****;*
(g) stocking for any of the purposes mentioned in (a) to (f).
The holder may make his authorization subject to conditions and limitations.
"3. The provisions of paragraph 2 shall apply in respect of harvested material only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents."

According to these provisions, the protection applies to harvested material subject to two cumulative conditions:

- the harvested material was obtained through the unauthorised use of variety constituents;
- the holder has had no reasonable opportunity to exercise his right in relation to the said variety constituents.

The interpretation of those provisions is of particular importance for plant breeders.

2.3 Draft explanatory note prepared by UPOV

An issue which is subject to discussion is whether the plant variety right holder can prevent the importation of harvested material (say apples) when the variety constituent (a tree) of the protected variety has been reproduced and grown in a country where the variety is not protected.

UPOV is currently working on explanatory notes on acts in respect of harvested material under the 1991 Act of the UPOV convention.

In the draft dated 1 October 2010 (UPOV/EXN/HRV Draft 5 corr.), it is written:

"Unauthorized use" refers to the acts in respect of the propagating material that require the authorization of the holder of the breeder's right in the territory concerned (Article 14(1) of the 1991 Act), but where such authorization was not obtained. ***Thus, unauthorized acts can only occur in the territory of the member of the Union where a breeder's right has been granted and is in force.****"*

The Committee believes that this statement is subject to criticism. In particular, according to such interpretation, a plant variety right holder cannot act against the importation, in Europe, of harvested material if said plant variety holder has sold a tree in a country where the variety is not protected although it did not authorise the propagation of the material. In other words, the sale of propagating material in a country where the variety is not protected is considered as an implicit authorisation to propagate the propagating material. This would seem erroneous.

Our opinion is that the first condition (that the harvested material is obtained through the unauthorised use) means that the right holder must not have authorised the reproduction of the variety constituents, irrespective of whether the variety is protected or not in the country where the variety constituents are multiplied and grown.

We believe that this issue is of interest to the AIPPI and that AIPPI should consider:

i) a resolution concerning appropriate interpretation of Article 14 of UPOV 1991 for the Korea Congress in 2012 and/or

ii) provision of comments on the matter to UPOV.

September 2, 2011