<u>Colloquium "Modern Plant Breeding and Intellectual Property Rights" on</u> January, 26th, 2001 in Einbeck.

The Community plant variety rights system was created by Council Regulation (EC) No 2100/94 as the sole and exclusive form of Community protection of industrial property in respect of plant varieties. I want to concentrate on a number of aspects that are specific to this system and the rights obtained under it. I shall consequently not mention those substantial elements in which it does not differ from other systems based on the 1991 version of the UPOV Convention, such as the conditions that have to be satisfied in order to qualify for protection, the scope of the protection, the duration of the protection and the concept of dependent plant variety rights

The subjects I should like to consider are:

- the Community regime relating to the so called farmer's privilege (exemption);
- the relationship between the Community plant variety rights system and national plant variety rights systems;
- the interfaces between the Biotechnology Directive and the Community plant variety rights system.

The Community regime relating to the farmer's privilege

The legal consequences associated with Community plant variety rights, laid down in Chapter II of Council Regulation (EC) No 2100/94 (which I shall refer to from now on as the basic regulation), are, as I said, in line with the relevant binding provisions of the UPOV Convention, 1991 Act. In terms of the scope that the UPOV Convention allows the contracting parties for their own policy – specifically the possible extension of the list of acts requiring the authorisation of the holder of the plant variety rights and the possible restriction of the holder's rights in regard to the re-use of "farm saved seed" – the Community legislators only availed themselves of the second option. A regime not conspicuous for its simplicity (described by Bernard le Buanec, secetary general of Assinsel in a recent contribution to a UPOV seminar in Uruguay as "a rather sophisticated approach") concerning the modalities under which farm saved seed may be used by farmers, is contained in Article 14 of the basic regulation, which is worked out in detail in a specific Commission regulation (Commission Regulation (EC) No 1768/95). In a nutshell, what the regime amounts to is that a "farmer's privilege" has been created for varieties of the most important agricultural crops protected by Community plant variety rights. With the exception of a precisely defined category of small farmers, farmers who take advantage of this privilege must pay remuneration for using farm saved seed as propagating material. The size of this remuneration has to be agreed between the plant variety rights holder concerned and the farmer, or between representative organisations of farmers and plant breeders at Community, national or regional level. In the absence of an agreement of this kind, the amount of the remuneration is set at 50% of the usual remuneration for the production under licence of propagating material of a variety that is protected by plant variety rights. In a number of countries, such as the United Kingdom, Germany, Sweden and the Netherlands, agreements on the amount of the remuneration for the use of farm saved seed have been made between organisations of breeders and farmers. In practice, the implementation of these agreements tends to run up against not inconsiderable resistance from the farmers. Taking action against farmers who are not prepared to pay involves considerable expense (not least legal costs) and is made even more difficult by the lack of adequate information about the extent of the use of seed from protected varieties at individual farm level. In this context, it should be pointed out that monitoring the system is the responsibility of the holders of the plant variety rights, and that in principle no support or assistance is provided by official bodies.

The option provided by the Community legislators that agreements regarding the remuneration for farm saved seed and the procedures for collection may be made at national or regional level has meant that significant differences have grown up within the Community in terms of the extent to which farmers pay a remuneration for the use of farm saved seed. In due course this situation could lead to an undesirable "harmonisation" at the lowest level of remuneration.

Under the terms of Article 11 of the Biotechnology Directive, the regime outlined above concerning the farmer's privilege also applies to source material on which there is a patent, which is sold to a farmer for agricultural use by or with the permission of the patent holder.

When looking to the two forms of intellectual property right the farmer's privilege is therefore a neutral factor. The question arises as to whether the patent holders will succeed in bringing about an effective remuneration scheme for the use of patented source material at regional or Community level. The nature of the right does not appear to offer the patent holder any advantage in this respect over the holder of a plant variety right. In view of the fact that varieties as such are not eligible for patenting, the source material in question – in most cases being a specific plant variety – will if covered by a patent in most cases also be protected by a plant variety right. Joint action on the part of the patent holder and the holder of the plant variety right, in so far as they are not one and the same person or legal entity, against the farmer who is re-using the material would consequently seem to be the most sensible course.

A frequently asked question is whether it is possible to exclude the farmer's privilege in the framework of a community plant variety right contractually. I cannot answer this question with a simple yes or no. I will refrain myself to some observations in respect of the relevant articles of the basic regulation. A striking feature of that regulation (article 14(1)) is that the farmer's privilege is cast in the form of a mandate – one might almost say an entitlement – for the farmer to use farm saved seed , whereas in the UPOV Convention the option to introduce a farmer's privilege is described as a restriction of a plant variety right and hence only indirectly as an entitlement for the farmer.

Under the terms of the provisions of Article 13 (2) of the basic regulation, the holder of a plant variety right is entitled to make his permission to use a protected variety subject to conditions and restrictions. Is the contractual

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freedom of the breeder as laid down in this provision restricted in respect of the sale of seed to a farmer as far as the use of farm saved seed is concerned? The relationship between said article 13(2) and article 14, containing the provision in respect of the farmers' privilege, is expressed by the words "notwithstanding article 13 paragraph 2" as laid down in the first paragraph of article 14. As "notwithstanding" expresses a contrast, its meaning could be that the provision in respect of the farmers privilege affects the right of the breeder as described in article 13(2) giving the farmer a mandatory right to use farm saved seed, that could not be restricted by contract. In the French version the word "nonobstant", which has the same meaning as "notwithstanding" is used. In the German version in stead of "notwithstanding" the word "unbeschadet" appears, which means just the opposite. This is also the case with the word "onverminderd" as used in the Dutch text version. On the basis of these language versions it could be defended that the farmers privilege could be limited by contract.

The conclusion is that in respect of a variety, as far as protected by a Community plant variety right, the different language versions of the basic regulation seem to lead to different answers in respect of the possibilities to exclude contractually the farmers' privilege. The final answer should be given or by the legislator, when harmonising the different language versions, or , when the legislator fails to act, by, in last resort, the Court of the European Communities in Luxemburg.

What is the situation in this respect as regards plant material within the scope of a patent? Article 11 of the Biotechnology directive implies that the extent and conditions of the farmers privilege as regards propagating material covered by a patent correspond to those under article 14 of the basic regulation. In other words: the same unclear situation exists here as described before in the framework of the Community plant variety system.

Whatever, any attempt to restrict the farmer's privilege contractually will probably run into the same sort of practical problems as the implementation of the fee regime for the re-use of farm saved seed.

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The relationship between the Community plant variety rights system and the national systems

The creation of the Community system was not intended to put an end to the existing national plant variety rights systems. As we read in the preamble to the basic regulation, the Community regulators envisaged the coexistence of the Community system and national systems once the Community system was introduced. Article 3 of the basic regulation expressly states that the provisions of this regulation do not affect the powers of the Member States to grant national property rights for plant varieties. There is one exception to this principle which I shall address in a moment. It was clear to everyone involved in the creation of the basic regulation that national plant variety rights regimes would inevitably become less important. In this respect, the precedent of the European patent system was an obvious pointer.

This predicted development is now confirmed a number of years after the start of the Community system. The number of applications for national plant variety rights dropped off considerably, often by more than fifty percent, in countries with a limited plant variety rights system (in terms of numbers of applications). In contrast, countries like Germany, the Netherlands and France, although also faced with a significant downturn in the number of applications, still have sizeable plant variety rights systems. It is worth noting that these inevitable consequences for the Member States have not created any obstacle to co-operation between the Office and the authorities of the Member States, either on the creation of the Community system or once this system came into effect.

In the first place, the contribution of the Member States is evident at policy level in the framework of the meetings of the Administrative Council of the Community Plant Variety Office, which is made up of representatives of the Member States. At executive level, the Member States support the Community system by making available research capacity for DUS testing. The basic regulation (Article 55, first paragraph) obliges the Community Plant Variety Office to use the competent offices in the Member States for this research. There is no reciprocal obligation for the Member States to carry out this research. Despite this, all the eligible Member States have proved willing to perform services for the Community Plant Variety Office. This is, I should add, not entirely an expression of altruistic Community feelings. The Office has to pay all the costs associated with the examinations. Calculations done over the past year reveal that in many cases the remuneration paid by the Office to date, which were at the same level as the examination fees charged by the Office to the applicants, did not cover the real costs. This finding resulted in the Office's raising the level of the fees paid to the examination offices significantly. This increase, at least for the time being, is not being funded by means of a corresponding increase in the examination fees charged to applicants but by drawing on the financial reserve that the Community Plant Variety Office has built up over the years. This would seem to be justified, given that the applicants who have contributed to the creation of this reserve in the past – by paying fees that were higher than the cost of the activities of the Community Plant Variety Office that they were intended to fund – are predominantly the same as the future applicants who will benefit from what is effectively a subsidised examination fee. A structural solution for the financing of the DUS examinations will have to be found in the longer term.

Let me quote a few figures in order to give you some idea of the size of this operation. Last year 2232 000 Euros were budgeted for the financing of the technical examinations undertaken on behalf of the Office. The estimate for this item this year is 3 354 000 Euros. According to the budget, out of this over 1 100 000 Euros increase, 843 000 Euros will have to be drawn from the reserves.

National and Community rights systems also interact in relation to rights granted. Article 92 of the basic regulation contains a prohibition on cumulative protection. If a Community plant variety right has been granted in relation to a

variety, neither a national plant variety right nor a patent may be granted for that variety. If the holder was granted a national plant variety right or a patent *before* a Community plant variety right is granted, he cannot invoke these other rights for as long as the Community right is in force. As far as the relationship between Community and national plant variety rights is concerned, the tenor of this article seems quite clear. Both types of right can, after all, have the same subject matter – a specific plant variety. Should the situation arise, the national plant variety right must give way. The relationship between a Community plant variety right and a national patent is more complicated.

Under the terms of Article 53(b), of the European Patent Convention, by which all EU Member States are bound, a patent may not be granted in respect of a plant variety. Accordingly, it would seem that the prohibition contained in Article 92 cannot envisage the granting of a patent in respect of a specific plant variety. It cannot, after all, be assumed that the Community legislators wanted to regulate a situation that could not occur in practice. Or was it their intention to regulate a possible future situation arising after a change of article 53 (b) of the European Patent Convention?

In view of the ruling of the Enlarged Board of Appeal of the European Patent Office of 20 December 1999 in the Novartis case (Case G 0001/98), a patent claim is not excluded from patentability even though it may embrace an - indeterminate- number of plant varieties. This being so, a meaningful interpretation of the ban on cumulative protection in so far as it relates to a Community plant variety right and a patent would appear to be -

- firstly that the granting of a patent in respect of a plant variety is ruled out in so far as the variety is protected by a Community plant variety right and
- secondly, that a patent that embraces plant varieties cannot be invoked in respect of a variety in the event that and for as long as the variety is also covered by a Community plant variety right granted after the granting of the patent.

I am aware that this interpretation does not sit well with Directive 98/44/EC of 6 July 1998 concerning the legal protection of biotechnological inventions (usually referred to as the Biotechnology Directive). However, this directive came into being later than the basic regulation and, for this reason alone, cannot be used to assist in the interpretation of the basic regulation.

The interface between the biotechnology directive and the Community plant variety system.

The biotech directive has been mentioned several times. In general I am of the opinion that the directive contains necessary clarification as regards the limits and possibilities of patent protection of living material. Article 12 of the directive is of great importance for plant variety right protection systems in the EU. This concerns the provision on compulsory licences. Let us look at the different parts of the article in turn.

"1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety."

This paragraph allows a breeder who cannot acquire or exploit a plant variety right without infringing a prior patent to apply for a compulsory licence to use the invention in question. If the licence is granted, the patent holder is entitled to a "cross-licence" to use the protected variety. I assume the word "use" in the last sentence of this article has the same broad meaning as "exploitation". The result of granting compulsory licences to holders of plant variety rights and

patent holders is that both can then exploit the plant variety which falls within the scope of both a plant variety right and a patent at the same time.

It is apparent from this provision that the legislator clearly thinks it possible that not just the exploitation but the very acquisition of a plant variety right in respect of a plant variety falling within the scope of a patent may constitute an infringement of that patent. Whether this is deemed to be so in a specific case will, in the case of a national plant breeders' right be determined by rules under the relevant national laws of the Member State concerned. The situation is more complicated in the case of an application for a Community plant variety right. In the theoretical situation that acquiring a Community plant variety right would constitute an infringement of one or a limited number of national patents not covering the whole territory of the EU the question would arise whether this would create an impediment for granting a Community plant variety right. An important consideration here is that the territorial scope of a Community plant variety right cannot be restricted, for example to the territory of those Member States where its grant does not constitute an infringement of a patent. The Directive provides no guidance here. I shall come back to this point when we discuss the research exemption.

"2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention."

With one exception, this provision is a mirror image of the first paragraph. The difference is that the acquisition of a patent cannot, in the legislator's view, lead

to the infringing of a plant variety right granted previously. As we have seen, the Directive does not exclude the possibility that somehow the very fact of acquiring a plant variety right may constitute an infringement of a patent.

- "3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
 - (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence
 - (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety."

Condition (a) places the prime responsibility in respect of the exploitation of the two rights squarely on the parties concerned.

Condition (b) sets stringent terms for the granting of an application for a compulsory licence. I agree with that, given the initial premise that the prime responsibility for the exploitation of a property right must rest with the right-holders themselves. It is striking, however that this condition departs from the usual condition for the grant of a compulsory licence, namely that it must be on grounds of public interest. This is a complicating factor in the application of the second part of paragraph 4 of this article.

"4. Each Member State shall designate the authority or authorities responsible for granting the licence. When a licence for a plant variety can be granted only by the Community Plant Variety office, Article 29 of regulation (EC) N° 2100/94 shall apply."

The first sentence details the situation and refers to national plant variety rights. It needs no further comment. The second sentence, however, does. The bald statement that where only the Community Plant Variety Office can grant a licence, Article 29 of Regulation No (EC) 2100/94 shall apply, might lead one to conclude that in this case the condition "on grounds of public interest" stated in Article 29 will apply rather than the terms of the Directive referred to earlier. However, this would unbalance the whole system envisaged by article 12.

A second question arises regarding the territorial validity of a cross-licence or compulsory licence granted by the Office. It would seem obvious that -

- In the case of a cross licence awarded by the Office this should be limited to a territory equivalent to that covered by the compulsory licence awarded to the CPVR holder by the relevant patent authority; and
- In the case of a compulsory licence awarded by the Office it should be limited to the territory in which the biotechnological invention is patented.

Apart from biotechnological material which is registered and not available to the public, the Biotechnology Directive lays down no rules as regards further research on patented biological material or its use in a breeding programme. To my mind, the legislator's failure to stipulate that the concept of the breeders' exemption, seen by many breeders as essential to the system of plant variety rights, is applicable to plant material covered by a patent, represents a missed opportunity. And this despite the fact that the farmers' privilege, which is not exactly popular with breeders, has been brought within the scope of patent law.

Since the legislator has failed to effect harmonisation in this regard, the question of how far breeders may use biological material in breeding programmes and acquire plant variety rights for any newly developed plant variety will have to be decided on the basis of the result of claims in respect of that patent and on the basis of the national law of the country concerned. National judges in the different Member States may not always take the same

view regarding the scope of the principle of research exemption embodied in national patent laws.

If it should transpire that breeders' ability to use varieties protected by plant variety rights in their breeding programmes has no counterpart in the patent regime, I believe further Community legislation will be needed. I would make the point that if breeders are not allowed to work with patented biological material, the breeders' exemption in respect of all varieties protected by plant variety rights on one hand, and falling within the scope of a patent on the other hand, will cease to have any meaning. This would in my opinion affect seriously progress in the breeding industry.

This concludes my contribution.

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Angers, January 2001

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