

## **Plantum NL position on patent- and plant breeders' rights**

On 6 May 2009, Plantum NL adopted a new position as regards the relation between patent- and plant breeders' rights. This position is as follows:

- 1. Biological material protected by patent rights should be freely available for the development of new varieties.**
- 2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.**
- 3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.**

### Explanation

#### **Plant breeding**

Plant breeding, or in other words the development of new varieties, has contributed significantly to the considerable increase in agricultural productivity of the past few decades, and is essential in order to be able to continue to guarantee food safety in the decades ahead. Furthermore, new varieties are being adapted to suit the requirements of the growers and the consumers through the introduction of innovative traits, improved taste and higher percentages of healthy components. This is how varieties are developed, for example, that are resistant to diseases and plagues, which in turn leads to a reduced need for crop protection products. The contribution of plant breeding will continue to be essential in the decades ahead, as the world faces up to the challenge of feeding its expanding population against the backdrop of climate change, shrinking reserves of fossil fuels and a changing diet in those countries experiencing rapid economic growth.

Plant breeding is the process in which different genetic varieties are combined (via amongst others crossing), following on from which the progeny displaying the best combination of traits are chosen (selection). In order to create a commercial variety, this process of crossing and selection has to be repeated several times, meaning that it takes on average between 7 and 15 years from the first crossing. All stages of the process involve the use of various high-tech procedures which serve to improve and/or speed up the process. Methods such as EMS mutagenesis, gene mapping, embryo rescue, double haploidisation and selection based on DNA markers have all become part of the current (standard) plant breeding process. Whilst the development of new techniques makes the process of crossing and selection ever more high-tech, it does not alter the process in essence. The breeding of new plant varieties will always occur by means of the crossing of the right genetic traits and the selection of the best progeny.

Plant breeding companies have always invested a relatively high percentage of their turnover in research and development (R&D). Between 15 and 25% of the turnover is invested in new research, on average. The fact that plant breeding has become ever more technology-driven in the past decades has not changed this situation. It may well be that the overall level of investment costs has risen sharply in the past decades, but these costs have increased in line with the turnover growth of the companies.

In order to recoup these investments, forms of intellectual property rights have been created, including patent- and breeders' rights.

### **Plant breeders' rights**

As the plant breeding sector became more professional in the early twentieth century, the need arose to protect the varieties which were being developed by means of intellectual property rights. Led by a number of European countries, it was purposefully decided not to try to use the already well-established patent rights for this purpose, but instead to create a new form of intellectual property rights, especially tailored to plant breeding: plant breeders' rights. Plant breeders' rights were laid down in the international UPOV Convention of 1961. 66 countries have implemented this treaty within their national legal system. In addition, the EC has implemented the most recent version of the treaty (UPOV'91) in Council Regulation (EC) No. 2100/94 on Community plant variety rights. Plant breeders' rights offer protection of a plant variety providing that variety is clearly distinguishable from all other varieties which are known to exist at the time of the application<sup>1</sup>.

This is determined on the basis of the variety's visible characteristics. Plant breeders' rights give the developer of a new variety the possibility to prohibit others from producing or selling plant propagating material of that variety, and, that being the case, it affords the breeder temporary exclusivity.

#### *The breeders' exemption*

At the same time, plant breeders' rights – through the so-called *breeders' exemption* – give other breeders the possibility to use the protected variety for the development of new varieties, and to use and exploit<sup>2</sup> those new varieties without permission from the original holder of the breeders' rights. So plant breeders' rights protect a combination of genetic building blocks created by the breeder, but those building blocks, as such, can be used freely in creating new combinations and thus new varieties.

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<sup>1</sup> and providing the variety complies with all other requirements pertaining to protection, namely uniformity, stability and novelty. The variety must also be designated by a suitable variety denomination.

<sup>2</sup> Unless the new variety is essentially derived from the original variety (see art. 14 par. 5 UPOV 1991).

**The breeders' exemption**

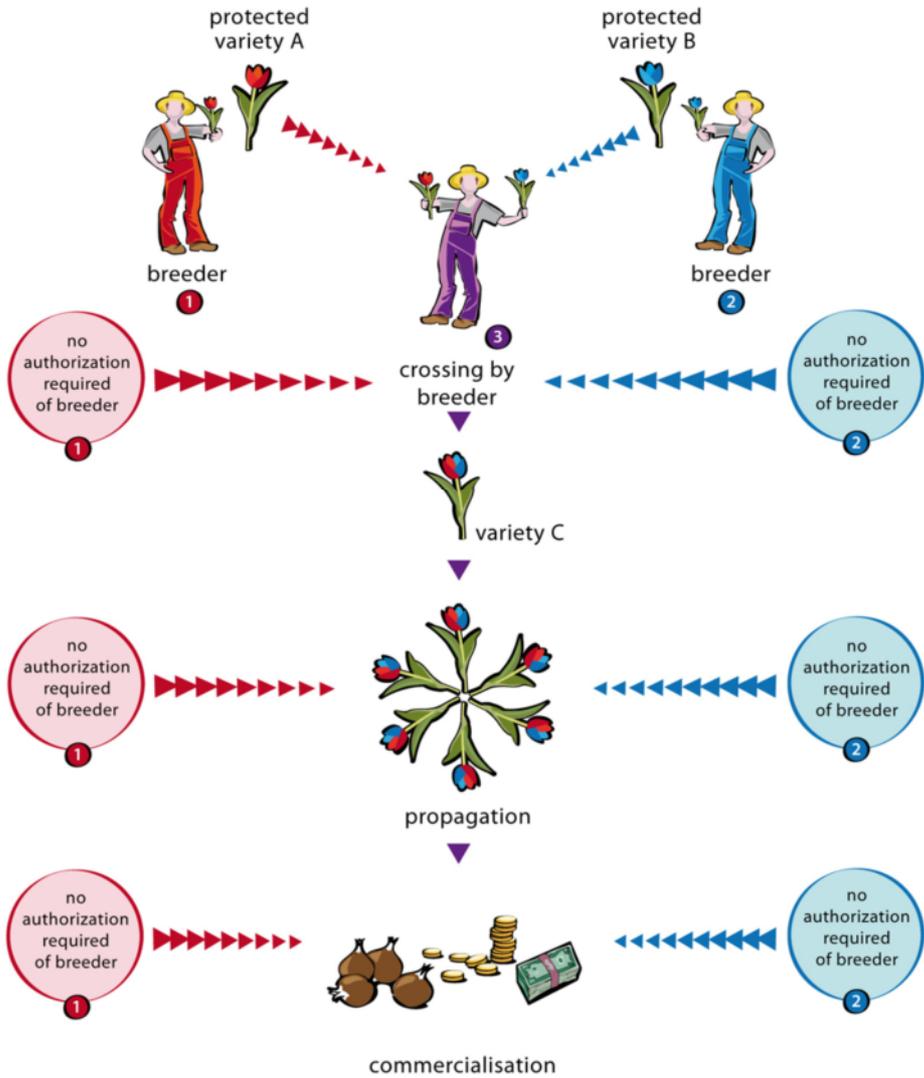


Figure 1: Diagram of the breeders' exemption

In this way, plant breeders' rights have found a balance between rewarding the breeder for his efforts in developing a new variety on the one hand and, on the other hand, creating the possibility for the continual improvement of varieties by other breeders, for the benefit of other links in the chain of production and consumers. This makes plant breeders' rights, in effect, a form of open innovation and reflects the two main aims of intellectual property rights: it provides a financial-economic stimulus for inventiveness and it serves a social interest. In this case, social interest consists of ever further improved plant varieties becoming available, coupled with a wide choice of varieties with traits the market demands.

Also thanks to plant breeders' rights, significantly profitable plant breeding companies have developed, which are able to continue to invest in the development of new and improved plant varieties.

### **Patent rights**

Providing they fulfil the necessary requirements, inventions can be protected under patents. An invention has to be new, the result of the act of invention, and to be able to be used for an industrial purpose. The aim of patent rights is two-fold: to reward the inventor by providing a temporary period of exclusivity on the one hand and, on the other hand, to further stimulate the process of innovation by means of the publication of the inventions.

#### *Patentability*

Despite the fact that plant breeders' rights have been created as *the* intellectual property rights specifically for the protection of plant varieties, patent rights have been gaining in importance in the past decade. Traits built into plant varieties, for instance, are often protected by patents. Patents are also granted on processes. It is explicitly laid down in Europe that plant varieties cannot be patented. In spite of this, the Enlarged Board of Appeal of the European Patent Office ruled in 1999 that varieties can come under the scope of a patent, providing that these varieties are not individually claimed<sup>3</sup>. This can be relevant in the case of plant varieties which exhibit patented traits or in the case of plant varieties which are the result of a patented process. This means in practice that plant varieties can be protected, either directly or indirectly, by patent rights. Unlike plant breeders' rights, patent rights do not include any provision that could be considered the equivalent of the breeders' exemption.

### **Definition of the problem**

#### *Scope of patent rights*

Since patent rights do not have a provision which can be compared to the breeders' rights, varieties containing patented traits are not freely available for further breeding<sup>4</sup> and newly-developed varieties which still come under patent protection are not allowed to be used and exploited freely. The same applies to varieties which have been developed using a patented process. This gives the patent holder an exclusive claim to genetic material and he can protect certain genetic building blocks from use by others.

#### *Mutual interests of the patent holder and society as a whole*

As far as innovation within the plant breeding sector is concerned, society as a whole benefits hardly, if at all, from the fact that it is compulsory for a patent holder to publish details of his invention, or that his plant material may be made available via a deposit.

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<sup>3</sup> Case No. G0001/98 (Transgenic plant / Novartis).

<sup>4</sup> In most countries, that is. As far as the EU is concerned, the right to be allowed to develop new varieties using varieties which come under the scope of a patent has been explicitly included in patent law in France and Germany.

It goes without saying that new varieties are always developed out of existing varieties. Therefore, in order to serve the social interest by encouraging that new and improved plant varieties can continue to be developed in the future, it is essential that existing varieties can be used for the purpose of further plant breeding. As far as plant material is concerned, the publication of an invention or a deposit does not contribute in any way to the stimulation of innovation, and therefore represents no added value for society as a whole, if the protected material itself may not be made freely disposed of for the purpose of the development of new varieties.

In this way, the current patent legislation has upset the balance which plant breeders' rights had previously managed to achieve in the plant propagating material sector. Plantum NL is afraid that this will lead to a situation whereby only the plant breeding companies with the largest patent portfolio will be able to survive, which in turn will mean that, in the future, the decisions regarding which varieties are introduced onto the market will be in the hands of just a few companies. This means that just a couple of players will be at the beginning of the chain of production in the plant sector. This is not in the interest of the plant breeding sector itself, the grower nor the consumer, and neither is it in the interest of society at large.

The patent holder can, of course, grant licences. However, there is no guarantee whatsoever that each breeder would obtain a licence or would obtain a licence on acceptable terms and conditions. Moreover, often, in practice, not just one but several licences will be needed, making a difficult situation even more difficult. It will be clear that open, continued innovation, which has been so characteristic of plant breeding until now, is hampered by this.

#### Plantum NL's view on the role of patent rights

For the aforementioned reasons, Plantum NL makes a case for the following changes to patent rights:

- 1. Biological material protected by patent rights should be freely available for the development of new varieties.**
- 2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.**
- 3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.**

In Plantum NL's opinion, it is not sufficient to allow patented varieties to be used freely for plant breeding purposes whilst the trading in new varieties still requires a licence. As long as there is no guarantee that a licence will be obtained, it would be irresponsible to invest several millions in a plant breeding programme which may end up having to be abandoned. Therefore, no plant breeding takes place with patented material until the licence negotiations are complete. By the time it becomes clear whether a licence will or will not be granted, and hence whether further breeding will be possible, the patent holder has been able to completely monopolise the crop or the trait concerned. In view of the very long development period, it is no longer possible at that point to set up a competitive breeding programme.

Patent rights do however present the possibility to request a compulsory licence at the time of development of a new variety that could be eligible for protection under plant breeder's rights. The developer of the new variety must be able to demonstrate in this case that the variety constitutes a significant technical progress of considerable economic interest. It is difficult to demonstrate this in advance. Furthermore, the developer must demonstrate that it was not reasonably possible to obtain a voluntary licence. Once again in this case, the outcome is so uncertain that a plant breeding company will not want to risk many years of investment in order to develop a new variety without having any guarantee of being allowed to sell the new variety in the future. Under the breeders' exemption contained within the plant breeders' rights, none of this is necessary, since the breeder who develops a new variety is deemed to be independent from others as long as he creates a variety which is sufficiently distinguishable.

Plantum NL is definitely not against patent rights, which we view to be a very valuable form of intellectual property rights. Plantum NL is, however, of the opinion that in the case the invention is expressed in a plant variety, plant breeders' rights are a more suitable form of intellectual property rights, in view of the nature of the object which needs protecting, since breeders' rights include the breeders' exemption.

In addition, plant breeders' rights, compared with patent rights, are an easily accessible intellectual property right. Applications for plant breeders' rights are actually assessed by independent and expert authorities and granting plant breeders' rights does not depend on technological descriptions. Moreover, plant breeders' rights are granted relatively quickly and, compared with patent applications, are hardly ever challenged (this is undoubtedly connected with the breeders' exemption). The consequence of all this is that applying for and preserving plant breeders' rights is, in practice, very much cheaper than applying for and maintaining a patent.

Plantum NL also sees a role for patent rights in the plant propagating material sector, though, e.g. to protect innovative processes or techniques. Plantum NL is of the opinion that the varieties which have been developed using a patented process should be allowed to be used freely for the purposes of further breeding, whilst use of the patented method itself should indeed require a licence. In addition, reproduction with the aim of selling of the patent holder's varieties, which have been developed using the patented method, should require permission from the patent holder. The same is true for varieties with patented traits which are introduced onto the market by the patent holder(s).

The above in accordance with the breeders' exemption as laid down in the UPOV Convention.

### **Why has Plantum NL adopted a new position?**

Plantum NL has always been a staunch supporter of the breeders' exemption. Plantum NL underlined the importance of the breeders' exemption at the time of the implementation of the European Union Directive 98/44/EC on to the legal protection of biotechnological inventions (hereafter: Biotech Directive) and advocated for an exemption for plant breeding to be included in the Patents Act. This proposal was not adopted at the time.

It was still assumed that patents would be held mainly by biotech companies which were not themselves involved in plant breeding activities. They would require the help of plant breeding companies in order to enter the market, which would then give the plant breeding companies a strong position from which to negotiate. In the meantime, it has become apparent that those patents which interfere with the breeders' exemption are in fact held by plant breeding companies. The patent holders are therefore able to introduce their own varieties onto the market and hence do not require the help of any other plant breeding companies. In addition to this, there have been a number of other recent developments which are a significant cause for concern to Plantum NL, namely:

- There has been a significant increase in the number of plant-related patent applications. The number of patent applications currently stands at approximately 4500, most of which have been filed in the past 10 years.
- The general position within the sector has always been that plant breeding should be freely available. However, a licence should be required for commercial purposes. Due in part to this position, France and Germany included an exemption for plant breeding in their national patent law at the time of the implementation of the Biotech Directive. However, since 2004, a number of companies with strong patent portfolios have been advocating that this position should be changed, namely to disallow further breeding of progeny containing a patented trait. These companies are not happy with the decision of France and Germany, and they are strongly resisting the adoption of this exemption by other countries. This harder line has resulted in some companies explicitly requesting that their competitors abandon plant breeding programmes which allegedly infringe their patent **applications**. This has the **immediate** effect of dramatically hampering innovation and posing a threat to those companies which are trying to develop competitive varieties.

The overwhelming majority of Plantum members believe that these developments pose a threat to the tried and tested system of open innovation within the plant breeding sector. In their opinion, this will have serious consequences for most plant breeding companies and the subsequent links in the food chain, right up to the consumer. First and foremost, we can expect a price increase for plant propagating material, since any costs which are associated with obtaining licences and applying for or defending patents will be passed on to the growers. Not all plant breeding companies will be able to obtain licences for important traits, as a result of which the growers will be faced with a more limited choice between the different suppliers of a particular crop. Finally, the expectation is that there will be even more consolidation as some plant breeding companies will no longer be able to maintain a competitive position in the market. This lack of players keeping up the competitive pressure will slow down the level of innovation in general across the sector.

Plantum NL is an industry body representing companies which are active in the field of plant propagating material. In this matter of utmost importance, Plantum NL acts in the interests of an overwhelming majority of its members. In addition, it is very important for Plantum NL's members that the agri- and horticultural sectors remain strong, and these sectors will not benefit from any restriction to the range of varieties available.

Finally, an industry body of this size is obliged to consider the interest of society as a whole as well. The world food supply benefits when there is sufficient competition between the plant breeding companies and when open innovation is preserved, and this is exactly the intention behind plant breeders' rights.

### Recent developments

The politicians in the First and Second Chambers of the Dutch parliament have also expressed their concern at these developments. As a result of this, the Minister of Agriculture, Nature and Food Quality and the Minister of Economic Affairs —Verburg and van der Hoeven respectively — have ordered an investigation into the socio-economic impact of patent rights in the plant breeding sector. It is expected that the final report will be sent to the Second Chamber at the end of 2009.

Since Plantum NL wishes to be able to provide adequate input for this investigation and since Plantum NL's members have clearly expressed that they regard a change in the current situation to be essential, Plantum NL has dutifully formulated a new position as of 6 May 2009. Plantum NL is fully aware that it is not possible to incorporate a breeders' exemption in its entirety in the Patents Act without changing the Biotech Directive. Plantum NL does believe that it is possible to incorporate a provision which would allow plant breeding using varieties which come under the scope of a patent, as France and Germany have done (breeders' exemption with limitations), without requiring a change to the Biotech Directive. This may seem like a step in the right direction, but as far as Plantum NL is concerned, this does not go far enough. Plantum NL is a strong advocate of incorporating the freedom for plant breeding as well as the freedom to commercially exploit the newly developed varieties as specific provisions in the Biotech Directive.

The diagram below shows which activities are allowed without a licence for a variety that comes under the scope of a patent, whereby the first three columns with regard to a variety which is introduced onto the market by the patent holder and the final column with regard to a newly developed variety.

	Production or reproduction (copy) of the patent holder's variety	Scientific research with the patent holder's variety (research exemption)	Crossing and selection with the patent holder's variety (plant breeding)	Commercial exploitation of a new variety which still comes under the scope of the patent
Biotech Directive	NO	*	*	NO
Patents Act	NO	YES	NO	NO
Patent law in France and Germany	NO	YES	YES	NO
Plantum NL proposal	NO	YES	YES	YES

\* There is no specific provision regarding this in the Biotech Directive, which leaves room for interpretation at a national level.

The incorporation of the breeders' exemption into the Biotech Directive will require national patent law and the European Patent Convention to be amended accordingly. At the same time, Plantum NL advocates that the breeders' exemption should be incorporated into the proposed text for the Community Patent Regulation. This is the only way to ensure a level playing field in Europe on this matter.

### **Conclusion**

Based on the above argumentation, Plantum NL is of the opinion that adoption of its position best guarantees continuity and diversity of companies in the sector. As before, companies will be able to earn back their investment costs: on the one hand since in the case of plant breeders' rights it is not allowed to reproduce someone else's variety without permission from the owner, and on the other hand because it takes a considerable amount of time to create a variety with the same trait(s) as another, competitive, variety. In spite of the fact that the plant breeding process has become shorter thanks to new techniques, it still takes a good few years. The breeder of the first variety is able to secure a strong commercial position in the market in this time. We know from past experience that a second supplier cannot make up for this lost time if his variety does not represent a real improvement. And it is this mechanism which, when combined with a full breeders' exemption, ensures the desired progress in terms of innovation within the sector.