

**Problem-solving approaches
to the issue of the overlap between
patent law and breeders' rights
in the plant breeding sector**

Mr C. G. Trojan
31 July 2012

Introduction

During the General Consultation between the former Minister of Agriculture, Nature and Food Quality and the House of Representatives on the future of plant breeding, a request was made, with a carried motion¹, in preparation for the legislative procedure and as a follow up to the report '*Veredelde zaken (Breeding Business)*'², to work out both the option of a limited and a comprehensive breeding exemption, and to examine the legal possibilities or impossibilities in national, European and global legislation and regulations so that these options can be discussed. The Minister of Economic Affairs, Agriculture and Innovation (hereinafter referred to as 'the Minister') submitted the requested analysis with his letter dated 21 February 2011.³

This analysis indicated that the introduction of a comprehensive breeding exemption in patent law is not deemed possible without the amendment of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter to be referred to as EU Directive 98/44/EC) and the amendment of the TRIPS Agreement (The Agreement on Trade - Related Aspects of Intellectual Property Rights). The analysis stated, furthermore, that a standpoint could not yet be adopted regarding the desirability or feasibility of a comprehensive breeding exemption and that, from the point of view of a meticulous weighing of interests, further investigation was required first, also in view of the interests of sectors other than the plant breeding sector.

In his letter of 11 April 2011 (Appendix 1 of this report), the Minister turned to the interest groups, the Confederation of Netherlands Industry and Employers (VNO-NCW), Plantum, Niaba, Nefarma and the Dutch Federation of Agricultural and Horticultural Organisations (LTO) with the question of how they viewed the feasibility and desirability of a comprehensive breeding exemption and whether they could suggest any possible alternatives.

In his letter of 16 August 2011⁴, the Minister gave an interim report on the ongoing consultations between the interested parties. The consultations comprise two parts: a written and an oral part. The written consultations reveal that various parties, comprising interest groups and individual companies both in and outside the plant breeding sector, have reasoned standpoints for or against a comprehensive breeding exemption in patent law. The companies which oppose a comprehensive breeding exemption include seed companies.

The written consultations between the interest groups were concluded in September 2011. A summary of the contribution, which was drawn up at the time and has been approved by the groups, is enclosed with this report (Appendix 2). This input formed part of the basis for the discussions I have held with the parties stated below.

During this process, another three motions were accepted by the House of Representatives, two of which were submitted during the Continued General Consultation on Biotechnology held on 22 June 2011 and the third at the Continued General Consultation on Greenhouse Farming held on 16 February 2012, namely:

¹ Parliamentary papers II 2009/10, 27 428, no. 165.

² Parliamentary papers II 2009/10, 27 428, no. 162 with appendix.

³ Parliamentary papers II 2010/11, 27 428, no. 182 with appendix.

⁴ Parliamentary papers II 2010/11, 27 428, no. 202.

1. The motion submitted by Mr Van Bemmel⁵ requesting that the feasibility and desirability of the introduction of a comprehensive breeders' exemption at the European level and the possible alternatives be investigated with other stakeholders;

2. The motion submitted by Mr Ormel,⁶ requesting that an independent chairperson be asked to implement the consultations with all the parties who have a direct interest in plant breeders' rights and patent law, based on the consideration that a comprehensive exemption can be included in the Biopatent Directive (EU Directive 98/44/EC) provided it causes no unacceptable damage to sectors other than the plant breeding sector, such as the medical and industrial biotechnology sectors;

3. The motion submitted by Mr Van Gerven⁷ requesting, among other things, that civic organisations such as the Dutch Federation of Agricultural and Horticultural Organisations (LTO), Oxfam Novib and Greenpeace be involved in the consultations referred to under point 2, that an independent chairperson be appointed within a month and that a final report be sent to the House of Representatives this summer at the latest.

Pursuant to the above, in his letter dated 14 March 2012,⁸ the Minister announced that Mr C.G. Trojan had been appointed chairperson and intermediary for the oral consultations with the interest groups on the desirability and feasibility of a comprehensive breeding exemption in patent law and possible alternatives. In accordance with this motion, Oxfam Novib and Greenpeace were also involved, in addition to the LTO which, incidentally, was already involved from the beginning of the written consultations. The Minister undertook, moreover, to send the final report on these consultations to the House of Representatives this summer.

Finally, during the General Consultation on Biotechnology on 5 April 2012⁹, the Minister for Agriculture and Foreign Trade also undertook to involve parties active in ornamental plant cultivation¹⁰ in the intersectoral consultations on the breeding exemption. In executing my duties and drawing up this report, I have taken the aforementioned motions and undertakings of both ministers into account.

On the basis of the principles and preconditions outlined above, I have looked in depth at the issue of the overlap between patent law and plant breeders' rights and held individual consultations with the following parties in the period between 19 March and 20 June 2012. The sequence of the discussions was solely determined by the invitees' own obligations. The discussions took place as follows:

Large companies, represented by Unilever (19 March 2012) and DSM (20 June); Oxfam Novib (29 March); LTO (30 March); Plantum (30 March); Greenpeace and Bionext jointly (2 April); Niaba with representatives from Syngenta and Keygene jointly (3 April); Nefarma (5 April);

⁵ Parliamentary papers II 2010/11, 27 428, no. 197.

⁶ Parliamentary papers II 2010/11, 27 428, no. 198.

⁷ Parliamentary papers II 2011/12, 32 627, no. 7.

⁸ Parliamentary papers II 2011/12, 27 428, no. 213.

⁹ Parliamentary papers II 2011/12, 27 428, no. 230.

¹⁰ The ornamental plant cultivation sector was represented by the Dutch Flower Auctions Association (VBN).

The Steering Committee Industry Solution to Interface of Plant Breeding Rights and Patents, hereinafter referred to as the Steering Committee (chairperson, 7 May); VBN (7 May) and VNO-NCW (9 May 2012).

On the basis of the contributions delivered by the aforementioned parties, I drew up a draft memo which was sent to all of them. This memo was discussed in a restricted meeting with representatives from Plantum, LTO, Niaba and Nefarma on 2 July 2012 and, with a few alterations, subsequently on 3 July 2012 with the aforementioned interest groups.¹¹

The memo and the subsequent oral and written comments delivered by the parties involved form the basis of this present report. Contrary to what might have been expected, I will not be putting forward a single solution to the problems of imbalance resulting from the overlap between patent law and plant breeders' rights but a number of problem-solving approaches which have emerged from the discussions with these interest groups. The reasons for these problem-solving approaches are explained in detail below.

This report is structured as follows:

1. Regulations for the specific protection of plants and plant varieties.
2. The overlap between plant breeders' rights and patent law.
3. The definition of the problem.
4. Arguments put forward by proponents of and opponents to changes to the system.
5. What is at stake? Getting the problem into proportion.
6. Points of departure for problem-solving approaches.
7. The problem-solving approaches indicated.
8. The problem-solving approaches in more detail.
9. A simultaneous national and international approach.
10. Final conclusions and recommendations.

¹¹With the exception of the Steering Committee; Oxfam Novib was unable to attend.

1. Regulations for the specific protection of plants and plant varieties

International regulations in the field of industrial property are based specifically on the protection of plants and plant varieties.

The principles of plant breeders' rights

Plant breeders' rights can be granted for a plant variety. The legal requirements for this are: novelty, distinctness, uniformity and stability. Plant breeders' rights are regulated in the UPOV Convention¹² and implemented in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights and the Seeds and Planting Materials Act 2005 (*Zaaizaad- en plantgoedwet 2005*). The point of departure of both the UPOV Convention and the European Patent Convention is the prohibition of overlapping protection of plant varieties by patent law and plant breeders' rights. In Article 27, the TRIPS Agreement lays down that World Trade Organization (WTO) member states may exclude 'plants' and 'essentially biological processes', provided plant varieties are protected either by patents or by an alternative effective system or by any combination thereof. The UPOV Convention and the aforementioned Council Regulation (EC) No 2100/94 form effective alternative systems.

The breeders' exemption

Plant breeders' rights recognise what is known as the breeders' exemption. This exemption gives breeders the opportunity to use varieties protected by plant breeders' rights to breed or discover and develop new plant varieties.¹³

Because of the limited extent of the protection conferred by plant breeders' rights (protection for the repeated breeding of propagating material of a single variety, operations concerning material harvested from the variety and operations concerning products which have been produced directly using material harvested from the variety),¹⁴ new varieties may be commercially exploited without permission from the holder of plant breeders' rights. Moreover, breeders' rights can be granted, on application, for new varieties which meet the aforementioned requirements for plant breeders' rights.

¹² The UPOV Convention (*L'Union internationale pour la protection des obtentions végétales*, International Union for the Protection of New Varieties of Plants) of 2 December 1961 last revised in 1991.

¹³ Seeds and Planting Materials Act 2005, Article 57(3), opening lines, and 57(3)(c); International Union for the Protection of New Varieties of Plants (UPOV Convention), Article 15(1), opening lines, and 15(1)(iii); Council Regulation (EC) No 2100/94 on Community plant variety rights, Article 15, opening lines, and 15(c).

¹⁴ Seeds and Planting Materials Act 2005, Article 57.

2. The overlap between plant breeders' rights and patent law

Since the emergence of biotechnology, there has been an increase in patent protection for plant-related inventions, both with regard to gene technological processes and products with genetically determined characteristics.

EU Directive 98/44/EC has harmonised patent law for biotechnological inventions, particularly with regard to the patentability of biotechnological inventions and the scope of protection provided. This Directive also lays down that an invention concerning plants is patentable, if the technical feasibility of this invention is not confined to a particular plant variety.¹⁵ EU Directive 98/44/EC also lays down that plant varieties and essentially biological processes for the production of plants are excluded from patentability.¹⁶

Processes are 'essentially biological' if they consist entirely of natural phenomena such as crossing or selection.¹⁷

These areas have been explained in more detail in recent legal precedents.¹⁸ The Enlarged Board of Appeal of the European Patent Office (EPO) decided that a non-microbiological process for the breeding of plants, which involves the crossing of entire plant genomes and subsequent selection of plants, is not patentable. No process of this kind, or one which contains a step of a technical nature which enables or facilitates this process escapes this prohibition.

The protection conferred by a patent for (an invention concerning) biological material which, as a result of the invention, has obtained certain characteristics shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.¹⁹ Irrespective of the fact that a plant variety as such is not patentable, a plant variety can thus de facto fall under the protection of a patent as a result of the comprehensive scope of protection provided by patents on biotechnological and more specific plant-related inventions.

Under plant breeders' rights, thanks to the breeders' exemption, a breeder may use starting material which is protected by plant breeders' rights for further breeding. In principle, this is not permitted under patent law because, although patent law contains a research exemption, it does not yet recognise a limited breeding exemption.²⁰ A legislative proposal to change the Patents Act 1995 to this effect is in preparation.

¹⁵ Directive 98/44/EC, Article 4(2).

¹⁶ Directive 98/44/EC, Article 4(1).

¹⁷ Directive 98/44/EC, Article 2(2).

¹⁸ That is, the cases T 83/05 (G2/07) on broccoli and T 1242/06 (G1/08) on tomatoes, which were handled by the Enlarged Board of Appeal of the European Patent Office.

¹⁹ Directive 98/44/EC, Article 8(1).

²⁰ In order to distinguish between them, these two forms of exemption are referred to as a breeders' exemption (under plant breeders' rights) and a breeding exemption (under patent law).

Varieties in which patented characteristics occur, which were conferred by the invention in question, are no longer freely available for further breeding because the commercial user of these varieties needs permission (licence against payment) from the patent holder to use them. The same applies to plant varieties which have been developed by means of a patented process.

As a result of this development, the situation has arisen that plant material can fall under plant breeders' rights providing protection for unique plant varieties, but can, at the same time, also fall under patent law granted for inventions conferring certain characteristics, provided, as stated earlier, the invention is not limited to a specific plant variety with regard to feasibility. This overlap between plant breeders' rights and patent law, which has arisen with the emergence of modern technologies for plant breeding, has disrupted the specific balance between them.

3. The definition of the problem

The increasing influence of patent law is limiting the free availability of and access to biological material for plant breeding. This development is causing concern because the Netherlands has a leading role in plant breeding in various fields, including food crops and ornamental plants.

According to Plantum et al., the increasing influence of patent law is impeding innovation in plant breeding as a whole and limiting biodiversity, and this is leading to a situation whereby the plant breeding companies with the largest patent portfolios determine what varieties come onto the market, thus paving the way for dominant market positions.

These concerns, which are largely forward looking, are widely supported in the House of Representatives and now also in the European Parliament.²¹

The essential issue is, therefore, to find a solution to guarantee plant breeders easy access to biological starting material in the spirit of the innovation model of plant breeders' rights. This must be realised without totally eroding patent law and causing consequent damage, and without opening the door to radical amendments to EU Directive 98/44/EC, which is, after all, also important for other sectors, such as medical and industrial biotechnology. According to the aforementioned parties, solutions should be sought in the (proposed more or less far-reaching) changes to the system discussed below.

²¹ Resolution adopted by the European Parliament of 10 May 2012 on the patenting of essential biological processes, P7_TA(2012)0202.

4. Arguments put forward by proponents of and opponents to changes to the system

Proponents

Plantum, with the support of LTO, Greenpeace, Oxfam Novib, VBN and Bionext,²² advocates the introduction of a comprehensive breeding exemption in patent law, so that breeders can develop new plant varieties and exploit them commercially, making use of patent-protected biological material, which is subject to patent rights, without permission from the patent holders, as is the case under plant breeders' rights.

These proponents of changes to the system would like the same freedom and opportunities as those under plant breeders' rights. They would prefer to see patent law amended to the extent that, roughly speaking, it provides the same (more limited) protection as plant breeders' rights. Patent law should, thus, be amended to provide scope for the free use of the available biological material for breeding and commercial exploitation of the resulting improved products. Permission from the holder of the patent relating to the material would then no longer be needed. This would benefit the innovative power of the breeding sector, as experience with the, as yet, more commonly applied plant breeders' rights in the sector shows. The amendment of patent law could also lower what is now a high entry barrier for new companies wishing to enter the plant breeding sector.

Proponents would like a comprehensive exemption, but not a full one

In its plea for a comprehensive breeding exemption in patent law, Plantum still makes a distinction between patents on applied techniques and those on (genetically determined) plant characteristics. The breeding exemption in patent law should only relate to plant characteristics (products), not the techniques (processes) as such, because breeders' interests lie primarily in free access to the relevant biological material for plant breeding purposes.

According to Plantum's standpoint, the exemption should not relate to the commercial cultivation of plants (which are not improved further) which are subject to patents.²³

These points of departure correspond with existing practice under plant breeders' rights: that is, the use of propagating material protected by plant breeders' rights for plant breeding purposes is permitted, but not the commercial use of propagating material already protected by plant breeders' rights.

New plant varieties arising from varieties previously protected by plant breeders' rights are, on the other hand, freely commercially exploitable as a result of the more limited scope of protection (compared with patent law) conferred by plant breeders' rights. The latter do not extend to new plant varieties developed from varieties protected by plant breeders' rights.²⁴

²² Proponents of a comprehensive breeding exemption in patent law include: The Dutch Produce Association, Flora Holland, the Royal General Bulb Growers' Association (Koninklijke Algemeene Vereeniging Voor Bloembollencultuur, KAVB); Parliamentary papers II 2010/11, 27 428, no. 202, as well as VBN, Parliamentary papers II 2011/12, 27 428, no. 230, pp 31 and 33.

²³ Plantum's standpoint in the matter of patent law and plant breeders' rights pp 6 and 9.

²⁴ With the exception of essentially derived plant varieties.

According to the proponents, a comprehensive breeding exemption will have only positive effects on plant breeding. Innovation in plant breeding will no longer be delayed because access to biological material which is subject to patent law will be simplified, negotiations on patent licences will no longer be necessary and the related costs will therefore be saved. Furthermore, a comprehensive breeding exemption will prevent conflicts regarding patent infringement so that breeders are no longer inconvenienced by patent law.

In their recently announced standpoints, the European Seed Association (ESA)²⁵ and the International Seed Federation (ISF)²⁶ emphasised the great importance of both plant breeders' rights and patent law, and a good balance between them, for plant breeding. Among other things, they argued for the introduction of a limited breeding exemption in patent law in the interests of this sector.

Damage foreseen by these proponents if the system is not changed

On request, Plantum, VBN and LTO specified the disadvantages and/or damage they expect in the future if the system is not changed. According to these parties, plant breeding is a growing sector. The Netherlands is the largest global exporter of plant reproductive material, with an export value of approximately €2.5 billion, and this sum increases every year.

There are disadvantages at various levels: on the individual and the sector levels. To begin with, individual companies must incur research and transaction costs because they have to examine whether the biological material they wish to use commercially is subject to patent rights. Breeders will then have to negotiate on licences for the use of the desired material and the conditions (such as the price). This price will have to be charged on to buyers and, ultimately, the consumer. It should be mentioned at this point that costs for research into the patent position, transaction costs and the fees for the necessary licences are usual in other sectors. Such patent-related costs are, however, relatively new to the plant breeding sector where, until recently, use was predominantly made of plant breeders' rights.

Plant breeders, particularly small entrepreneurs with little experience, are afraid that, on top of the aforementioned costs, costs will also have to be paid for prolonged legal procedures if patent holders accuse them, justly or unjustly, of patent infringement. If patent holders do not wish to grant licences, this will have a broader effect on the innovation possibilities in the sector, and there will be less freedom of choice for the breeder, slower innovation, higher barriers for new entrants, possibly more parties leaving the market²⁷ and a further concentration of plant breeding companies which, as a result, have increasing market power.

²⁵ ESA Position on Intellectual Property Protection for plant-related inventions in Europe, (ESA 12.0100) Brussels, February 2012.

²⁶ ISF View on Intellectual Property, Rio de Janeiro, 28 June 2012.

²⁷ Moreover, LTO pointed out the problem of the decreasing willingness to invest in biological breeding, while the biological sector is growing globally. This is a matter of concern given the growth in scale of the plant breeding sector. This matter will not be taken into consideration in this document.

Opponents

The interest groups Niaba, Nefarma, and a group of large companies (DSM, Philips, Shell and Unilever) belong to the group of opponents to radical changes to the system and, in particular, to a comprehensive breeding exemption in patent law. AKZO Nobel, Biofarmind, Dow Benelux, ENZA Zaden, Europa Bio, Keygene, Monsanto, Nunhems Zaden, NXP Semiconductors, Syngenta, Tata Steel Europe and the Association of the Dutch Chemical Industry (VNCI) are also among this group. A striking point is that the opponents to a comprehensive breeding exemption include several large seed companies.²⁸

Niaba is of the opinion that plant breeders' rights and patent law can exist side by side without problems. Large investments are needed to develop and launch biotechnological innovations in any sector on the market, including that of plant breeding and these large sums will only be invested if they can be recovered. A good intellectual property protection, which takes into account the nature of the achievement (an invention or a plant variety) is essential to this end.

Opponents to changes to the system fear serious damage to innovation and the innovation climate

It is not surprising that whereas proponents foresee great advantages in the introduction of a comprehensive breeding exemption in patent law, opponents expect these same advantages to be detrimental to *their* interests.

If a comprehensive breeding exemption is introduced, patent holding companies will lose income from the sale of patents or licences because others will be able to carry out patent-protected activities and exploit the products commercially without the permission of the patent holders in question. Breeders will then be able to profit freely from costly investments in research and development made by others. According to the opponents, this will lead to an undesirable erosion of patent law. Patent holders will, thus, lose revenue and be unable to recover the costs of innovations. The rate of innovation will decrease because fewer innovations will be realised – innovations which are much needed – including in the plant breeding sector. There is, furthermore, the risk that access to knowledge will be hampered if results which can now be accessed through patents are kept secret in future as an alternative to patent protection because this is cheaper and provides longer-term protection.

Opponents to changes to the system include various types of companies:

- Companies which have based their business model solely or predominantly on generating revenue from patents (particularly those related to plant characteristics) and will therefore suffer direct losses;
- Large vertically integrated multinationals in the plant breeding sector which are both patent holder and breeder and hold significant market positions;
- Companies in biotechnology, the pharmaceutical industry and the chemical sector which are afraid of product losses if others use or develop escape routes through plants.

²⁸ Parliamentary papers II 2010/11, 27 428, no. 202.

Opponents to a comprehensive breeding exemption in patent law fear that, as a result, licence revenue will decline and that it will no longer be possible to recover investments already made. This will, in any case, be detrimental to small and medium-sized enterprises and industry. The effects of a comprehensive breeding exemption on knowledge institutes have not been investigated.

Within the context of the consultations, Niaba, DSM, Unilever and Nefarma have indicated that, among other things, the introduction of a comprehensive breeding exemption will be detrimental to various sectors. Not only will the plant breeding sector itself be disadvantaged, but also the biotechnology industry (particularly the pharmaceutical, chemistry and biobased economy sectors) and others.

A comprehensive breeding exemption will be detrimental to the **plant breeding sector** itself because more than a hundred parties in this sector are already active with patent applications, as is evident from a recent analysis carried out by the NL Patent Office.²⁹

The distinction between 'native' and 'man-made' plant characteristics will cease on the introduction of a comprehensive breeding exemption. In addition, products made with new breeding technologies (insofar as they are not regulated as genetically modified organisms [GMOs]) will then be freely available to third parties for breeding purposes and the commercialisation of newly developed varieties. This will lead to lower investments for the development of new plant characteristics and, thus, to fewer new plant varieties. A comprehensive breeding exemption could lead to a situation whereby companies move their activities to countries outside Europe.

The introduction of a comprehensive breeding exemption will lead to enormous losses for the **biotechnology sector in general**, according to opponents.³⁰

In the **pharmaceutical industry**, there are currently at least 15 'plant-made pharmaceuticals' in the making, including vaccines and medicines.³¹ Expensive product developments of this kind can, however, only continue to take place if the costs incurred can be recovered and effective patent protection is essential to this end.

In the **biofuel industry**, scientists are searching industriously for enzymes which can be used to convert inedible plant residues to renewable raw material for fermentation to fuel. The development of these enzymes entails high investments and a great deal of R&D effort.

Plant-related and biotechnological inventions are equally important for the **chemical and cosmetic industries**.

²⁹ Parliamentary papers II 2011/12 27428, no. 231 with appendix: 'Plant Breeding: The Sector from the Patent Perspective'.

³⁰ According to information from Niaba, Nefarma, DSM and Unilever, we are talking about markets which, in 2020, will have estimated values of USD 50 billion for bio-ethanol as biofuel, USD 35 billion for biogas, USD 9 billion for biobased chemicals and USD 3-5 billion for enzymes and yeasts.

³¹ These include vaccines against HIV, influenza, hepatitis C and medicines for the treatment of diabetes, dental caries, cystic fibrosis, various types of cancer and malaria.

In the **'food and feed' industry**, ingredients for foodstuffs, such as aromatic substances, flavourings, vitamins and enzymes, are developed from natural raw materials. It is estimated that a third of food additives are prepared by fermentation. Production in plants and plant cells are on the horizon but could, on the introduction of a comprehensive breeding exemption, provide an escape route along which competitors could produce without permission from the patent holders, so that the latter will be unable to recover their investments.

Finally, not only companies within the biotechnology sector, but also those outside it, are afraid of the precedent effect which could result from a (discussion on) the amendment of EU Directive 98/44/EC. The damage in all of these sectors will be all the greater because, on the disappearance of intellectual property protection for plant-related inventions, there will be no protection through intellectual property law left in other sectors (such as in the plant breeding sector which has plant breeders' rights for plant varieties). Exchanging views on the possible amendment of the Directive will require a great deal of time. Topics other than plant breeding, such as the protection of inventions in the field of human health and human genetics, could also be raised. A prolonged period of legal uncertainty will be detrimental to Dutch competitiveness and, more generally, the European business and investment climate.

Intermediate position of the VNO-NCW

During the consultations, the VNO-NCW has repeatedly emphasised that it is very important that solutions be sought in close consultation so that those found are endorsed by all the parties involved. The preferred solutions will be those which minimise the losses incurred by whatever parties may be involved. The situation therefore requires great scrupulousness.

5. What is at stake? Getting the problem into proportion

The limited number of patents for non-genetically modified plants

According to data from the European Patent Office ³², a total of 9,167 patents were applied for and 1,690 European patents granted for plant-related inventions between 1990 and February 2012. The patents granted comprised 1,602 relating to genetically modified plants and 88 (< 5%) relating to non-genetically modified plants.

During the discussion on the patents granted, the importance of the characteristic for which the gene/genes in question codes/code is also being looked at. Given the fact that, in Europe, hardly any licences are granted for GMOs, the problem is, at the moment, relatively limited for the Netherlands (which is primarily strong in vegetable crops and ornamental plants) and Europe. ^{33 34}

The problem of the overlap between patent law and plant breeders' rights may become more urgent if, in the future, licences are more freely granted for the production of genetically modified plants.

On the other hand, certainly seen from the global point of view, in time problems could arise in the light of the world food supply, climate change, preservation of biodiversity and the general interest of access to biological material for plant breeding purposes.

This applies particularly to product innovation in the sectors which are so important for the Netherlands: food crops and ornamental plants.

Primarily fears for the future

Incidentally, discussion has been going on for some time about the question of what processes and technologies should fall under the concept of 'genetic modification' and, in turn, what results of these technologies should fall under the term 'GMO'. This topic will not be taken into consideration in this document.

As is apparent from the previous section, irrespective of whether far-reaching changes are introduced in the patent protection system for biotechnological inventions or not, the main concerns of both proponents and opponents are for the future.

There is still time for more detailed analysis of the problems and tailor-made solutions

The actual or potential damage to the Dutch plant breeding sector from an increase in patents for plant-related inventions is limited at the moment, so there is still time for the further analysis of the scope of the problem and the search for appropriate solutions. This does not alter the fact that the more patented plant inventions accumulate, the more problems can be expected because licences risk becoming prohibitively expensive ³⁵ while a single patented characteristic could be so crucial that the lack of access to it might, in itself, be a severe hindrance to plant breeding.

³² Presentation by the European Patent Office at the Niaba meeting on 3 April 2012, Nieuwspoor, The Hague.

³³ According to Plantum, there is a trend of relatively increasing numbers of patent applications relating to native traits and inventions relating to non-genetically modified (non-GM) plants.

³⁴ Incidentally, a patent relating to a single essential plant characteristic may sometimes be deemed indispensable, for example in the case of resistance to a plant disease or insect damage.

³⁵ The Steering Committee is paying explicit attention to solving this issue.

6. Points of departure for problem-solving approaches

A solution to this particular problem which, as is evident, involves conflicting interests, will chiefly have to be sought in a direction which provides scope for innovation in plant breeding, primarily with an eye to food security and product innovation in the ornamental plant sector.

This will mean that losses in cases in which plants and products derived from plants are used for other purposes can be minimised as far as possible. The patent protection for these other purposes will have to be left unchanged to prevent or limit the loss of licence revenue.

These problem-solving approaches should, moreover, have no, or as little as possible, precedent effect on other sectors.

The Minister has sent a letter³⁶ to European Commissioner Barnier, asking for the evaluation of EU Directive 98/44/EC and raising the question of whether and, if so, to what extent patent-protected inventions relating to changed plant characteristics – and varieties present on the market – must fall under the exclusive protection of patent law. The letter can, in this light, be seen as a prelude to a European exchange of views, the subject of which should, as far as possible, be placed within the framework indicated above.

The report on the development and implications of patent law in the field of biotechnology and genetic engineering,³⁷ which has already been announced and is expected to appear before the end of this year, could be the first step for discussion on the amendment of the Directive. It is therefore important that the Netherlands, in good time, seek contact with France and Germany for a coordinated contribution to this discussion. After all, these countries have similar interests in plant breeding.

Opponents to a comprehensive breeding exemption have indicated that, among other things, the solution to the problem must primarily be sought within the sector, so as to entail the least risk of undesirable side effects, as described above. This is endorsed by prominent figures from the leading economic sectors, Chemistry, Biobased Economy and Life Sciences & Health. They let it be known that they shared the concerns already expressed by various companies and sectors on the possible introduction of a comprehensive breeding exemption. They think that the solution lies in making good agreements within the sector, between breeders and patent-holding companies. This is, in their opinion, not only the most obvious solution, but also the solution which will entail the least risk of undesirable side effects. According to these prominent figures, a sound and reliable patent system is essential for the development of the aforementioned leading economic sectors.

³⁶ Parliamentary papers II 201/12, 27 428, no. 219, with appendix.

³⁷ Report pursuant to Article 16, opening lines, and 16(c) of EU Directive 98/44/EC.

7. The problem-solving approaches indicated

This section first discusses several general considerations regarding existing possibilities and then goes into the types of solutions, the degree of difficulty of realising these solutions and the effects that can be expected, for example, for the legal certainty. The possible problem-solving approaches are then explained in more detail.

Utilising existing possibilities

Before examining the problem-solving approaches, it is important to note that opponents to a comprehensive breeding exemption in patent law argue that it would be better to first utilise the legal possibilities which already exist in conflicts between parties about patent law.

These possibilities include: conducting opposition proceedings against granted patents, requesting the full or partial annulment of patents (for example, in the case of alleged infringement of a patent) and requesting a compulsory licence in the event that a patent holder does not voluntarily cooperate with a request to grant a licence, or sets such unreasonable conditions for doing so that the licence negotiations are unsuccessful. The organisation of patent pools is also a possibility. In most cases, the court can decide on a request for a compulsory licence in an action brought to that end.³⁸

In the general interest of the Netherlands, Curaçao or Saint Martin, the Minister can grant a compulsory licence under a patent, if the application of the patented invention could help solve a problem of general interest and if other possibilities are deemed inadequate. Situations of crisis, such as an outbreak of a contagious animal or human disease, an environmental catastrophe, severe plant disease or insect plagues which could lead to food scarcity might qualify as a 'problem of general interest'.

With regard to the compulsory licence in connection with not being able to obtain or exploit plant breeders' rights to a plant variety without infringing a patent of a previous date, the condition is laid down that the plant variety must represent a considerable technical advance of substantial economic importance in respect of the invention which is protected by the patent.³⁹

Such high requirements are laid down for the aforementioned possibilities of compulsory licences in the general interest, and in connection with not being able to obtain or exploit a plant breeders' right, that it is not expected that they will often be used in practice. Under certain circumstances, there may be a case of misuse of a dominant position if a patent holder refuses to grant a licence. In such cases, the competition law may provide a solution.

³⁸ Compulsory licences in the general interest, which are granted by the Minister, form the exception here. Compulsory licences are regulated in the Patents Act 1995, Sections 57 and 58.

³⁹ EU Directive 98/44/EC, Article 12(3), opening lines, and 12(3)(b); Patents Act 1995, Section 57(5).

Several general considerations regarding problem-solving approaches

The table below shows all the solutions identified during the consultation process. They are discussed in more detail later in this report.

Table: List of the solutions identified:

	Measure	Comments
a	Comprehensive breeding exemption	Requires amendment of (inter)national regulations
b	Limited patentability	Requires amendment of (inter)national regulations
c	Limited scope of protection by patent law	Requires amendment of (inter)national regulations
d	Limited breeding exemption	Is under preparation
e	Improvement of the quality of patenting	Started some time ago
f	General knowledge about patent law on plants	Awaiting recommendations from Niaba and Plantum
g	Counter function	Awaiting recommendations from Niaba and Plantum
h	Licensing code of practice	Is under preparation
i	Wide publication	Existing possibility
j	A patent watch	Awaiting recommendations from Niaba and Plantum
k	Legal precedents	Is already ongoing

Here a distinction is made between problem-solving approaches relating to patents which have already been granted, on which the effect will be limited to the remaining term of the patent, and patents yet to be granted, on which the effect will be more prolonged, because these patents have not yet been granted and/or their term has not yet commenced.

It is, furthermore, advisable to take note of the nature of the solutions and time it will take to realise them, particularly those that entail the amendment of international regulations.

Problem-solving approaches for current patents

The following solutions can, in principle, be considered for the short and medium term for current cases, that is, patents which have already been granted:

- A licensing code of practice;
- A limited breeding exemption;
- A comprehensive breeding exemption;
- Legal precedents.

Problem-solving approaches for future patents

The following solutions can, in principle, be considered for future cases of patents yet to be granted:

- The curtailment of double protection of plants and plant varieties;
- The redefinition of terms from EU Directive 98/44/EC, such as the definition of 'essentially biological processes';
- More detailed delineation of the patentability of inventions concerning products and processes as referred to in Article 3 of EU Directive 98/44/EC;

- More detailed delineation of the scope of protection conferred by patent rights granted for biotechnological inventions.

Two forms are conceivable, according to the possibilities deemed legally appropriate, namely a 'radical' or 'less radical' form.

A less radical form

It certainly cannot be ruled out that, in its coming report on the development and implications of patent law in the field of bio and gene technology, the European Commission will, on the basis of recent legal precedents, give a more detailed legal interpretation which could lead to stricter testing against the patentability requirements inventions must meet in order to be eligible for patenting.

A radical form

This form will at least require the amendment of EU Directive 98/44/EC and the European Patent Convention at the European level and/or the implementing rules based on them, as well as the amendment of the national legislation of the countries involved. It is now up to the European Commission to suggest amendments to the Directive. Conformity with the TRIPS Agreement will have to be examined, depending on how far reaching the amendments are.

It is clear that realising amendments of this nature will be no easy matter as they will require European and/or global support.

Chapter 8 gives a more detailed overview of the various possibilities given here which could contribute to solutions to the problem in question. Firstly, I will go into the types of solutions which can be distinguished and which of their aspects merit attention. To begin with, a distinction can be made between solutions which do or do not require the amendment of national and international regulations.

Measures requiring the amendment of regulations

Problem-solving approaches which require the amendment of (patent) regulations are as follows:

- a. A comprehensive breeding exemption;
- b. Limitation of the patentability of biotechnological inventions;
- c. Limitation of the scope of protection conferred by patent law for biotechnological inventions;
- d. A limited breeding exemption (is already under preparation in the Netherlands).

The point of departure of such amendments should, as far as possible, be that biological material from plants or constituents of plants should not enjoy unnecessary protection under either plant breeders' rights or patent law, at least in those cases in which one of these forms of protection has undesirable effects on the other.

Amendments to European regulations can, if necessary, be accompanied by built-in transition provisions.

This type of solution requires political support and the procedure is time-consuming, while the outcome of the political decision-making is less certain in advance because it will usually be a compromise.

A comprehensive breeding exemption and a procedural limitation of patentability or scope of protection will, in any case, require in-depth discussions at the European and international levels. Amendment of EU Directive 98/44/EC or the European Patent Convention (of which 37 countries are members) will be no easy matter because of the time needed, the complexity of the issue and the risk of a precedent effect for other subjects or industrial sectors.

It is, for this reason, important to keep working on other solutions at the same time. These other solutions can, in the meantime, be considered and shaped, practical experience showing where most progress can be achieved.

Measures not requiring the amendment of regulations

This category of measures includes:

- e. improving the quality of patenting: 'raising the bar'⁴⁰;
- f. improving general knowledge about patenting: marking and detection;
- g. introducing the counter function;
- h. licensing code of conduct;
- i. wide publication;
- j. introduction of a patent watch;
- k. legal precedents.

The advantages of this category of measures are:

that interested parties are more able to take matters into their own hands;
practical expertise and experience relating to biotechnology, plant breeding, patent law and plant breeders' rights are available;
progress can be achieved faster and the outcomes can take the specific wishes, circumstances and concrete casuistry of those involved more into account.

⁴⁰ This does not apply to the Dutch system because, pursuant to the Patents Act 1995, patents are granted without the invention being tested against the patenting requirements. The court does test in cases in which a conflict is brought before the court and will then, of course, observe the relevant legal precedents and, if necessary, ask preliminary advice from the European Court of Justice if questions arise on the interpretation and application of EU Directive 98/44/EC.

8. The problem-solving approaches in more detail

a. A comprehensive breeding exemption

A comprehensive breeding exemption will, in any case, require the amendment of EU Directive 98/44/EC (and possibly also of Article 30 of the TRIPS Agreement), because of the current ample scope of the patent protection⁴¹ for plant-related inventions. The advice requested by the Minister from the Council of State on the conformity of a comprehensive breeding exemption with EU Directive 98/44/EC and the TRIPS Agreement will soon be available. This advice can be incorporated in the further consideration and estimation of the likelihood of success of more or less radical changes to the system.

As already mentioned in section 4 of this report, an unconditional comprehensive breeding exemption will be detrimental to several sectors. It is therefore vital to establish how a delineation of this kind could be used in such a way as to minimise damage to sectors others than the plant breeding sector.

An in-depth, time-consuming discussion at the European level will be needed to motivate the European Commission to propose an amendment. The Commission will only do so if there is sufficient **support** among member states and the various interest groups. This does not alter the fact that it may be meaningful to initiate the discussion on the access to reproductive material for plant breeding at the European level. The aforementioned letter from the Minister to Euro commissioner Barnier provides sufficient reference points with which to start a European discussion on access to genetic propagating material for plant breeding. The European Commission's report on EU Directive 98/44/EC expected at the end of 2012 can form a 'leg up' for an exchange of views of this kind.

b. Limitation of patentability

Limiting the patentability of biotechnological inventions is worth considering within the framework of EU Directive 98/44/EC.

An **interpretative statement** concerning Article 2 of the Directive could be a possible solution. This Article gives, among other things, a definition of the terms 'biological material', 'microbiological process' and a 'process for the production of plants'. A more detailed clarification and explanation of these terms, ensuing from legal precedents, among other things, may provide better understanding of the non-patentability of certain biotechnological inventions.⁴²

⁴¹ EU Directive 98/44/EC, Articles 8-10.

⁴² This is also the German Federal Assembly's approach. This concerns, among other things, the wish expressed in the adopted motion no. 17/8344 of 17 January 2012 not to grant patents for conventional breeding methods for plants (and animals) or for (to summarise briefly) descendants obtained by these methods and products derived from them.

In proceedings brought before the European Patent Office (among others, concerning broccoli and tomatoes), the Enlarged Board of Appeal has already laid down that combining classical methods for producing plants and other technical steps in a single patent application does not lead to patentability of the invention in question.

A farther-reaching alternative is to limit the patentability of plant-related inventions by amending the relevant articles of EU Directive 98/44/EC.

Such an approach has a number of advantages:

- An approach of this kind is probably compatible with the TRIPS Agreement (Article 27);
- No established rights will be affected as the change would only apply to new cases;
- There is less danger of a precedent effect leading to other exceptions.

Incidentally, in the practice of patenting and legal precedents, there is already a certain tendency to raise the threshold and limit patenting for inventions featuring naturally-occurring characteristics.

Non-patentability of naturally-occurring characteristics will require the amendment of Article 3(2) of EU Directive 98/44/EC.⁴³ This Article lays down that biological material which is isolated from its natural environment or produced by means of a technical process can also be the subject of an invention, even if it previously occurred in nature.

If the non-patentability of naturally-occurring characteristics is opted for, extra attention will have to be given to the requirements in the description of the invention, because they will have to show that the characteristic in question does not have natural origins.

This implies that characteristics which are formed artificially, not by means of crossing and selection, but by, for example, chemical mutagens or radiation with, for instance, gamma sources or UV light, and via modern breeding technologies with recombinant DNA, in the genome in question could remain eligible for protection under patent law.

The patentability will then be limited by excluding inventions relating to genes which code for (natural) characteristics found somewhere in nature (all biological material) or more selectively in specific biological sources to be specified at a later date.

For the record, it should be noted that it is naturally not the intention here to make inroads on the interests involved with further developments for the benefit of, for example, the biobased economy and the pharmaceutical industry, by limiting the patentability of certain biotechnological inventions. The same applies to the possibility of limiting the scope of protection conferred by patent law for biotechnological inventions discussed below. The parties involved in the consultations have indicated that they are willing to further exchange views regarding the question of where a possible cut-off point should be introduced in patentability and the scope of protection of biotechnological inventions.

⁴³ Implemented in the Patents Act 1995, Section 2(a)(2), opening lines, and 2(a)(2)(a).

c. Limitation of the scope of protection conferred by patent law

According to breeders' experiences, the non-patentability of plant varieties as such does not stand in the way of plants falling under patent law pursuant to a patent granted for plant-related inventions. In their view, there is, therefore, in fact still *de facto* protection of plant varieties under patent law.

If (inventions relating to) plants as such are excluded from patentability, plants and constituents of plants can still fall under the protection conferred by patent law for biotechnological inventions, as long as the scope of the legal protection conferred by a patent also extends to plants. This is a result of the scope of the patent protection laid down for biological material⁴⁴ in EU Directive 98/44/EC:

“The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.”

The patent right granted in certain cases therefore also extends to plants with characteristics conferred by the invention.

The exclusion of the patentability of plant-related inventions (products and processes) will therefore not necessarily lead to plants (and/or plant varieties or species) no longer falling under the legal protection of granted patent rights. Limitation of the patentability of certain creative achievements deemed undesirable may therefore, at the same time, have to be linked to curtailment of the scope of protection conferred by the patent protection of biotechnological inventions. This will mean that not only the **origin** of the biological material that plays a role in the biotechnological invention (naturally occurring genes, from a plant, artificially altered genes) has to be looked at, but also its **purpose** in the intended application (in a constituent of a plant, a plant variety, plant species, or other biological or non-biological material) in relation to the scope of legal protection (which is open to curtailment).

EU Directive 98/44/EC (Article 8) currently lays down the requirement that the scope of legal protection for biological material has to do with the characteristics conferred by the invention. This means that the use of naturally occurring genes from the biological material of one organism inserted into the genome of a similar or different organism can lead to patentability. This is possible if the technical feasibility of the invention is not confined to a particular plant variety⁴⁵ and as long as the normal requirements laid down for inventions under patent law (novelty, inventive step and industrial applicability, including agriculture) are met and, as regards the scope of protection, the characteristic of the biological material in question is conferred by the invention.

⁴⁴ EU Directive 98/44/EC, Article 8.

⁴⁵ EU Directive 98/44/EC, Article 4(2).

The German Federal Assembly's motion 17/8344 of 17 January 2012 is interesting as regards the limitation of the scope of protection. This motion also requests that the protective effect of product-by-process claims in plants (among other things) be limited to the use of the process stated in the patent.

This probably refers to the **purpose-bound protection of substances**. It constitutes a curtailment of the patent protection (as regards the scope of protection) to the cases specifically named in the patent, so that cases not named or cases for which a plausible case has not been made will not fall under the patent in question.

The provisional conclusions regarding options b and c are as follows:

The problem-solving approach for breeders could lie in a limitation, to be laid down at a later date, of the non-patentability of plant-related biotechnological inventions (having regard to the natural biological origin of the gene involved) in combination with curtailment of the scope of protection insofar and for as long as the biotechnological invention is expressed in usable biological material to be selected at a later date.

d. A limited breeding exemption

A legislative proposal for the introduction of a limited breeding exemption is under preparation and will be submitted to the House of Representatives shortly. The Minister has informed the House of Representatives by letter⁴⁶ dated 13 June 2012 that he is still waiting for a response from the European Commission to his intention to introduce a limited breeding exemption.

Other measures

These measures do not entail the amendment of any official regulations.

e. Improving the quality of patenting: 'raising the bar'

The stricter application of the requirements for patenting will reduce the number of patents deemed undesirable and may increase the legal certainty of the patents granted. This is a matter which must be tackled at the political level through the representatives of the member countries of the treaties in question. The process has, incidentally, already been set in motion. The European Patent Office has already become demonstrably stricter, both in the patent-granting phase and the phase in which it is still possible to oppose a patent after it has been granted. Furthermore, it goes without saying that it will still be possible for contracting parties to the conventions concerned to intervene where necessary to maintain the required level of patent quality assurance.

f. Improving knowledge about patenting: marking and detection

Breeders may be unaware of whether propagating material to be used for breeding has been patented. It is worth considering making agreements on voluntary marking by means of specifications on commodities and packaging used on the market. These markings could show whether, and if so, how, in certain cases the user of the biological material in question can take into account patent rights attached to the material.

⁴⁶ Parliamentary papers II 2011/12, 27 428, no. 233.

Consultations on this and the following topic are currently being held with Plantum and Niaba. Both organisations will let us know the possibilities from their point of view in the autumn.

g. Introducing the counter function

Providers and users of vegetable material could set up a counter function to show what biological material has been granted patent rights (who owns the patent right and when it was applied for or granted). This will help growers or breeders make timely choices with regard to which materials to use and, in connection with the patent rights in force, which countries to choose for development and exploitation purposes.

h. Licensing code of practice

The initiative for such a code of practice has already been taken by a group of more than ten vegetable seed companies which have joined forces in the Steering Committee. Their objective is to arrive at clear, unambiguous and simple conditions under which licences can be granted under patent for specific plant characteristics. The point of departure here is 'free access, but the access is not for free'. Consultations are now going on with the Netherlands Competition Authority (NMA) and the European Commission to further elaborate this code of practice so that, in time, it will not only be possible to apply it to vegetables but to plant breeding in general. This initiative is expected to produce results far more quickly than the initiatives named in points b and c. The advantages of a solution of this kind are that it could apply globally and that it would provide participants with optimal legal certainty. It is, however, a voluntary system, the success of which would depend on the conditions to be laid down and the degree of participation of the patent holders.

i. Wide publication

Wide publication of the results of plant breeding research eligible for this would prevent the subsequent granting of legally valid patents for the underlying inventions. On the other hand, the likelihood of the application of such inventions may then decrease in the cases still requiring large investments to reach market maturity. In these cases, the investor will neither be able to enjoy patent protection, which would temporarily prevent competitors from using the invention, nor recover the investment costs incurred by means of revenue from licences.

j. Introducing a patent watch

A patent watch comprises suitable parties which jointly follow the developments relevant to their sector in the field of patenting. If necessary, patents deemed undesirable are opposed. This approach has already been accepted in animal breeding.⁴⁷

European animal breeding organisations have been cooperating since 2001 in the European Forum of Farm Animal Breeders (EFFAB) in monitoring patent applications which may affect

⁴⁷ WUR Report 523: '*Ontwikkelingen in octrooien die invloed hebben op het gebruiksrecht van dieren in de veehouderij* (Developments in patents that impact on the right of the use of animals in animal production)'

their operational management. Since 2010, all the participants have been following a group of jointly agreed patent applications. They regularly receive an overview of the developments relating to patent applications drawn up by a patent agent. The possible consequences of the applications are discussed and a decision taken together as to whether or not to oppose them. By means of this informal path, consensus is achieved on what can and cannot be patented. The International Committee for Animal Recording (ICAR) also has a patent watch which goes by the name of 'Sentinel'. If, somewhere in the world, notices of objection are registered against excessively broad patents, the various organised watch groups can assist one another in collecting information. Researchers are also regularly active in finding 'prior art', often scientific articles which cover claims in a patent application. This can lead to patent applications not being honoured because the invention no longer meets the novelty requirement because of the 'prior art' in question.

With targeted patent watches, Plantum and LTO could discover whether patents which are relevant to their members are justifiable and not too broad or whether oppositions or nullification actions should be filed. With patent watches, a detailed picture could also be obtained of the nature, scope, significance, impacts and trends (increases, decreases) of patent applications, patents on 'native traits' and patents conferring protection on non-genetically modified plants.

k. Legal precedents

Making test cases to establish legal precedents can be an effective means of clarifying the interpretation of existing regulations in actual practice, thus establishing clearer boundaries. More clarity has, for instance, recently been achieved regarding the scope of the legal protection of biotechnological inventions in the case *Monsanto versus Cefetra et al.*,⁴⁸ and on the patentability of plant-related inventions in general in the aforementioned cases involving broccoli and tomatoes. A combination of a patent watch set up by growers and breeders and the conducting of appropriate opposition proceedings against granted patents could expedite further delineation of patentability and the scope of protection of biotechnological inventions considerably. Insofar as excessively broad patents are deemed to be a problem, there is also the possibility of making test cases of situations perceived to be problematic in order to establish legal precedents. In such cases, legal precedents serve as examples and can affect licence agreements which have already been concluded. If necessary, the latter can be revised, taking the precedents into account.

⁴⁸ European Court of Justice, Case C-428/08.

9. A simultaneous national and international approach

My provisional conclusion is that it would seem advisable both to continue looking for solutions at the national level and, at the same time, to reflect further on the problem-solving approaches outlined above at the European level.

On the one hand, the question of how to guarantee plant breeders (more) free access to genetic propagating material could be raised in Brussels and, on the other, a number of measures could be taken at the national level which would enhance these moves.

The target could therefore be the simultaneous deployment of a whole range of possibilities at both European and national levels. Basically, consultations with the German and French governments will have to show the extent to which joint action can lead to solutions with sufficient support which can then be elaborated in more detail.

After all, these countries also have a significant plant breeding sector. The appearance of the European Commission's report on the implications of patent law on bio and gene technology would be a suitable moment for the presentation of a jointly developed Dutch/German/French contribution.

10. Final conclusions and recommendations

The above analysis of the issue and the possible solutions described have led me to the following conclusions and recommendations:

1. The overlap between plant breeders' rights and patent law which has arisen with the emergence of modern technologies for plant breeding has disrupted the specific balance between patent law and plant breeders' rights as a result of which the free availability of and access to biological propagating material for plant breeding is at stake.
2. The point of departure for restoring this imbalance is to find problem-solving approaches to guarantee plant breeders easy access to biological starting material in the spirit of the innovation model of plant breeders' rights, without totally eroding patent law and causing consequent damage, without opening the door to radical changes to EU Directive 98/44/EC, and without making inroads on the significant interests of other sectors, such as medical and industrial biotechnology.
3. There is no single solution to the problem of the overlap between patent law and plant breeders' rights; a range of solutions at national and European level will be required which will have to be elaborated and deployed at the same time. A simultaneous national and international approach based on a continuous, constructive dialogue between government and interest groups would be advisable.
4. The government and relevant interest groups must specify the national solutions already identified in greater detail – expeditiously. This applies particularly to the realisation of a licensing code of practice and the introduction of a limited breeding exemption in the Patents Act 1995. Clarifying legal precedents in the field of patentability and the scope of protection conferred by patent rights granted should be encouraged, as should 'raising the bar' in patenting. Knowledge of patent law covering plant material should be improved with a view to reducing the legal uncertainty in this field.
5. The report to be published by the European Commission before the end of this year based on Article 16(c) of EU Directive 98/44/EC will form a suitable occasion to raise the subject of the overlap between plant breeders' rights and patent law and the access of the plant breeding sector to biological propagating material at the European level. In this context, the letter from the Minister to Euro commissioner Barnier provides good reference points for a European exchange of views.
6. The amendment of EU Directive 98/44/EC will require a great deal of effort and sufficient support from EU member states and interest groups. It would, therefore, be advisable to consult with Germany and France – countries with significant plant breeding sectors – with a view to drawing up a joint contribution to the discussions at the European level.
7. Changes to the system by means of amendments to EU Directive 98/44/EC should be as limited as possible and plant specific in nature in order to prevent a precedent effect and possible damage to sectors other than the plant breeding sector.

A further delineation of definitions in the Directive in question so as to arrive at a suitable limitation of the patentability and scope of plant-related biological inventions seems most logical and could possibly be realised by means of an interpretative statement. A comprehensive breeding exemption will require a much more radical intervention in patent law, possibly raising questions regarding compatibility with the TRIPS Agreement, and will be much more difficult to realise without the addition of a great many clauses.

Appendices:

1. Letter from the Minister of Economic Affairs, Agriculture and Innovation to the interest groups.
2. Summary of responses from the interest groups during the written phase of the consultations.

> Return address PO Box 20101 2500 EC The Hague



Mr B.E.M. Wientjes
VNO-NCW
PO Box 93002
2509 AA THE HAGUE

**Directorate-General for
Entrepreneurship and
Innovation**
Department of Innovation

Address
Bezuidenhoutseweg 20
2594 AV The Hague

Postal address
PO Box 20101
2500 EC The Hague

Invoice address
PO Box 16180
2500 BD The
Hague

T +31 (0)70 379 8911
(general)
www.rijksoverheid.nl/eteni

Handled by
Dr J.H.A.A. Uitzetter

T +31 (0)70 379 7942 F
+31 (0)70 379 6480
j.h.a.a.uitzetter@minez.nl

Our reference
O1/1/ 11044179

Date 11 APR 2011

Concerning: Breeding exemption in patent law

Dear Mr Wientjes,

As you will already be aware, an analysis of the legal possibilities of a breeders' exemption in patent law in the light of international regulations was recently submitted to the House of Representatives at its request (Parliamentary papers II 2010/11, 27 428, no. 182, with appendix).

In brief, this analysis states that:

- in the light of international regulations, a limited breeding exemption is already deemed feasible.
- a legislative proposal to introduce a limited breeding exemption in the Patents Act 1995 is currently under preparation.
- because of the need for conformity with international regulations, particularly the TRIPS Agreement and EU Directive 98/44/EC, a comprehensive breeding exemption is not deemed feasible at the present time.
- if there is sufficient support, a possible amendment of the aforementioned Directive and, in as far as this is necessary, the TRIPS Agreement, would require some time.
- in order to ensure that the interests are weighed meticulously, further investigation is needed into the desirability and feasibility of a comprehensive breeding exemption, also in view of the interests of sectors other than the plant breeding sector.
- it is not yet definite that the Netherlands will argue for the introduction of a comprehensive breeding exemption in the patent law of EU member states or more internationally, because in addition to the advantages, there are also disadvantages to a comprehensive exemption.

During the recent period of parliamentary exchange of views on Plantum's wish to introduce a comprehensive breeding exemption in patent law, alternatives for solving breeders' problems have emerged (including those proposed by P. van der Kooy in: 'Towards a Breeders Exemption in Patent Law?' [2010] E.I.P.R., no. 11, pp 545-552).

Alternatives which may be faster than amending EU Directive 98/44/EC or the TRIPS Agreement may contribute to solving breeders' problems. I would be pleased to elaborate on these – and, if applicable, other – alternatives with you within the framework of the forthcoming investigation. I would be grateful for your cooperation in this matter. My aim is, after this coming summer, to inform the House of Representatives of the outcomes of this investigation and to further define a position on the solutions deemed feasible.

Setup of the investigation

In order to ensure that the investigation progresses as efficiently as possible, it will begin with a written phase. Views will be exchanged in a later phase, on the basis of this written phase.

Phase 1.

- **Determination of the desirability and feasibility of a comprehensive breeding exemption in patent law;**
- **Identification of possible alternatives for solving breeders' problems, and their assessment by the trade associations involved, VNO/NCW, Plantum, NIABA, Nefarma and LTO.**

You are requested, in connection with:

- a. **Assessment of the desirability:** to indicate, with reasons, what you think of the introduction of a comprehensive breeding exemption in patent law. In your reply, please indicate the positive or negative consequences you expect for companies in your sector and why you endorse or oppose the introduction of a comprehensive breeding exemption.
- b. **Assessment of the feasibility:** to indicate, with reasons, how you estimate the feasibility of the introduction of a comprehensive breeding exemption in patent law, for the EU and globally. In your reply, you can, for example, indicate whether, and if so, what interest groups have or will express national or international opinions on a comprehensive breeding exemption, so that these standpoints can be taken into account in good time with a view to creating support, where applicable, and the obstacles (time related and otherwise) you feel can be expected in an international discussion on this topic.
- c. **Alternatives:** to name alternatives, if possible, and to indicate their advantages and disadvantages.
- d. **Prioritisation of solutions:** to indicate, with reasons if possible, what alternatives are preferable in your opinion, also taking into account the estimated time involved in their realisation compared with the introduction of a comprehensive exemption in patent law.

Please ensure that I receive your reply to this letter no later than six weeks after its date. I am assuming that you will have no objection to your contribution being shared with the other participants. If this is not the case, please inform me accordingly.

Phase 2

Assessment of the outcomes of phase 1 by means of written reports

The 'yields' from phase 1 will be summarised in a report, along with provisional policy-related conclusions, as quickly as possible. This report will serve as input for phase 3.

Phase 3

Administrators' consultations with interest groups

The written report from phase 2 will form the basis for these consultations. The objective of the consultations is to lay the foundation for the best-supported roadmap for realising the targeted solutions.

Phase 4

The House of Representatives will be informed in more detail on the basis of the results from the earlier phases. This is expected to take place after the summer recess.

This letter has been sent to the organisations, VNO-NCW, Plantum, NIABA, Nefarma and LTO.

I trust that you are willing to cooperate with this request, the objective being to arrive at feasible and workable solutions to the problem in question through close consultation with all the interested parties,

Yours sincerely,

[Signature]

Maxime Verhagen
Minister of Economic Affairs, Agriculture and Innovation

Analysis of the written consultations with the trade associations and VNO-NCW on the patenting-related problems facing breeders¹

In addition to an unsolicited response from several large companies, the written consultations with the trade associations and VNO-NCW yielded the points below.²

During the consultations, those involved were asked to take a standpoint, giving reasons, on

1. the desirability of a comprehensive breeding exemption in patent law and
2. the feasibility of a comprehensive breeding exemption in patent law and
3. to name possible alternative options and
4. to allocate a priority to them.

1. The desirability of a comprehensive breeding exemption in patent law

Proponents: Plantum and LTO.

Opponents: NIABA, Nefarma and the large companies.

VNO-NCW: Seek a solution which takes the interests of all parties into account.

Plantum's arguments for a comprehensive breeding exemption:

- o Will prevent erosion of plant breeders' rights.
- o Patent law is not used to protect inventions but to protect the genetic biodiversity of agricultural and horticultural crops.
- o Preservation and access to genetic sources are under threat.
- o The 'open source innovation' of plant breeders' rights with guarantees of reasonable remuneration for the developer of new varieties is negated by patent law.
- o The imminent monopoly positions in breeding are socially undesirable.
- o Patent law is not intended for the protection of plant varieties that now fall under it.

¹ The state of affairs as of 23 August 2011. The interest groups have approved the summaries of their contribution.

² This contribution is the joint response of DSM, Dow Benelux, NXP Semiconductors, Philips, Shell, Tata Steel Europe, AkzoNobel and Unilever (the large companies).

LTO's arguments for a comprehensive breeding exemption:

- o Plant breeding is crucial to the Dutch economy, partly because of the choice of leading economic sectors.
- o The breeding sector is running into problems with patents for applied technologies and plant characteristics.
- o In fact, patents make it impossible to use the best material for producing new varieties.
- o Only a full breeders' exemption will be adequate to prevent growers and the knowledge infrastructure from being sucked into the revenue model of the biotechnology-focused seed companies.
- o LTO advocates retaining plant breeders' rights and the related full breeders' exemption, including for varieties developed with modern biotechnology, in conformity with Plantum, VBN and DPA's standpoint.

NIABA's arguments against a comprehensive breeding exemption:

- o Erosion of patent law, biological material will be free of charge and it will no longer be possible to recover high investments without licence fees.
- o It will inhibit innovation: less patenting and more secrecy (as a form of protection) can be expected.
- o Competitive disadvantage for innovative breeding and biotech companies with intensive R&D activities, as opposed to traditional breeders.
- o It will have a negative impact on Dutch and European export economy.
- o Export outside the Netherlands or Europe will be unlawful.
- o The problem has not been clearly defined; what patents are we talking about?
- o Inventions will be freely copied through plants, it will have negative consequences for the public health of the third world and the development of plant vaccines will be hampered.
- o Access to propagating material will decrease, due to stricter contract conditions and supplies of propagating plant material to countries with poorer patent protection may be discontinued, resulting in the loss of knowledge and jobs and a reduction in the supplies of desirable plant breeder's produce.
- o The requisite renegotiation of EU Directive 98/44/EC will lead to a great deal of legal uncertainty and endless discussion on 'no patent on life'.
- o Companies are likely to move to countries with more reliable patent protection which will be detrimental to policy concerning the leading economic sectors which has already gone into force.
- o A hand has already been extended: NIABA agrees with a limited breeding exemption.

Nefarma's arguments against a comprehensive breeding exemption:

- Full exemption will destroy innovation.
- It will be possible to use patented inventions without payment to the inventors who have made considerable investments.
- This will not solve breeders' problems and will damage other sectors.
- Comprehensive exemption is contrary to the Biopatent Directive (EU Directive 98/44/EC) and the TRIPS Agreement.
- Full exemption will lead to enormous damage to thousands of innovative companies, including those within the plant breeding sector.
- Full exemption will lead to the erosion of patent law and compromise the patent system.
- Publishing inventions but not paying for their use, regardless of considerable investments.
- Full exemption will mean free licences and will be contrary to Article 31 of TRIPS (reasonable compensation obligation).
- It will inhibit innovation, because secrecy will become an alternative form of protection and there will no longer be any research (in the Netherlands) as investments can no longer be recovered.
- The problem has still not been clearly defined: how many and what patents are blocking plant breeding and how long do they still have to run?
- In the first instance, use the current options provided by patent law before taking radical steps which may have negative consequences outside the plant breeding sector.
- A comprehensive breeding exemption will be detrimental to access to material, because other protection measures will lead to secrecy, strict licensing conditions for further use and a possible import stop to Europe to prevent free use in the Netherlands or Europe.
- This form of piracy will be detrimental to plant breeding, (bio)pharmacy and the use of plants as a source for the development of new medicines.
- In this way, inventions in biotechnology will be easier to achieve by means of plants (rather than other organisms) than by making them freely copiable.
- The absence of patent protection for plants will lead to companies moving their R&D elsewhere and new developments concerning plant-made pharmaceuticals will take place elsewhere.
- As a result of the requisite and time-consuming amendment of EU Directive 98/44/EC and the TRIPS Agreement, there will be a prolonged period of uncertainty which will affect legal certainty, so that Europe's competitiveness will be disadvantaged in respect of other countries.
- The precedent effect could lead to more requests from other sectors for 'special treatment'.
- There is a risk that R&D activities will be moved to countries/continents with clear patent protection.
- It will have negative consequences for the European and Dutch economies.
- The Dutch leading economic sector policy cannot be lived up to in this way.

Large companies' arguments against a comprehensive breeding exemption:

- Erosion of patent law, while plant breeders' rights only provide protection for plant varieties. Genetic material will only be partially protected by means of patent law.
- Patent law will be easy to circumvent. Investment will not be forthcoming.
- A comprehensive exemption is contrary to the Biopatent Directive (EU Directive 98/44/EC) and the TRIPS Agreement.
- A negative precedent effect can be expected, with a domino effect on other sectors which will also plead for exemption.

2. The feasibility of a comprehensive breeding exemption in patent law:

Plantum and LTO are optimistic about its feasibility.

NIABA, Nefarma and the large companies rate feasibility as 'low'.

VNO-NCW: seek a solution which takes the interests of all parties into account.

Plantum's arguments for the feasibility of a breeding exemption:

- The feasibility of the full breeding exemption is a political choice. If the political body opts for it, the question is whether there will be legal hindrances. This does not appear to be the case in Plantum's analysis.
- Biotechnology companies are primarily engaged with the development of new (breeding) technologies and hardly at all with the development of new plant varieties. These new technologies will still be patentable and will remain eligible for licence fees. The full breeding exemption will have no influence on this.
- Very profitable business operations are possible in the plant breeding sector without the use of patents on plant characteristics; this has been indisputably established in the last 70 years.
- Plant breeders' rights have stimulated innovation and will continue to do so.
- The legal opinion of a reputable international law firm has shown that the Biopatent Directive (EU Directive 98/44/EC) could be amended.
- The article by Mr P. van der Kooy also shows that a full breeders' exemption in patent law is 'TRIPS-proof'.
- It is important to involve the business community in the way in which the law and regulations are amended at the EU level so that no unnecessary detrimental effects arise for companies outside the plant breeding sector.

LTO's arguments for the feasibility of the breeding exemption:

- A thorough approach based on unambiguous political will is needed in the Netherlands.
- Life Sciences companies must be convinced that it is not our intention to jeopardise their positions and that they serve higher interests.
- LTO has already taken action at the COPA-Cogeca level to exhort the EC to evaluate the Biotechnology Directive (EU Directive 98/44/EC).
- Amendment of the Biotechnology Directive (EU Directive 98/44/EC) will only be possible if the political body and the industrial community pull together.

NIABA's arguments against the feasibility of the breeding exemption:

- The organisation is afraid that the process will be very prolonged and that earlier discussions will be repeated.
- Expects large conflicting interests and that the sectors will take a stand against one another because the Biopatent Directive (EU Directive 98/44/EC) is not only important for plant biotechnology, but also for medical and industrial biotechnology. Biotechnology is the key technology for biobased economy.
- Stagnation in innovation can be expected as a result of a new period of uncertainty about the content of the Biopatent Directive (EU Directive 98/44/EC).
- Nefarma, Biofarmind, VNCI, DSM, Shell, Philips, Unilever, Nunhems, Enza Zaden, Monsanto and Syngenta are also against a comprehensive exemption.
- The introduction of a comprehensive exemption lacks international support.
- Europe is in danger of becoming isolated with regard to supplies of innovative products resulting in conflicts, trade disruption and possible sanctions from the WTO.
- The risk of problems with importing plant material with biotechnological inventions will force Europe to become self-sufficient with regard to cattle feed and food crops.

Nefarma's arguments against the feasibility of the breeding exemption:

- Impossible from the practical point of view and negative consequences on its introduction.
- Prolonged period of legal uncertainty and big risks if the Patent Directive (EU Directive 98/44 /EC) is renegotiated.
- All the elements of the Directive will come under discussion again.
- Finding a political compromise will be extremely time consuming.
- Prolonged legal uncertainty will have negative effects on the European innovation climate.
- R&D activities will be moved outside Europe.
- The solution must have international support.
- TRIPs will also have to be renegotiated.
- On introduction in the Netherlands or Europa, there is a likelihood of trade disruption and conflicts with the United States and South America.

Large companies' arguments against the feasibility of the breeding exemption:

- Not feasible because of TRIPs and the Biotechnology Directive (EU Directive 98/44/EC). The amendment of TRIPs and the Biotechnology Directive is neither desirable nor realistic.

3. Alternatives and 4. their prioritisation

Plantum's alternatives and prioritisation:

1. Legally regulated automatic licensing for a fixed payment.
2. A prohibition on patents on anything that occurs naturally.
3. A sector solution to arrive at a system in which breeders can operate under reasonable conditions and without delays in obtaining licences for the use of all biological material for improving and marketing new varieties.

Solution in accordance with the criteria:

1. **Access to all biological material;** this concerns all the biological material which is put on the market or is available in the public domain.
2. **Access for all who are engaged with plant breeding activities.**
3. **A simple system of access.**
4. **Access is free.** This means that all biological material may be used for the breeding and commercialisation of a product, including any desired part of the DNA of the biological material which has been cross bred into the material in question, without having to ask for permission and/or make agreements on this in advance for commercialisation.

LTO's alternatives and prioritisation:

Evaluate and amend the European Biotechnology Directive (EU Directive 98/44/EC) as soon as possible.

NIABA's alternatives and prioritisation:

1. Seek a solution within the plant breeding sector, including the current dialogue on licences under preconditions, along with other ongoing initiatives such as the introduction of a limited breeding exemption, improvement of the quality of patenting and knowledge about patenting.
2. The quality of patenting could be improved and a clearer explanation of the Biopatent Directive (EU Directive 98/44/EC) achieved by, among other things, accelerating the opposition procedure against patents in actual cases and generating general rules for similar cases in the future.
3. Existing legal possibilities include being able to enforce access to biological material by means of patent law and to prevent monopolisation by means of competition legislation.

Nefarma's alternatives and prioritisation:

1. Seek a solution within the plant breeding sector by means of dialogue, with or without an independent intermediary. Give this dialogue sufficient time.
2. Provide more information on the possibilities under the existing Directive.
3. First take stock of the knowledge and experience of countries in which a limited exemption has already been introduced.
4. Leave scope for the ongoing quality improvement processes, such as 'Raising the bar' for patenting at the European Patent Office, and legal precedents which provide rapid clarification of the interpretation of the Patent Directive (EU Directive 98/44/EC).

5. Use other alternatives, such as compulsory licences, along with competition legislation to prevent monopolisation.

VNO-NCW:

Does not outline any substantive alternatives, but does indicate that the initial discussions show possibilities.

Large companies' alternatives and prioritisation:

1. Work out a solution through a trade association, if necessary with the assistance or intermediation of third parties, with the possibility of licensing via a sector-related group (for example by means of a barcode and other identification of licences for manufacturers and the 'fast moving consumer goods' distribution channel).
2. Legal procedure based on unfair competition (misuse of a dominant position or the possible misuse of patent law).
3. Compulsory licences and legal precedents in this field through test cases.
4. Only if the existing set of instruments is shown to be ineffective should we look at whether additional measures are needed.
