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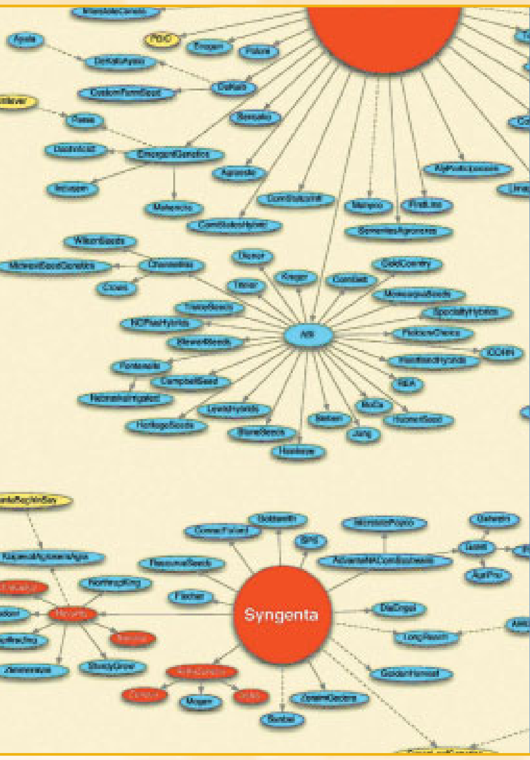
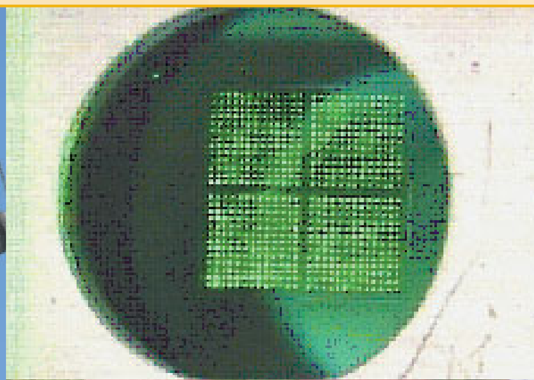
Breeding Business

The future of plant breeding in the light of developments in patent rights and plant breeder's rights

Niels Louwaars, Hans Dons, Geertrui van Overwalle, Hans Raven, Anthony Arundel, Derek Eaton, Annemiek Nelis




CGN Report 2009-14 (EN)

Centre for Genetic Resources, the Netherlands (CGN)

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Ministry of Agriculture, Nature and Food Quality

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Contents

Summary

Plant breeding serves an important public interest. Two intellectual property (IP) systems are relevant for the protection of innovations in this sector: plant breeder's rights and patent rights. Some exemptions play an important role in plant breeding, such as the 'breeder's exemption', which is unknown in patent rights. This study shows that patent rights together with the technological developments in biology contributes to the current concentration in the plant breeding industry and that this is threatening future innovation.
The study leads to a number of recommendations; the most important are:
- *amendment of legislation and regulations,*
- *increasing the quality of patents, and*
- *improvement of the way that innovators use their patent rights.*

Initiatives within the policy fields of economy, biodiversity, international cooperation,, and knowledge are proposed as well.

Upon request of the Netherlands Minister of Agriculture, Nature and Food Quality a study has been conducted into the future of plant breeding in the light of developments around plant breeder's rights and patent rights. The following questions were formulated:
- Present a review of the trends in the different plant breeding subsectors and the production of plant propagation material and in plant biotechnology. What is the situation of the concentration of companies and the role of intellectual property in this? Who are the main patent holders in plant breeding?
- What are the socio-economic consequences of these developments for the diversity of companies and adequate market competition? What are possible consequences for the (inter)national breeding sector, the role of Dutch companies, and for developing countries? What are the possible consequences for the use of genetic diversity, for food security and quality, and for the production of green raw materials (biobased economy)?
- Which positive and negative effects are to be expected for which parties as result of these developments and how could undesirable effects be restricted or prevented?
- Which legal aspects play a role when taking measures to prevent undesirable effects? Which different legal systems in the world play a role in this?

The study comprised an investigation into relevant trends in the plant breeding sector and a number of semi-structured interviews with stakeholders. This report describes the major trends, analyses these trends in the light of the questions above, and formulates recommendations based on a number of normative points of departure for arriving at conclusions.

Innovative plant breeding plays an important role in a number of public objectives, such as food security, environment, sustainability, and a number of transitions in the rural area, e.g. to a 'biobased economy'. The plant breeding sector is of high economic significance with a steadily growing export value and a significant 'spin off' to the trade in final products, in particular ornamentals. The Dutch plant breeding sector holds a very strong position in vegetable crops, ornamental crops, and potatoes. The Netherlands plays a leading role in fundamental, strategic and applied research in plant genetics and plant breeding. The strong knowledge sector in The Netherlands is important for the plant breeding sector, including foreign seed companies that often have major R&D activities in The Netherlands.

Innovation in plant breeding is dependent on specific knowledge, the development and application of new technologies, access to genetic resources, and capital to utilise those factors. Access to technology as well as genetic material is essential for the development of new plant varieties. Competition and profitability of the plant breeding sector play a major role in the sustainability of the total food chain. Farmers and growers have an interest in competition in the seed market.

Plant breeding is characterised by continuous innovations and the ever ongoing development of new varieties that ever better meet the requirements of producers and consumers. The driving force behind this innovation is acquiring or increasing market share. The plant breeder's rights system is a specifically designed legal system for the protection of plant varieties. Plant breeder's rights give the developer of a new variety the right to exclude others from commercialisation. The breeder's exemption ensures that other breeders may in a sort of 'open innovation' use such a protected variety in their own breeding programme, making the best properties of these varieties available to the breeding programmes of competitors.

Technological developments showed a rapid progress in recent decades. One significant change results from the developments in molecular biology, initially outside agriculture, which led to the introduction of patent rights in the breeding sector. This system of intellectual property rights (IPR) certainly not only applies to genetic modification but to an ever broadening range of new techniques that make plant breeding more efficient and effective.

Patent positions in combination with technological developments have in recent decades led to a large consolidation move among breeding companies. For most crops only a few companies are controlling a large part of the world market. This makes a growing part of the global food supply dependent on a few companies. The access barrier for new companies to the plant breeding sector is high, where IPR plays a role next to the large amount of knowledge and expertise required to set up a breeding company and the long development period for new varieties. Farmers and growers fear that their freedom of choice is threatened and that no varieties will be developed for certain crops that specifically meet their requirements when the decision power in breeding moves away from The Netherlands.

Plant breeder's rights and patent rights may be conflicting in plant breeding. Specific liberties of breeders and farmers are lost with the patentability of plant-related inventions. The significance of access to genetic resources for the development of new plant varieties was already recognised at the time of the Plant Breeders' Decree of The Netherlands ("Kwekersbesluit") in 1941 and has as 'breeder's exemption' been confirmed in more recent international treaties such as the International Union for the Protection of New Varieties of Plants (UPOV 1961/1978/1991), the Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO-TRIPS - 1994), and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA - 2001).

Patent rights hold possibilities for strategic use, which may lead to lack of clarity in the market and to monopolistic behaviour. It may also lead to high costs of legal assistance. Plant breeder's rights have no such effects.

The study also focuses on aspects of biodiversity and developing countries. Recent analyses of the trends in genetic diversity of crops indicate that in Northwest Europe and North America genetic erosion has been brought to a halt and that diversity increases as result of a widespread use of genebank materials and new techniques, making use of such materials in breeding more effective. It is uncertain whether this trend is also visible at a global scale and whether it will continue when the number of breeding programmes diminish as a result of further concentration in the sector. The discussions about the roles of IPR in plant breeding also concern developing countries. These countries have difficulty in meeting the international IP protection requirements while at the same time optimising their IPR systems to meet the needs of their own society. Trade-related aspects of IP may conflict with development-related aspects. A policy aimed at restoring the balance between the rights of the inventor on the one hand and public interests at the other in The Netherlands implies that developing countries should be able to find this balance within the frameworks of TRIPS. This means that The Netherlands should not on its own, or via the EU, impose stricter IPR requirements on developing countries (in trade agreements) and should in UPOV also take the interests of developing countries in the interpretation of the Convention (in particular farmer's exemption and non-commercial use) into account.

The research team has formulated the following normative assumptions on the basis of literature research, analyses of the main trends in plant breeding, discussions with experts on the Advisory Board and interviews with stakeholders:

- Plant breeding should make a sustainable contribution to global food supply and sustainable agriculture and horticulture.
- Access to genetic variation is essential for future crop breeding.

- Innovation capacity in the breeding sector should be preserved, and even strengthened.
- Competitive strength in the sector should be preserved by a diversity of companies.
- The Netherlands breeding sector should be enabled to defend its competitive position in a fair way.
- Proper safeguards should be created for obtaining a decent and profitable market share.
- Intellectual property rights should stimulate innovative strength.

Patent rights, together with the way these are granted and exerted, contributes to a decreasing diversity in breeding companies and threatens innovation in plant breeding. The general conclusion on the basis of the normative assumptions above is that the patent system needs to be amended. This can be reached by: amendments of legislation and regulations, by increasing patent quality, and by improvement of the way that innovators use their patent rights.

Amendment of regulations is necessary to increase the room for innovation in plant breeding. This can be reached by restricting the scope of patents in plant breeding, and more specifically by reinstating the exemption of patents on plant (varieties) or by introducing full breeder's exemption in patent rights. Both options should preferably be implemented at European level, possible via a revision of the Biotechnology Directive, and preferably in consultation with other countries with a significant plant breeding sector (such as the USA, Japan, and China). Because implementation of the proposed amendments may take a long time the report also contains recommendations for other policy options that can be introduced simultaneously, such as tightening of the evaluation criteria for granting patents and banning the strategic use of IP rights that stimulate monopolistic tendencies in plant breeding.

Finally, the recommendations of the report discuss some legal consequences of the policy options and formulates recommendations for related policy areas such as competition law (economic policy), access to genetic resources in biodiversity policy, IP aspects of development cooperation policies and knowledge policy.

1. Introduction

1.1 Background

The direct cause for conducting a study into the future of plant breeding for agriculture and horticulture in the light of plant breeder's rights and patent rights is the Senate debate on the budget of the Netherlands Ministry of Agriculture, Nature and Food Quality on 27 January 2009 where biotechnology, and the underlying relationship between patent rights and plant breeder's rights, was discussed. This subject was also raised during a hearing of the Lower House of Parliament on 28 January 2009. On 8 April 2009 the subject was again discussed in a Parliamentary Committee Meeting about socio-economic aspects of genetically modified organisms (GMOs).

The Minister of Agriculture, Nature and Food Quality, in consultation with the Minister of Economic Affairs, has then assured that a study would be carried out into the roles of patent rights and plant breeder's rights in plant breeding. Wageningen University & Research Centre has then been commissioned to form an interdisciplinary team to study the relationship between patent rights and plant breeder's rights, as well as into the impact of these regulations on the structure of the plant breeding sector in the Netherlands and abroad.

Such questions are not new. The Netherlands Agricultural Research Council has already in 1984 discussed the relationship between plant breeder's rights and patent rights in plant breeding with far-reaching conclusions[1].

1.2 Research questions

The assignment for this study reads as follows:

- Present a review of the trends in the different plant breeding subsectors and the production of plant propagation material and in plant biotechnology. What is the situation around the concentration of the companies and the role of intellectual property in this? Who are the main patent holders in plant breeding?
- What are the socio-economic consequences of these developments for the diversity of companies and adequate market competition? What are possible consequences for the (inter)national breeding sector, the role of Dutch companies, and for developing countries? What are the possible consequences for the use of genetic diversity, for food security and quality, and for the production of green raw materials (biobased economy)?
- Which positive and negative effects are to be expected for which parties as result of the sketched developments and how could undesirable effects be restricted or prevented?
- Which legal aspects play a role when taking measures to prevent undesirable effects? Which different legal systems in the world play a role in this?

The following research questions have been formulated to arrive at well-founded answers:

1. Which trends can be observed in the plant breeding sector?
    - *Technological* trends. Which are the technological trends in the various subsectors of plant breeding?
    - *Socio-economic* trends. Which are the main trends in the organisation and structure of the plant breeding sector? Can a concentration of companies be observed in the sector or in certain subsectors?
    - *Trends in IPR*. How has IPR evolved? Who are the main patent and plant breeders' right holders in the plant breeding industry?

[1] NRLO, 1984. Kwekersrecht en octrooirecht in relatie tot genetische manipulatie bij planten (Plant breeder's rights and patent rights in relation to genetic manipulation in plants). Studierapport no. 14d. The Hague, Netherlands Council for Agricultural Research.
(In Dutch) 'Such a patent right on one gene would then form an absolute barrier for the use of certain varieties by farmers and breeders. The commission assumes that the legislators have not intended such an unrestricted monopoly in either of the legal systems.'

2. What is the impact of these trends on the plant breeding industry?
   - *International.* What are the possible consequences of these developments for the diversity of companies in the (international) plant breeding sector and for competition in this sector? What are the possible effects on the use of genetic diversity? For maintaining food security? For the *biobased economy*? And for developing countries?
   - *Netherlands.* What are the consequences of these developments for the diversity and competition in the Dutch plant breeding industry? Which are the (positive and negative) effects for which parties as result of the identified developments?
3. Which are the options for effective policies?
   - *Legislator*. Which measures can be taken by (national, European or international) legislators to restrict or reverse possible negative effects of these trends in the light of the relevant policy objectives?
   - *Executive bodies*. Which initiatives can be taken by (national, European or international) authorities and bodies to restrict possible undesirable effects?
   - *Users.* To which behaviour can IP users themselves be stimulated? Which behaviour is desirable and contributes to the policy objectives?

1.3 Research group

The study has been carried out by a team of scientists, supported by an Advisory Board, acting as sounding board during the study.

1. Research Team
   - Dr. Anthony Arundel, United Nations University (MERIT), Maastricht University
   - Prof. Dr. Hans Dons, Management Studies, Wageningen University
   - Derek Eaton, MSc, LEI, Wageningen UR
   - Dr. Niels Louwaars, MSc, Centre for Genetic Resources (CGN), Wageningen UR
   - Dr. Annemiek Nelis, Center for Society and Genomics, Radboud University Nijmegen
   - Prof. Dr. Geertrui van Overwalle, LLM, Tilburg Institute for Law, Technology and Society (TILT), University Tilburg
   - Hans Raven, LLM, Intellectual Property Expert
   - Yrrah Stol, MSc, Center for Society and Genomics, Radboud University Nijmegen
2. Advisory Board
   - A. van Elsen, MSc, Plantum NL
   - Dr. P. van der Kooij, LLM, Leiden University
   - Prof. M. Koornneef, Max Planck Institut für Pflanzenzüchtung, Köln, Germany
   - Prof. R. Rabbinge, Wageningen University
   - P.C. Schalkwijk, MSc, AkzoNobel
   - Dr. J. Staman, Rathenau Instituut
   - J. Winnink, MSc, Netherlands Patent Office
   - J. Wisse, MSc, NIABA
3. Principals
   - J. Satter, MSc, Ministry of Agriculture, Nature and Food Quality
   - Dr. J. Uitzetter, LLM, Ministry of Economic Affairs
   - M. Valstar, MSc, Ministry of Agriculture, Nature and Food Quality

1.4 Methodology

This report is the result of research, consultations and interviews. Most of the study work consisted of technical, socio-economic and legal research into the current trends in plant breeding and into the impact of these trends on the industry. The gained insights were presented to the Advisory Board for discussion. Contact was sought with the various stakeholders in the sector as a check against the reality of actual practice.

1. Trend analysis: relevant trends have been described and analysed on the basis of literature studies during the period May – August 2009.
2. The trends were discussed and decisions about the methodology of the follow-up were taken during a workshop with team, board members and principals (in Doorwerth, 21-22 July 2009).
3. This methodology comprises a number of interviews with stakeholders in the various plant breeding subsectors (Annex 1). The names of the interviewees were provided by the representatives of the plant breeding sector (Plantum NL) and biotechnology sector (Niaba) on the Advisory Board. In addition, members of the Advisory Board themselves have been interviewed and some additional persons on basis of the formulated questions.
4. A draft report was presented for discussion to Advisory Board and Principals during a meeting in The Hague (2 October 2009).
5. At the end of October a second draft of the report was presented for comments to Advisory Board and Principals.
6. The report was presented to the Minister of Agriculture, Nature and Food Quality in early December 2009.

1.5 Preface

After this Introduction the report consists of five parts.

- The first part (Chapter 2) describes relevant aspects of plant breeding and the two intellectual property systems on which this study focuses (plant breeder's rights and patent rights). These aspects are particularly relevant for readers without adequate background information on these subjects.

- Chapter 3 presents the results of the individual trend analyses: the significance of the sector in the Netherlands (3.1), technological developments (3.2), socio-economic developments (3.3), trends in intellectual property (3.4), trends regarding policy and use of genetic resources (3.5), and trends in developing countries (3.6). These trends provide the basis for the analysis in Chapter 5.

- Chapter 4 presents the views of stakeholders on these issues.

- Chapter 5 analyses the relationships between the observed trends and intellectual property on basis of a number of normative assumptions and on basis of the two objectives of patent rights and plant breeder's rights.

- Chapter 6 presents the answers to the questions raised and formulates recommendations on basis of some normative choices made by the Research Team.

2. Setting the scene – basic information on plant breeding and intellectual property

Preface

This chapter provides basic information on the two themes that are subject of this report: plant breeding and intellectual property. The chapter serves as background information for the reader and puts the analyses of the following chapters in perspective.

Section 2.1 on plant breeding presents the significance of the sector in society, the significance of genetic resources for the sector, a brief description of the most important business models and a description of the business economic background of the sector, illustrated by the situation in the vegetable seed subsector.

Section 2.2 introduces patent rights and plant breeder's rights, the functioning of these two intellectual property systems, and the relationship between both systems.

2.1 Plant breeding

2.1.1 Significance of plant breeding in society

Plant breeding is part of an innovation chain reaching from fundamental research through to the production and marketing of seeds and planting materials. This field of applied research makes use of a range of techniques and methods from different disciplines, in particular genetics and mathematical statistics, combined with plant physiology, phytopathology, and (bio)chemical analysis, in recent decades supplemented by a number of molecular biological concepts and techniques in plant biotechnology.

Plant breeding is the basis for propagation material in agriculture and horticulture and creates the plant varieties that form the cradle of a continuous yield increase of crops, thus making an important contribution to food security. Plant breeding also contributes to sustainability. Crops must adapt to systems innovations in crop production such as vegetable cultivation on rockwool on the one hand through to organic farming systems on the other, and transitions, e.g., towards 'biobased economy'. Plant breeding also contributes to a number of ecological policy objectives such as reduced environmental pollution by pesticides, to product demands by the market, such as baking quality of wheat, taste of fruit, diversity of ornamentals and vegetables (Cherry, Roma, tasty-tom and other tomatoes), and welfare and wellbeing (e.g. ornamental products).

Worldwide, plant breeding is also considered as a relevant technology for adaptation of food production to the changing climate. Tolerance to extreme weather conditions and advancing pests and diseases can often be incorporated into crop genetics. The Netherlands is rated as one of the top three countries in the world in terms of export value of seeds and planting materials. This provides the basis of a highly developed production sector, in particular in horticulture and potato, and highly qualified employment in the knowledge economy, which is one of the policy priorities of the government of The Netherlands.

All this makes that plant breeding plays an important role in a wide range of public issues around food, agriculture, trade, environment, and employment. A healthy plant breeding sector is therefore important for society. Healthy means innovative, profitable, accountable ('licence to produce') and robust. The last aspect refers to sector's need to be able to adapt to changing circumstances. This requires a sustainable research and development effort, a healthy economic starting position (own versus external capital), a flexible, open organisation structure, and an international orientation.

2.1.2 Plant breeding and genetic resources

There are the following stages in plant breeding: formulation of breeding objectives, creation of variation, selection, and testing and finalising varieties for the market. The nature of the last stages is strongly crop-dependent – cross pollinators require other selection methods than self-pollinators or vegetatively reproducing crops.

In the last phase of the process it is important that the variety meets the uniformity requirements for registration. A rapid production of sufficient basic seed is important from a business point of view so that the market can rapidly be provided with seed stock soon after final development and registration of a variety. Many seed crops generate most income during their first years (or even the first year).

Selection is a lengthy process with high costs. Traditional selection makes use of the breeder's eye, supported by statistical techniques. Selection of field crops must be carried out under different agroecological environments to select varieties that are optimally adapted to the local conditions. This is less relevant for crops grown under cover. Various innovations have speeded up the selection process in the 1960s and 1970s such as growing a second generation in the Southern Hemisphere, single-seed-descend, the formation of dihaploids, etc. Molecular biological techniques are increasingly used in the selection phase, marker systems in particular, which can make selection more effective and efficient. Such methods are often patented where the patent is usually restricted to the method without affecting the material selected by means of such methods.

Variation is traditionally created by the introduction of material from other regions and by crossing. Also here, unprotected innovations have been developed such as methods to enable crosses between related species and to induce mutations through chemical or physical means. And also here, molecular techniques open wide possibilities for characterisation of properties, selection of crossing parents, and for transferring properties within species (cisgenesis) or between species (transgenesis). Such methods are often patented, and unlike for marker systems, products originating from such techniques are often also covered by patent protection, i.e., the properties of plants characterised on basis of the genetic code.

In all this, genetic diversity is the basis for plant breeding. Selection is impossible without diversity and new varieties for farmers and growers cannot be developed without it. This makes access to this variation essential for breeders.

2.1.3 The breeding sector and its business models

Analysis of the companies involved in plant breeding reveals a number of business models that may be relevant in the analysis of the significance of IP in the industry. A number of companies are concentrating on one link of the chain whereas others have integrated the various links in their holding. Extra links have been formed in some subsectors such as the propagation of seedlings in the sector propagation material of vegetables.

Different business models can be distinguished; these are presented in Figure 2.1. Plant breeding companies traditionally integrating variety development, production and marketing of seed and/or other propagation material (type A). Others breed and produce seed in their home country but licence their varieties to companies in other countries (type B). A number of breeding companies have meanwhile developed their own capacity in applied biotechnology (type C). And there are companies specialising in plant breeding biotechnology only, without being active in practical breeding, variety development, and seed production (type D). Some globally operating companies also have a strategic research capacity – between fundamental and applied (type E). These may cover the total chain and/or they may licence their technology to breeders.

Virtually all molecular-genetic breakthroughs, however, have been achieved by public research, following from fundamental research. The public sector principally deals with the areas that are not covered by commercial companies, in particular in pre-competitive research and often cooperates with the industry in applied research. Practical plant breeding by the public sector in The Netherlands is restricted to crops in which the commercial sector is not (yet) interested, such as fruits and new crops, e.g., for the biobased economy.

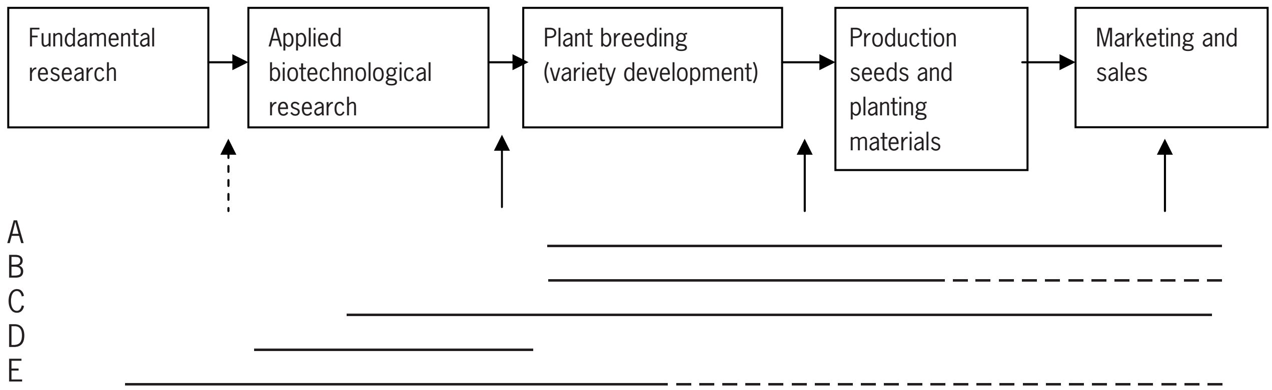

Figure 2.1. The innovation chain of which plant breeding is a link.

The vertical arrows in Figure 2.1 indicate where companies can generate their income. In the traditional breeding companies this is primarily the selling of seeds and planting materials (type A). Within this group of companies, however, quite different strategies are possible. This is mainly governed by differences in the organisation of the market for their products (differences between, e.g., bulbs, cuttings and seed). Granting licences for propagation on the basis of plant breeder's rights is important for many of these companies as well (type B). This in particular depends on the complexity of the production of propagation material and the size of the market. Production and selling by licence holders is often applied in the vegetative reproduction of bulbs and strawberries whereas in vegetable seeds the breeder controls these parts of the chain himself. Close cooperation between competing companies exists in cereals and even occurs in the breeding phase where the successful introduction of a new variety originating from shared crossing material leads to sharing of income. In ornamentals the use of breeding material for breeding by others may lead to a voluntary sharing of income generated by the new variety. This is based on a gentlemen's agreement but is nowadays increasingly laid down in contracts.

The originally traditional breeding companies are now also increasingly using biotechnology in their breeding programmes. The main focus of these companies (type C) remains on generating income by selling seed and not by generating income via licences on patents. The type C group of companies also comprises some companies originating from the (agro)chemical sector and that later became breeding companies via acquisitions and mergers. These companies are combining two business models – selling seeds and planting materials and acquiring market positions via licences on their patents.

Biotechnology companies (type D) are focusing on income from contract research for seed companies and on licence income from their biotechnological findings based on patent rights. This in particular concerns patents on molecular breeding techniques (e.g. Keygene) and on properties of plants ('traits' – BASF-CropLife). The value of such patents will in the end have to be paid at the level of the market for seeds and planting materials by the end users (farmers and growers).

Type E companies combine a large biotechnological capacity with the production and marketing of seed while at the same time licensing technologies to other breeding companies. This category comprises most multinationals in the seed sector that are also active in agrochemicals and/or pharmacy (united in CropLife), but also larger traditional breeding companies with a significant biotechnology capacity (e.g. RijkZwaan). The last part of the line in Figure 2.1 is dotted to indicate that for some of these companies the business model is largely, but not totally (as in type D companies), aimed at generating income from licences; income from seed sales is more important for others.

It can be concluded that different business models are operational in the breeding industry. And this results in large differences in the strategic significance companies attach to acquiring a market position based on selling seed and propagation material or based on a strong patent position. The differences in business models play an important role in the discussion about plant breeder's rights and patent rights.

2.1.4 Business economical aspects of breeding (case vegetable crops)

The global annual turnover of vegetable seeds is about € 2.7 billion. The concentration that has taken place in recent decades resulted in this turnover mainly being generated by the activities of only nine professional seed companies. Seeds form the basis for a product market with an estimated annual turnover of € 250 billion. The vegetable seed market shows an annual increase of 5-7%; vegetables belong to the most important food producers and they are good for human health.

The vegetable breeding sector produces a continuous flow of innovative new varieties for a number of crops. Breeding focuses on the following most important properties: resistances against pests and diseases, increasing yields, quality improvement (such as shelf life, taste), and increasing production efficiency. Companies that are introducing a new variety with a new trait usually have a lead of about four years, after which the competitors can introduce their own new varieties with the same trait. In such cases they make use of the 'breeder's exemption' (see 2.2.1). This is how this 'open innovation' system leads to a wide availability of such an innovation.

Investments in R&D by the top companies in this sector are very high, between 15 to 25 % of their turnover, and this level keeps track with the annual increase in turnover. Most of the top companies show an annual growth of 5-7%, with net profits exceeding 10%. Such growth can be realised in two different ways: by mergers and acquisitions or by autonomous growth. Companies with autonomous growth have to spend more on innovative R&D since they have to create new cultivars and new technology themselves.

Plant breeding is a long-term and therefore costly activity. Until the 1980s breeding was merely an empirical activity where breeders, on the basis of much knowledge and experience about traits of the reproductive material made crosses and selected the most suitable plants. This process was strongly affected by growing season, length of the generation cycle, growing conditions, and available space. This meant that the development of a new variety (e.g. a new hybrid) took 10-24 years, depending on the species. This development period decreased to 4-11 years over the last 30 years by application of a wide range of biotechnological methods, such as tissue culture, mutation breeding, DNA technologies, molecular breeding, etc. The application of modern technology has made plant breeding less time- and space-dependent and breeding processes have become much more efficient. This resulted in a reduction of the development period of a new variety by a factor 2.5. Even though the R&D costs increase strongly (by about 10% annually) the return of such investments is ensured by the faster production of new cultivars.

A breeding company tries to maintain, or preferably expand, its market share by developing good varieties.
A company can continue the development of new varieties if a good 'return on investment' is ensured. The long time needed for the development of a new variety entails high risks and costs. This requires an adequate protection against the misuse of varieties developed by the breeder with a lot of creativity and professionalism. In Europe, *Plant breeder's rights* provide, depending on the crop, a protection of 25 or 30 years; this is long enough because the success period of a variety is usually 3 to 7 years. Seed companies can recover their investments by increasing the price of innovative seeds. This is possible in view of the usually fairly low price elasticity of vegetable seeds caused by the seed price being only marginal in comparison to the total production costs of a plant, by seeds being essential as basic material for production, and by innovations giving the seed a worthwhile added value.

Currently, it is also possible to protect a new trait in a variety via patent rights, provided that the new trait does at least meet the criteria of novelty, inventiviness and industrial applicability, and if the invention is not restricted to one variety. The exclusivity for the patent holder means that these innovative traits cannot be used in breeding without permission (licence) of the patent holder.

2.2 Intellectual property in plant breeding

Plant breeding is the development of new varieties with new properties, enabling the company who places such varieties on the market to obtain or increase its market share. The development of a new variety or new breeding technique requires much time, effort and money. Making new varieties requires high investments that can only be recouped if the breeding companies can commercialise the variety for a certain period of time. To protect the rights of the breeder the legislator has developed systems to be used by the breeder and/or discoverer to protect himself against the risk that others can without permission simply copy, imitate and commercialise his result – the new variety or the new finding.

The first half of the 20th century saw the development of a specific type of property right for this sector: plant breeder's rights. The advent of modern biotechnology in plant breeding in the 1980s brought along another form of IPR: 'patent rights'. Both IPR systems are described in this chapter.

2.2.1 Plant breeder's rights

Plant breeder's rights represent the oldest form of protection available to plant breeders. Plant breeder's rights are a protection system specifically designed for the breeding of new plant varieties.

Two roads are open to the breeder seeking protection. He can choose *national* plant breeder's rights; plant breeder's rights were first introduced in The Netherlands in 1941. In 1961, however, the International Union for the Protection of New Varieties of Plants (UPOV) was established, resulting in a thorough revision of the Netherlands Seeds and Planting Materials Act. A drastic revision of the UPOV Convention in 1991[2] again led to an amendment of the Netherlands Act. The breeder can also choose so-called *community* plant breeder's rights, which apply throughout the European Union. Relevant regulations are included in the EU Regulation of the Council dealing with community plant variety rights.

National breeders' regulations, European regulations, and international plant breeder's rights treaties should be in agreement with the international IPR agreement *par excellence*, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) of 1994.

Subject of plant breeder's rights protection[3]

Variety. The Plant breeder's rights system grants protection to the breeder of a new plant variety. Variety is defined as: 'a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged'.
Breeding method. PBR only provides for a protection of the variety. PBR offers no protection for the method necessary to obtain this variety. This means that PBR is only meant to protect the product in the market.

Conditions for PBR protection

A variety must meet a number of conditions in order to qualify for protection: Distinctness, Uniformity, Stability - DUS), and novelty. These are discussed below:

Distinctness. The variety is deemed to be distinct if it is clearly distinguishable from any other variety of which the existence at the time of submission of the application is a matter of common knowledge. A variety can be distinguishable from an existing variety by a difference in morphological (e.g. flower colour) or physiological (e.g. salt tolerance) properties.

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2 International Convention for the Protection of New Varieties of Plants of 2 December 1961, as revised at Geneva on 10 November 1972, 23 October 1978, and 19 March 1991, Publication 221, Geneva, UPOV, 1994. See also http://www.upov.org/eng/convntns/1991/content.htm.

3 In the following reference is made to regulations as largely applicable to Dutch as well as Community plant breeder's rights.

Homogeniety (uniformity). The variety is deemed to be homogeneous if it is, having regard to the variation that may be expected from the particular features of its own reproduction, sufficiently homogeneous as regards its relevant characteristics.
Stability. The variety is deemed to be stable if in its essential characteristics it remains true to its description after repeated reproduction or propagation or, in case of a special reproduction cycle (e.g. in case of hybrids), at the end of each cycle.
Novelty. The variety is deemed to be new if propagating or harvested material has not been sold or otherwise disposed of, for the purpose of exploiting the variety, with the consent of the applicant longer than one year before the date of submission of the PBR application on the territory of the country where the application has been submitted. The term for other countries is four years (six years in the case of trees and vines). The novelty concept in plant breeder's rights does not refer to a certain variety not having existed before but to a variety not having been sold before. This plant breeder's rights approach of the novelty concept made many define this condition as the condition of *commercial* novelty.

Content of plant breeder's rights

Plant breeder's rights grant the holder the authority to forbid others to reproduce, handle, offer for sale, sell, import and export, or store propagation material of the protected variety.

Restrictions to plant breeder's rights

The PBR system provides for a number of restrictions on the exclusive right of the breeder. PBR does not extend to private actions, experimental actions (research exemption), or actions for breeding new varieties ('breeder's exemption'). The UPOV Convention also enables legislators to introduce a 'farmers' privilege' in their national plant breeder's rights. The Netherlands has on the basis of EU policy made use of this regulation for a number of arable crops of which farmers may, under conditions, reproduce seed for their own use without asking the breeder for permission.

Private use. The holder of plant breeder's rights can exert no rights on strictly private behaviour regarding the protected variety, in other words, the breeder cannot act against 'actions conducted private and not professionally'. This means that plant breeder's rights do not extend to private individuals who are, e.g., propagating flowers or vegetables for their own use.

Restricted commercial use - 'farmers' privilege'. The breeder can for a number of crops neither act against the practice that exists in the agricultural sector of the farmer who, after having sown lawfully acquired propagation material, keeps a small amount of seed from his own harvest to be sown for the next harvest, in other words, a breeder can in some cases not prevent that a grower 'uses the product of the harvest he has obtained by planting the protected variety within his own holding for reproduction purposes within his own holding'. A number of countries interpreted an earlier version of the UPOV Convention such that farmers could make propagation material available to their neighbour/colleague as well.

Scientific research – research exemption. The breeder cannot act against third parties that use the protected variety for experimental purposes.

Breeding new varieties – breeder's exemption. The breeder can neither act against third parties that use the protected variety as basic material for the development of new breeding products, in other words, the breeder cannot act 'against actions carried out in order to breed other varieties'. This restriction holds a fundamental confirmation of the rule of free access to protected varieties as original variety for the development of new varieties and the exploitation thereof. This means that plant breeder's rights do not protect or restrict genetic material for further use and that existing, already successful varieties can be used as basis for new varieties. This results in the genetic potential of the varieties showing an increasing line year after year. PBR do thus not prevent building on existing varieties already protected under plant breeder's rights.

2.2.2 Patent rights

Patent rights offer a second protection system that has for some years been available to the plant breeder. Plant varieties have in The Netherlands always been barred from patent protection because plant breeder's rights were available for the legal protection of plant varieties. From the end of the 1970s the call from the biotechnology sector for patent protection for plant related inventions became louder. The question arose whether plants resulting from modern, molecular plant breeding should be able to enjoy legal protection under patent rights which –although demanding higher protection requirements- offers wider protection.

A plant biotechnologist who seeks protection against illegal use of his invention via patent rights has two options. *National* patent rights is the first option (as PBR, patent rights is territorial – a patent is only valid in countries where it has been granted). He can also opt for a so-called *European* patent, which is currently valid in 35 states, including all Member States of the European Union. European patent legislation is covered by the European Patent Convention (EPC) of 1973 with a central service organisation, the European Patent Office (EPO), being established at the same time. National patent acts, the European Patent Convention, and the Biotechnology Directive must be examined for compatibility with the applicable international TRIPS agreement.

Subject of patent protection

Unlike in plant breeder's rights, where one variety is protected, the subject matter for which protection is sought is primarily determined by the applicant. The scope of the invention is described in the 'claims'. Patents are only granted for inventions. This excludes the following: discoveries, scientific theories and mathematical methods; aesthetic designs; systems, rules and methods for conducting intellectual work, for plays or for business management, as well as computer programmes; presentation of data. But how are plants considered under patent rights?

Initially, the patent route remained closed for plants. The existence of more specific protection, viz. plant breeder's rights, in Europe led to the exclusion of plant varieties from the scope of patent rights. In this respect the EPO stated that no European patents will be granted for plant or animal varieties, as well as essentially biological processes for the production of plants or animals. This ban on patents, however, was felt as outdated in view of a number of technological developments; this became apparent in the EPO granting policy that pointed towards a restrictive application of the patent ban on plant varieties. EPO defended the position that the exclusion only applies for plants in the genetically defined form of a variety and that the exclusion does not apply for plants that do not meet the profile of a variety and belong to the group of organisms that are taxonomically *higher* than the variety[4].

In view of the observation that some biotechnological inventions were not fully protected under the then existing state of legislation, administration of justice and jurisprudence in all Member States, which could obstruct completion of the internal market, the European Commission took the initiative to issue a European Directive governing the legal protection of biotechnological inventions. After a veto on this first proposal and on a second, amended, proposal of a directive, the Directive was finally approved in 1998 (the so-called Biotechnology Directive[5]). The Biotechnology Directive has been implemented in the different EU Member States and thus also led to some amendments of the Netherlands Patent Act 1995. The Directive has also been included in the EPC[6]. In principle this opened the way for patent protection being granted for plant-related inventions.

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4 See the EPO decision in the case Ciba-Geigy and the ruling in the case Lubrizol/Hybrid Plants, and the case Novartis – Enlarged Board of Appeal G1/98 on patent No. EP 0448511 B1.

5 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, PB.L., no. 213, 30 July 1998, p. 13.

6 The initiative for the EU Biotechnology Directive fitted into an attempt to exert indirect influence on the EPC and the EPO policy on biotechnological inventions. Negotiations between European Commission and EPO resulted in the EPO now being in line with the EU Biotechnology Directive. This is because the EU Biotechnology Directive was, by decision of the Management Committee of 16 June 1999, integrated in the EPC by adoption as Article 23 (b) of the Ancillary Regulations (see Official Journal EPO, 1999, 437 ff), which provision took effect on 1 September 1999. Fact is that the EU has no direct say whatsoever in the European patent legislator.

Plant genes. The European Directive contains no specific rules for the patentability of plant genes or gene sequences. This leads to the conclusion that gene sequences that have been isolated and characterised do in principle qualify for patent protection if they meet the criteria for novelty, inventiveness and industrial applicability. The industrial application of a gene sequence must, however, specifically be stated in the patent application by virtue of the EU Directive (Article 5) and the Netherlands Patent Act 1995 (Article 25, section 3),

Plants/plant varieties. The provision that plant varieties are not patentable has been maintained in the current Netherlands Patent Act 1995. This exclusion, however, needs to be put into perspective in the light of an additional provision introduced by the EU Biotechnology Directive stipulating that an invention concerning plants shall be patentable 'if the technical feasibility of the invention is not confined to a particular plant or animal variety'. Maintaining the distinction between plant and plant variety, however, gives cause to numerous interpretation problems and conflicts between patent rights and plant breeder's rights. An increasing number of patented plant properties is being inserted in plant material where in fact the propagation material of the plant variety is additionally protected via a patent, viz. an indirect patent protection of the plant variety.

Processes of essentially biological nature. Besides plant varieties, patents on essentially biological processes for the production of plants are excluded. The term 'essentially biological', however, is not a well-defined concept. The Biotechnology Directive provides clarity and stipulates that a process for the production of plants or animals 'is *essentially* biological if it consists entirely of natural phenomena such as crossing or selection. A process for the production of plants *not entirely* consisting of natural phenomena, however, is patentable. In this context, the presence of a technical step in breeding seems sufficient, which makes the exception in plant breeding hardly significant. A number of questions have been presented to the 'Enlarged Board of Appeal' of the EPO about the reading of this provision.

Conditions for patent protection

An invention must be new, inventive and industrially applicable in order to qualify for patent protection. These classic patentability requirements apply fully for biotechnological inventions.

Novelty. An invention is considered as novel if it constitutes no part of the state-of-the-art. The state-of-the-art is formed by everything already made publicly available through written or verbal description, through application or through any other means before the date of submission of a patent application.

Inventivity. An invention is qualified as the result of inventor activity if it is 'not obvious for someone skilled in the art'.

Industrial applicability. An invention is considered suitable for application in industry if its design can be produced or applied in any sector of the industry, including agriculture.

Content of patent rights

A patent grants the holder the right to prevent third parties to produce, use, offer for sale, sell, or for such purposes import the patented product without his permission. This also comprises the right to prevent third parties to use the patented process and to offer for sale, sell, or import a product directly obtained by means of this process.

The property that living matter is self-reproducing raises the specific question to which generation patent protection stretches. There is the legal provision (Art. 53a Netherlands Patent Act 1995) that patent protection offered for biological material that has obtained certain properties through the invention or for a product that contains genetic information, stretches to 'any biological material gained from this material by means of reproduction in the same or differentiated form and which has the same properties' and 'any material in which this product is incorporated and in which the genetic information is included and is exerting its function'. Patented genetic material can only be further used after obtaining the patent holder(s') permission. A plant covered by a patent can therefore not be used as crossing parent in plant breeding without permission of the patent holder.

Restrictions of patent rights

Patent rights provide for a number of restrictions on the exclusive right of the patent holder. Patent rights do not stretch to private actions, experimental actions (research exemption) or actions for (restricted) reproduction of propagation material (cf. farmers' exemption). Patent rights in Europe, however, do not contain an equivalent of the breeder's exemption, where patented material can freely be used as basic material for breeding and commercialisation of new varieties.

Private use. The patent holder can exert no rights concerning private actions for non-commercial purposes, in other words, the patent holder cannot act against 'actions performed privately and not commercially'. Patent rights do, in other words, not stretch to private individuals copying patented products for their own use.

Restricted commercial use – farmer's exemption. Contrary to the principle that patent rights stretch to each following generation in which the genetic material can be identified, it has been agreed that the sale by the patent holder of planting materials to a farmer for agricultural exploitation purposes, includes the right of this farmer to use the products of his harvest for further reproduction on his own farm (Art. 53c Netherlands Patent Act 1995). The PBR legal concept that gives the farmer right to restricted commercial use has in this way been brought into patent rights[7]. This rule is only implemented for the (arable) crops for which this right applies in PBR in the European Union.

Scientific research – research exemption. The patent holder can not act against third parties that use the patented product or process for scientific research. The Supreme Court of The Netherlands gave a very strict interpretation of this right, i.e., only pure scientific research comes under this exemption whereas research aimed at the development of a new commercial product does not. This is comparable to the situation in the US where the exemption is also strongly restricted as result of a court ruling[8] in the case Maley v. Duke[9]. This also leads to the situation that, e.g., GM plants cannot be used in scientific research which has recently led to critical articles in the scientific press[10].

2.2.3 Coexistence of plant breeder's rights and patent rights

The descriptions of both forms of intellectual property protection reveal fundamental differences between plant breeder's rights and patent rights as regards the subject of protection (PBR is granted for one, physically existing, variety; a patent is granted for products or processes as formulated in the claims), the condition for protection, content of the right, and the exemptions. It particularly applies to the exemptions that when both systems apply at the same time (as in case of a plant variety coming under the patent on a property or method) only those exemptions apply that are applicable in both systems. All other exemptions, such as the breeder's exemption, are subsidiary to the right of the other system (the patent). This means that when a variety protected under PBR is part of a patent claim, the variety may under PBR be used for further breeding whereas this may not under patent rights.

The coexistence of patent rights and plant breeder's rights is recognised in the EU Biotechnology Directive. The legal instrument provided in the Directive to enable coexistence between patent rights and plant breeders' is the compulsory licence.
Art. 12 (1) approaches the problems from the position of the breeder and stipulates that when a breeder can neither obtain nor exploit a PBR without infringing a patent of an earlier date, he may request a compulsory licence for non-exclusive exploitation of the invention protected by such a patent. Art. 12 (2) then deals with the problems in a similar way from the point of view of the patent holder and stipulates that when the holder of a patent on a biotechnological invention cannot exploit such an invention without infringing on a PBR of an earlier date, the patent

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7 In article 47 the EU Biotechnology Directive refers literally to the regulations on Community Plant Variety Rights.

8 Moschini, G.C., 2004. Research exemption and the economic incentive to Innovate. http://www.ipagcon.uiuc.edu/moschini.html.

9 Ludwig, S.P. & J.C. Chumney, 2003. No room for experiment; the federal circuit's narrow construction of the experimental use defence. Nature Biotechnology 21: 453.

10 Emily Waltz, 2009, Under wraps. Nature Biotechnology, 27.10.2009.

holder may request a compulsory licence for non-exclusive exploitation of this plant variety that is protected under PBR.
Art. 12 (3) lists the conditions that must be met by breeder and patent holder to obtain a compulsory licence. Breeder and patent holder must demonstrate that they have unsuccessfully approached the patent holder or PBR holder, respectively, to obtain a contractual licence and that the plant variety or the invention represent a 'significant technical progress or significant economic interest' in relation to the invention for which a patent is requested or for the protected plant variety.

3. Current trends in the plant breeding sector

Preface

Chapter 3 discusses some trends that are relevant for this study: trends in the economic significance for The Netherlands, technology, socio-economic developments, genetic resources, and the development of IP in developing countries.

- *The plant breeding sector has a large economic significance for The Netherlands with an export value steadily growing to 2 billion Euro, and an important spin off to the trade in consumer products, especially ornamentals. The plant breeding sector of The Netherlands holds very strong positions in vegetable crops, ornamental crops, and potatoes. Regardless of the ownership of companies R&D activities in The Netherlands contribute to the knowledge infrastructure and economy of The Netherlands (3.1).*
- *Technological developments showed rapid progress in recent decades. An important novelty is that significant developments in molecular biology are not originating from agriculture, and which made patent rights relevant for the sector. This certainly not only applies to genetic modification but to an ever broadening range of new technologies (3.2).*
- *There has been a significant consolidation among breeding companies during the last decades. For most crops only a few companies control most of the market, making a large part of the global food supply dependent on these companies. The main reasons are globalisation, technological developments, and intellectual property. The high access barrier for new companies is characteristic of the breeding sector. Here, patents play a role in addition to the knowledge and expertise required to set up a breeding company and the long development time of new varieties (3.3).*
- *Plant breeder's rights have been developed to give plant breeders, who had no access to patent rights, protection for their technically easily reproducible plant varieties. These rights have gradually strengthened along with the professionalisation of agriculture. Patent rights entered the sector via plant biotechnology after legal rulings in the USA in the 1980s, and in Europe following the Biotechnology Directive to which the European Patent Convention has been adapted. Numbers, quality and scope of patents create major challenges for the plant breeding sector (3.4).*
- *Recent analyses of the trends in the genetic diversity of crops show that the decrease in genetic diversity (genetic erosion) has been brought to a halt in Northwest Europe and North America and that diversity increases as the result of the use of genetic diversity from genebanks and new technologies making this more effective. Whether this trend can also be observed at the global level and whether this will continue when the number of breeding programmes further decreases as a result of the consolidation of the sector, remains to be seen (3.5).*
- *Developing countries have difficulties in meeting the international pressures to strengthen IP systems and at the same time optimally shape the IP systems for their own society. The trade-related aspects of IPR can conflict with development-related aspects (3.6).*

3.1 Relevance of the sector in The Netherlands

The plant breeding sector plays a major role in the Netherlands economy. It has been responsible for a steadily increasing export value of seeds and planting materials over the last 20 years. The most important sectors are horticulture (ornamentals and vegetables) followed by potato. Arable crops are, relative to the global value of such seeds, less important in The Netherlands. Total turnover is estimated at 2.5 billion €, involving a labour force of approx. 10,000 persons[11].

Table 3.1. Export value of seeds and planting materials, The Netherlands, 1998 - 2007.

Constant prices (2000)	1988	1993	1998	2003	2007
Seed potatoes	122,789	176,463	194,894	218,997	331,787
Vegetable seeds	103,234	171,916	253,733	435,693	619,484
Ornamental crops	363,152	507,115	586,418	755,047	881,633
Arable crops	75,728	58,035	105,551	149,069	151,750
Total	*664,904*	*913,530*	*1,140,597*	*1,558,806*	*1,984,653*

(in ,000 Euro, adjusted for inflation (using STAN Database for Structural Analysis, http://stats.oecd.org/Index.aspx?DataSetCode=STAN08BIS). Source LEI Wageningen UR, Den Haag.
NB. Excluding flower bulbs and trees.

These figures present the export value irrespective of the ownership or size of the companies involved. Breeding companies that have been taken over by foreign owners generally maintain a major part of their R&D in The Netherlands, whereas the management decisions on these programmes are moved abroad.
The Netherlands Government realizes that the presence of a strong private research infrastructure is important for the country, and invests heavily – partly because of that argument – in the public science infrastructure, and promotes public-private collaboration in breeding research, such as the Technological Top Institute Green Genetics. This institute, the Centre for BioSystems Genomics, and the DuRPH programme for potato blight resistance research are important initiatives contributing to both research and education that are relevant for the plant breeding sector.

The importance of The Netherlands is also illustrated by the listing of the top ten vegetable seed companies (Table 3.2). All these companies have their main office or an important research establishment in The Netherlands.

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11 Green Genetics, innovative plants for sustainable flowers and food. Businessplan for the Technological Top Institute Green Genetics, 10 november 2005. http://www.groenegenetica.nl/pro1/general/start.asp?t=documents.

Table 3.2. Top vegetable seed companies by sales figures, 2008.

Company	Country	Netherlands companies	Sales 2008 (million Euro)	World market share (%)
Monsanto	US	Royal Sluis, Bruinsma, the Ruiter Seeds, Western Seeds	560	20
Syngenta	Switzerland	S&G	415	15
Vilmorin	France	Nickersson-Zwaan	410	15
Bayer Crop Science	Germany	Nunhems	220	8
Takii	Japan	Takii Europe	180	7
RijkZwaan	Netherlands		175	6
Sakata	Japan	Sakata Holland bv	150	5
Bejo	Netherlands		150	5
Enza	Netherlands		140	5
Others			350	13
Total			*2,750*	*100*

Source: Seed industry.

3.2 Technological developments

From the 1980's onwards, major changes took place in plant breeding research as result of the application of modern biotechnologies. Commercial breeding had until then been based on traditional/classical breeding methods and plant biotechnology was limited to rapid in vitro multiplication of propagation material, the production of haploid plants for the rapid development of homozygous lines, etc. In the 1970s several scientific breakthroughs in fundamental biology were realised such as the discovery of restriction enzymes for the fragmentation of DNA, technologies for determining the base sequence of DNA, and the development of high-throughput sequencing later on. Unravelling the role of a DNA plasmid of the soil bacterium *Agrobacterium tumefaciens* in the transfer of DNA into plants was another major advance at that time.

Since the 1980s these new molecular technologies continue to be improved and they are now part of the plant breeder's tool box. The knowledge of molecular genetics is developing at high speed. Before long we will have access to genetic information of the complete genome of all major crops[12].

Application of these techniques is called molecular breeding, which uses enormous amounts of genetic data (bioinformatics), and which enables the combination of genetic information with information on gene expression (transcriptomics and proteomics), physiological data (metabolomics) and phenotypic data. The main breakthrough technologies are briefly described below.

3.2.1 Molecular marker technology

One of the largest leaps forward in molecular breeding was the development of marker technologies to visualize the genetic make-up of an organism (and thus also a plant). One of these breakthrough technologies, the AFLP DNA fingerprinting technology, was developed in 1990 by the Dutch biotech company Keygene in collaboration with a

[12] Bio-Era (2007), Genome Synthesis and design futures: implications for the US economy, Cambridge, Massachusetts.

number of seed companies[13]. Breeders can use DNA images based on this technology (comparable to a bar-code) to analyse the germplasm of their crops. If genetic analysis shows that a DNA marker is linked to a certain phenotypic trait it enables the breeder to select plants in the laboratory for the presence of the important trait, improving speed and efficiency, and decreasing costs of the plant breeding process. Marker-assisted selection also speeds up back-crossing for the introgression of genes into a desired genetic background. This is useful to introduce 'new' genes from distant sources (e.g. wild relatives) or from the latest commercial varieties into a company's breeding programme.

A recent improvement is based on SNP's (Single Nucleotide Polymorphisms), which offer the opportunity to have 'in-gene' markers that are more precise than 'linked' markers, and which can be more easily scaled up and automated.

3.2.2 Genetic modification

Another important tool is genetic modification, which produces transgenic crops. Genetic modification implies the introduction of genetic information into a cell (plant) in order to add a trait or character. This transfer of DNA may be done through biological (using the soil bacterium *Agrobacterium tumefaciens*) or physical (particle bombardment) introduction of DNA into the host.

Since the first commercial use of genetically modified maize in 1996, the GMO cropped area has increased to over 125 million hectares, in as many as 27 countries all over the world[14]. This, however, is mainly restricted to four main arable crops: corn, soybean, cotton and rapeseed, in which mainly two traits (insect resistance and herbicide tolerance) have been introduced. In Europe cultivation of GM crops is still limited (just over 100,000 hectare in 2008). Most of the strategic research focuses on other input traits, e.g. stress tolerances (salt, drought, other resistances), but also on some output traits, such as product quality (health-promoting substances such as vitamins). For example, Monsanto announced a drought-resistant wheat variety with a 9-10 % higher yield in dry areas. It may also be expected that GM technologies will play a role in the development of crops for the second generation of biofuels and other industrial uses of plants for a biobased economy. Over the past twenty years the technologies for the introduction of genes have been developed for almost all plant species that are important for humanity.

The introduction of a genetically modified plant on the market requires a safety analysis, both in terms of consumer health and ecological effects. According to a recent COGEM publication the total costs associated with the market introduction of one transgenic plant with one transgenic event is between 6 and 10 million euro[15].

Since market access of GM plants is strictly regulated, trends in the use of GM technology may be analysed on the basis of the applications for field trials. An analysis of 22,000 GM field trials in 27 OECD countries over 20 years shows that the share of CropLife companies (e.g. Monsanto, Pioneer, Syngenta) in the trials is 70% and the remainder is shared approximately equally between SMEs (e.g. Mogen, Florigene and Bejo) and large 'non-seed' companies (e.g. British American Tobacco, Shell, and Unilever). The share of the large seed companies is even higher for the major arable crops. In the period 2004/2008 almost half of the applications for testing were made by Monsanto (UNU-MERIT GM field trial database).

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[13] Hans J.M. Dons and Raoul J. Bino, 2007. Innovation and knowledge transfer in the Dutch horticultural system. In W. Hulsink and H. Dons (eds), Pathways to High-tech valleys and Research Triangles: Innovative Entrepreneurship, Knowledge Transfer and Cluster Formation in Europe and the United States. Springer 2007.

[14] ISAAA Report Global Status of Commercialized Transgenic Crops 2008, Clive James ISAAA.

[15] P. Schenkelaars, 2008. Costs related to market introduction of GM crops in USA and EU (in Dutch). Schenkelaars Biotechnology Consultancy for COGEM.

3.2.3 Trend: novel molecular breeding techniques

Next to the molecular marker technologies and genetic modification methods described above, a number of interesting new molecular technologies have been developed, such as:

- Molecular Mutagenesis
- RNA-i
- Reverse Breeding
- Grafting on GM root-stock
- Agroinoculation as means of selection
- Cisgenesis/intragenesis

More developments will emerge that will have a value for modern plant breeding. Such technologies will undoubtedly contribute to the development of innovative crop varieties. It is yet unclear whether or how plants developed via these new technologies will be considered within the regulatory classes of GMO. Some recent reports give more information about the different methods and the applicable regulations.[16]

3.2.4 Impact of new technologies on R&D investments

The high costs of new technologies in breeding programmes go together with business-economic advantages. Investments in the development of a new variety in the 1980s were spread over quite a number of years. Even with the increased demands and increased complexity of the market, modern plant breeding has been able to force the development time back by a factor of 2.5 (various vegetable crops), resulting in a shorter earn-back period of the higher R&D costs.

However, R&D costs have, as a result of the introduction of new technologies and higher demands from the market in particular, increased markedly; in vegetable breeding by an annual average of approx. 10%. The R&D costs as a percentage of the turnover in the sector have remained fairly stable. This means that when the size of the market does not increase by the same 10%, economies of scale have to be sought by increasing turnover. The total market has to be covered by an ever diminishing number of more internationally operating players.

However, the biotechnological tools will become cheaper as technologies mature. DNA sequencing is a key technology. It is the basic step in identifying genes and their function. Due to technological improvement the costs related to sequencing will be much lower in the near future and breeding programmes on the basis of the comparison of DNA sequencing of individual breeding lines becomes available ('breeding by sequencing').

3.2.5 The future

Plants will continue to form the basics for the quality of human life. The main breeding goals are clear and will not change much in the future, but there will be a continuous need for new varieties to enhance yield and yield stability, to improve quality and health, enable sustainable agricultural and horticultural development and to cope with new challenges such as climate change and salinity.

If the trend continues, new inventions based on high quality fundamental and strategic genetic research are likely to support plant breeding further. It is not possible to predict what kind of breakthrough technologies will be developed, but without any doubt a number will be based on high-throughput sequencing, all-omics and phenotyping, new types of genetic markers, and new genetic modification systems. All these and other technologies will be contributing to modern future breeding methods.

A scenario study by the OECD[17] predicts a widespread use all these technologies in 2030, including marker-assisted breeding, in all breeding programmes in the world. GM varieties of major crops and trees will have been developed with improved content (starch, oil, lignin) for industrial applications, and there will be GM plants and animals for the

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[16] VROM, 2007. Responsible breeding with genetic modification 'Developments in plant breeding techniques and GMO regulations'. (In Dutch). The Hague, VROM.
COGEM, 2006. New techniques in plant biotechnology (In Dutch). COGEM Advice and Monitoring (CGM/061024-02).

[17] OECD, 2009. The Bio-economy to 2030, designing a policy agenda. Paris, OECD.

production of pharmaceuticals and other valuable products[18]. Whether these technological opportunities will also lead to commercial successes not only depends on successful innovations but also on other factors, such as costs related to research, market introduction and regulations, public acceptance of GM products, and –last but not least- balanced IP policies that stimulate innovation and competition.

3.3 Socio-economic developments

3.3.1 Developments in the structure of the sector

Seed production and initial commercial plant breeding in Europe started in the mid 19th century, creating a wide range of family-owned and farmer-cooperative companies. Formal plant breeding in the USA started in the public sector, following the establishments of the Land Grant colleges and more specifically after the establishment of the experimental stations in 1887. Until World War II, new breeding companies were started. Since then very few significant new companies have emerged, and most of these only in ornamental plant breeding. Since the 1970s the number of companies in Europe and North America decreased sharply as a result of mergers and acquisitions. In the Netherlands this started with the merger of Sluis & Groot (est. 1867) and the Cooperatieve Zaaizaadvereniging West Friesland (Cooperative Seed Association, est. 1935) into 'Zaadunie'. From 1968 onwards (petro)chemical and pharmaceutical companies gain an interest in seed companies, initially in the USA and from the mid-1970s also in The Netherlands. An example is the acquisition of Dutch vegetable seed companies by (eventually) Monsanto (Table 3.3).

Table 3.3. Development of the position of Monsanto in vegetable seeds in The Netherlands.

1988	Bruinsma (est. in 1941) taken over by Asgrow
1992	Royal Sluis (est. in 1868) taken over by Peto Seed
1994	Merger of Peto Seeds and Asgrow Seeds in Seminis Vegetable Seeds
2005	Seminis taken over by Monsanto
2008	Western Seed and DeRuiter Seeds taken over by Monsanto

The data of Table 3.4 show that the global seed market has grown considerably, from an estimated 18 billion US$ in 1985 to 34 billion US$ in 2006. This is due to a combination of factors:

- globalisation (more countries using commercial seed),
- more farmers within these countries purchasing seed, and
- gradually increasing prices of seed.

The first factor, globalisation, mainly includes the opening up of commercial seed markets for major commodities (soy, maize) in Latin America and professionalisation of seed production in parts of Asia and Africa.

The aspect that more farmers use purchased seed may be explained by the growing awareness of farmers of the benefits of using good seed, the expansion of hybrid maize, cereals (pearl millet, rice) and vegetables in developing countries, and also by the larger role of intellectual property rights. For example, the introduction of UPOV 1991 made seed saving less interesting for farmers; the introduction of 'shrink wrap' contracts on seed bags in North America (comparable to those used on software) may make seed saving illegal. Moreover, the introduction of patented GMO technology turned formerly commercially less interesting self-fertilising crops like soybean and cotton into block busters with large markets for commercial seed.

[18] (reports of OECD and the Netherlands Trend Analysis Biotechnology 18 2007, 2009).

Finally, seed prices steadily go up with the quality delivered by advanced seed technology, but particularly through the introduction of genetic traits that have a value for the farmer. This trend goes hand in hand with the professionalisation of agriculture and horticulture, where every opportunity to raise yields and product quality is embraced.

Table 3.4. Changes in seed company turnover 1985 – 2006 (in million US$).

1985		1996		2006	
Company	mUS $	Company	mUS $	Company	mUS $
Pioneer	735	Pioneer	1500	Monsanto	4028
Sandoz	290	Novartis	900	DuPont-Pioneer	2781
Dekalb	201	Limagrain	650	Syngenta	1743
Upjohn-Asgrow	200	Advanta	460	Limagrain	1475
Limagrain	180	Seminis	375	KWS Saat	615
Shell Nickerson	175	Takii	320	Land O'Lakes	550
Takii	175	Sakata	300	Bayer BioScience	465
Ciba Geigy	152	KWS	255	Delta PineLand	417
VanderHave	150	Dekalb	250	Sakata	410
CACBA	130	Cargill	250	DLF Trifolium	365
Global seed market	18,000		30,000		34,000
Top 4 (%)	8		12		30

Adapted from: leBuanec, 2007[19].

At the global level, the top seed companies have developed from a market share of 8% in 1985 to close to 30% in 2006. This is the result of mergers and acquisitions that have taken place. For example, Sandoz and Ciba Geigy merged into the new company Syngenta; the major share of Advanta (vanderHave) are in the 2006 column found under Limagrain, while Seminis, Dekalb/Asgrow and seed programmes of Cargill (and since 2007 also Delta & Pine Land) are now part of Monsanto.

Table 3.4 shows the dominance of the so-called integrated life science companies such as Monsanto, Dupont, Syngenta and BayerCropScience, that have important other business areas next to seeds, such as agrochemicals and pharmaceutics. Two important 'commodity companies' have heavily invested in the seed sector: milk (Land O'Lakes) and cotton (Delta & Pine Lands – now Monsanto). Some traditional seed companies remain in the top ten: Limagrain, KWS and DLF-Trifolium.

Many of the acquisitions over the period 1996-2008 are presented in Figure 3.1, which also indicates the relative market share of the principal companies by the size of the circle.

19 Bernard le Buanec, 2007. Evolution of the Seed Industry in the Past Three Decades presentation at the 2007 ISTA Congress (with few updates). ISTA News Bulletin No 134 October 2007.

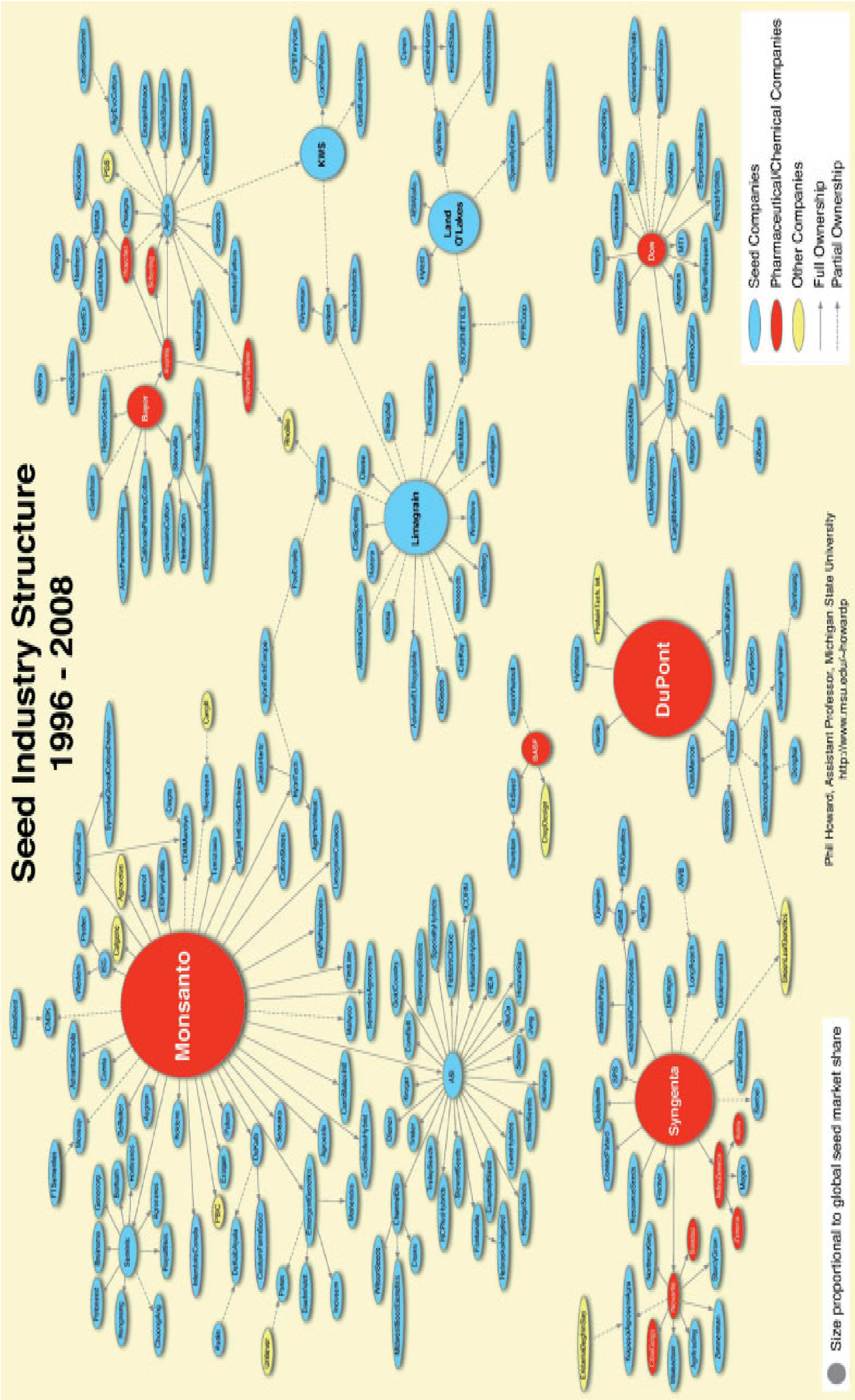

Figure 3.1. Structure of the seed industry (Source: Phil Howard, used with permission).

3.3.2 Organisation of the sector in The Netherlands

The Netherlands plant breeding sector consists of the following subsectors:

In the past, Dutch breeding companies, such as Van der Have and Cebeco, held significant positions in arable crop breeding. This sector, however, showed many acquisitions resulting in many breeding activities being withdrawn from the Netherlands. European companies such as Limagrain (French) and KWS (German) are strong in cereals, but a private Netherlands company (Wiersum) and a cooperative (Agrifirm) are still active as well. The maize and sugar beet seed market is mainly covered by daughters of large foreign companies. For fodder crops the Netherlands company Barenbrug and the Danish company DLF-Trifolium are important players on the European market, besides Limagrain (French), Eurograss (German), and Van Dijke semo (NL). Dutch companies play a major role in the seed potato sector: HZPC and Agrico are important players, together with Averis Seeds (associated to Avebe). Other companies, such as Meier, play a smaller role, and there are many small breeders who select clones for commercialisation by the large companies. Seed potatoes are often produced under licence.

Some large and medium-sized players from The Netherlands are active in vegetable seeds (see 3.1); these companies hardly issue production/marketing licenses but they mutually exchange technology licenses.

In recent years there have been several acquisitions in ornamental seeds as well. The situation in vegetative ornamentals shows a wide variation; there are many crops and many players from the Netherlands who are all carrying a limited number of crops and which are active in sub segments. Vegetative propagation material (cuttings, bulbs, scales, young plants) is largely produced on the basis of licenses. Examples of some leading breeding companies in this sector are Royal van Zanten, Dekker Chrysanten, Fides, and Anthura.

3.3.3 Important drivers and contributing factors to concentration

Globalisation and technological development can be seen as fundamental driving forces behind increasing concentration[20]. The possibilities of lowered trade barriers and increased integration of supply chains across countries have offered new business opportunities for the breeding sector. On a related note, increased economic development in many emerging and fast developing economies, in East and Southeast Asia and Latin America, has stimulated demand for high-quality seeds and planting materials[21] while the development of modern biotechnology has also driven this concentration.
Possibilities such as genome sequencing and marker-assisted selection constitute a modern set of generic tools that can be applied to many crops and for different purposes, implying increased economies of scale for larger companies, particularly in the early phases of knowledge development when the technologies are still expensive. Genetic modification of crops, for example for insect resistance or herbicide tolerance, is one such technology. The impact of these technological developments on the concentration in the sector is enhanced by the legal protection of such techniques, where it is important to distinguish between the different forms of IP. PBR gives an exclusive right to one plant variety, which is restricted by breeder's exemption which gives competitors the right to use the variety for further breeding. This prevents the formation of broad monopolies in a specific market. A patent that can be applied in a number of varieties and even a number of crops can give a company control over different markets and over the breeders that wish to use the technology in their breeding programmes. This potential market power is best exerted by companies that are combining a worldwide physical presence with a large legal capacity.

The concentration in the sector is not only the result of the merger of companies but also of the lack of new companies. New companies have hardly been established in The Netherlands since the 1960s, except in breeding for organic farming and ornamentals. Main causes of this phenomenon are the long development time of commercial

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[20] Vriend, Huib de, and Piet Schenkelaars. 2008. *Oogst uit het lab: biotechnologie en voedselproductie (In Dutch; Harvest from the lab: biotechnology and food production)*. Utrecht, the Netherlands: Jan van Arkel. www.oogstuithetlab.nl.

[21] Eaton, D., and R. Wiersinga. 2009. Impact of Improved Vegetable Farming Technology on Farmers' Livelihoods in Asia: an Overview of Results of Case Studies in Five Countries. Report 08-022. Den Haag: Agricultural Economics Research Institute (LEI), January. http://www.lei.wur.nl/uk.

products (long investment horizon), the ever increasing knowledge level required for modern plant breeding (in particular the main arable crops and vegetables, and increasing in ornamentals) and the access to genetic resources and technology. Genetic resources are indeed freely available from genebanks but this material needs an extra long development time in comparison with modern advanced varieties. The access barrier gets even higher when such varieties would no longer be freely available if they fall under patent rights.

Besides the three basic factors for concentration in the sector (concentration, technology, IP) there are two additional reasons that specifically apply to the market of genetically modified crops: registration costs and liability. The requirements for biological safety (for consumption and environment) of genetically modified plant varieties require high expertise of the applying company and entail very high research and administration costs. As for pharmaceuticals, the registration dossiers are not available to competitors, by some therefore considered as pseudo IPR[22]. When the registration is withdrawn just before expiry of a patent on a GMO this does not become part of the public domain. The deregulation costs result in GM technology only being applied in crops with a high (international) market potential and only by companies that can support the investment of millions. This means that small companies and public institutions do not introduce GM whereas large companies use this argument to ask high prices for their technology and that they need strong IP protection to achieve this.

Liability plays an ever increasing role in GMOs. In particular in the US, but also in an increasing number of countries, the rules on liability present a significant company risk. To restrict this, companies make every effort to prevent misuse of their technology. This is broadly implemented under the term ‘stewardship’. An example: farmers growing insect-resistant maize must in many countries sow a strip of non-Bt maize to decrease the chance of the insect adapting to the resistance gene. Companies consider it their task to enforce a responsible use of the technology upon users throughout the chain through to the farmer (and possibly even further) via contractual relationships. This may give them a degree of control over license holders and their customers. Only large companies can deploy such ‘stewardship’ methods and this means that they are benefiting most from the control they exert. Some companies introduce complex ‘stewardship’ programmes also for non-GM varieties.

3.3.4 GM and the position of European companies

Although GM currently plays a minor role in Europe, this development is highly significant for the European plant breeding sector. The GM debate is closely interwoven with IP matters, although IPR in biotechnology is not restricted to GM. The European moratorium on GM crops created room for European companies to increase their market share in Europe but it also means that material of the large arable crops developed for the American market, is hardly available for European breeding. The share of the large biotechnology companies in GM testing (chapter 2) shows that they have an enormous lead. When the European moratorium would be abolished, these companies will have their GM varieties ready for the European market and it will be impossible for the traditional European seed companies to catch up on this head start, certainly not as long as the patents on the GM properties are still effective in plant breeding as is the case now.

3.4 Trends in Intellectual Property Rights

3.4.1 Historical perspective

Patent rights, as internationally harmonised for the first time in the Paris Convention 1883, have not been granted for plants during the first century of its existence. Plant breeder’s rights have developed since the ‘Kwekersbesluit’ (‘breeder’s decision’) in The Netherlands in 1941 into an internationally harmonised system with currently 66 countries (+ the EU) that have acceded to the UPOV Convention[23]. Subsequent revisions of the Convention have led

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[22] World Bank, 2006. Intellectual Property Rights. *Designing regimes to support plant breeding in developing countries.* Washington DC, World Bank Agriculture and Rural Development. Report # 35517, 77 p. (see: http://siteresources.worldbank.org/INTARD/Resources/IPR_ESW.pdf.

[23] www.upov.int.

to a gradual strengthening of the position of the breeder, which may be considered a logical consequence of the professionalisation of agriculture in the member states (in 1991 mainly OECD countries). Patent protection of plant varieties is only possible in few countries, including the USA.

Various international agreements intend to harmonise the patent laws and implementation systems: the Paris Convention (1883), and the Patent Convention Treaty (1970/2001) and the Patent Law Treaty (2000). An important novelty was the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS, 1994) of the World Trade Organisation that provides minimum requirements for national IPR laws. TRIPS has a specific clause in Article 27(3)b on the protection of plant varieties:

> *'Members may also exclude from patentability:*
> *plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'*

The patent system became important for the plant breeding sector following subsequent court decisions in the USA:

- Diamond vs. Chakrabarty (1980)[24], which involved the first patent on a man-made micro-organism.
- In 1985, plants were considered patentable following the ruling in ex Parte Hibberd[25].
- In J.E.M. AG Supply, Inc. v. Pioneer HiBred International, Inc.,[26] the U.S. Supreme Court held that utility patents may be issued for plant varieties and plant seeds, and that rights under either the Plant Patent Act of 1930 or the Plant Variety Protection Act of 1970 would not reduce the patentability.

Recently, however, a trend appears in jurisprudence in the USA that reduces the expansion of the patent system in agriculture to some extent. Patents on *expressed sequence tags (ESTs)* are not accepted since 2005 because of insufficient proof of 'industrial application' and the publication requirements (*see In Re Fisher* [27]). A recent ruling on a patent on a (human) gene is even more restrictive, based on a perceived lack of inventiveness (see *In re Kubin*[28]). It may be expected that the United States Patent and Trademark Office (USPTO) will respond to these rulings with a more restrictive policy towards granting patents on plant traits.

Although these rulings only apply to patents in the USA and that their scope has not been fully confirmed it is assumed that this restrictive trend will also manifest itself in Europe. The current situation in Europe has been described in Chapter 2. An important case concerning the scope of patents on plants is the current case of *Monsanto v. Cargill*[29] which raises the question as to the scope of the protection of a patent on a transgenic *plant* (in this case soybean) and the plant *trait* (in this case glyphosinate resistance) embedded in this plant. Article 9 of the Biotechnology Directive stipulates that 'the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, in which the product in incorporated and in which the genetic information is contained and performs its function'. The dispute is about the fact whether the genetic information still performs its function when grain and flour (in this case soybean flouw) of the patented, transgenic plant is traded. The Court of The Hague has in September 2008 referred the case to the European Court of Justice for prejudicial advice.

Parallel to the debate on the restriction of research exemption in patent rights that would obstruct biotechnological research in the public sector[30], and which would restrict academic freedom[31], also the breeder's exemption is

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[24] 447 US 303, 206 USPQ 193.

[25] *Ex parte Hibberd, 227* U.S.P.Q. 443 (Bd. Pat. App. 1985).

[26] J.E.Ag Supply v. Pioneer Inc. 534 US 124.

[27] *Re Fisher*, 421 F.3d 1365 (Fed Circ 2005).

[28] United States Court of Appeals for the Federal Circuit (CAFC), 3 april 2009, *In re Marek Z. Kubin and Raymond G. Goodwin* (zie http://www.cafc.uscourts.gov/opinions/08-1184.pdf).

[29] For more details, see 'Harvesting Royalties for Sowing Dissent? Monsanto's Campaign against Argentina's Patent Policy' (www.grain.org en http://snipurl.com/23xnu).

[30] Nottenburg, C., P.G. Pardey & B.D. Wright, 2002. Accessing other people's technology for nonprofit research. Australian Journal of Agricultural and Resource Economics 48(3): 389-416.

subject of discussion[32]. An important argument in this discussion is the fact that since the development of a variety in traditional plant breeding used to take some 10 years, this has reduced by using modern techniques resulting in a much shorter period for recovering investments. Some larger companies argue for a 10 year “time lock” on the breeder’s exemption. In the proposal this is not a legal measure but an agreement between companies. Another important development is the introduction of the concept of essentially derived varieties. This implies that breeder’s rights on a new, distinguishable variety that strongly resemble the parent variety as a result of the application of particular methods of plant breeding or biotechnology (such as repeated backcrossing, genetic transformation or mutation) – may be dependent on the rights over the parent variety. Legal interpretation of this concept is difficult and the industry tries to reach agreement about the interpretation of the concept for a number of crops via the measurable concept of genetic distance between varieties. Another development in breeder’s rights is the restriction of farmer’s privilege, a subject beyond the direct scope of this study.

3.4.2 Trends: plant breeder’s rights

Data about the number of PVP grants in the Netherlands show a continuous increase to about 250 new varieties per year for all non-ornamental crops, followed by a dramatic decrease after 1996. This decrease was the result of the establishment of the Community Plant Variety Office where breeders could make one application for all countries of the European Union (Figure 3.2). The graph clearly illustrates that the number of new varieties showed a steady increase during the 40 years covered by the graph. Separate graphs are presented for ornamentals because their numbers are much higher than for the other subsectors (Figures 3.4 and 3.5).

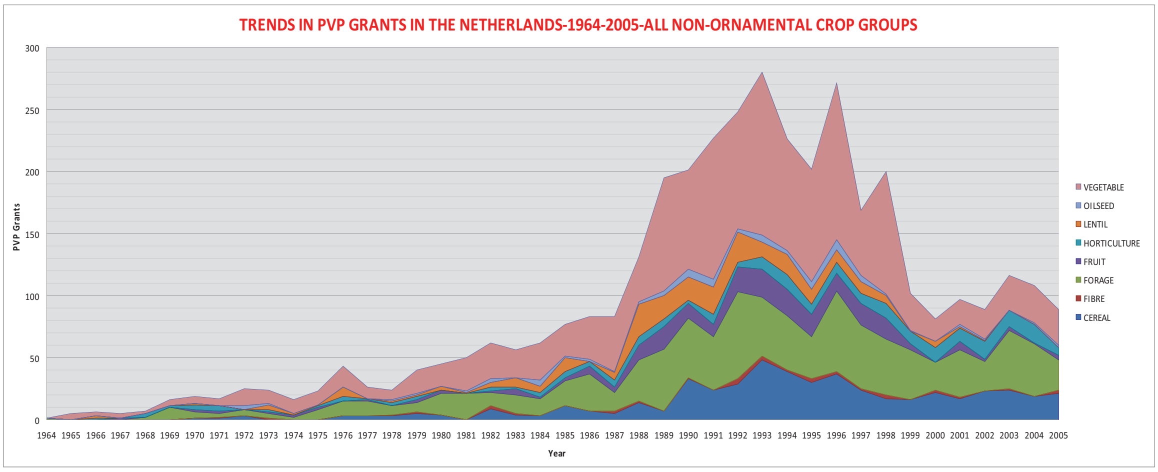

Figure 3.2. Trends in PVP grants in The Netherlands for non-ornamental crops, 1964-2005.

31 Under wraps, 2009, Emily Waltz, Nature Biotechnology 27/10, 2009.

32 ISF, 2004. Protection of intellectual property and access to plant genetic resources. Proceedings of an international seminar, Berlin, 27-28 May, 2004, Nyon, International Seed Federation.

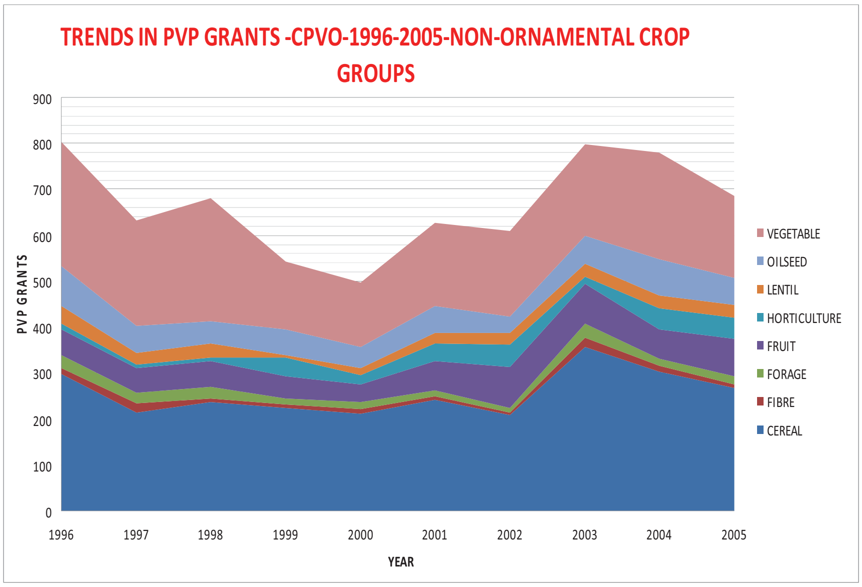

Figure 3.3. *Trends in PVP grants for non-ornamental crops by CPVO, 1996-2005.*

Division of the PVP grants over the different crop group shows that cereals and vegetables are the main crop groups. It should be noted that no breeder's rights are requested for many vegetable crops in view of the fact that the economic life of a new variety is no more than a few years and that most income can be generated during the time required to register such varieties (1 to 2 years). Another reason is that most vegetable varieties are hybrids than cannot be reproduced.

Figures 3.4 and 3.5 show the numbers of PBR grants for ornamental crops in The Netherlands, where a maximum of 1000 new varieties was reached in 1993. The significance of plant breeder's rights for ornamentals originated from the large number of species combined with the economic value of fairly small changes (e.g. colour mutants). Another reason is the vegetative reproduction of most flower crops making exact copying easy and –therefore- protection extremely valuable. The number of applications for Community breeder's rights for this crop group are also very high in comparison with other crops. In 2008 CPVO dealt with 3012 applications, about half (54%) for new varieties of ornamental crops, a quarter (26%) arable crops, 14% vegetable crops, and 6% fruit varieties. These applications are tested in field experiments[33].

33 Annual report 2008: http://www.cpvo.europa.eu/documents/Rapportannuel/AR2008EN.pdf.

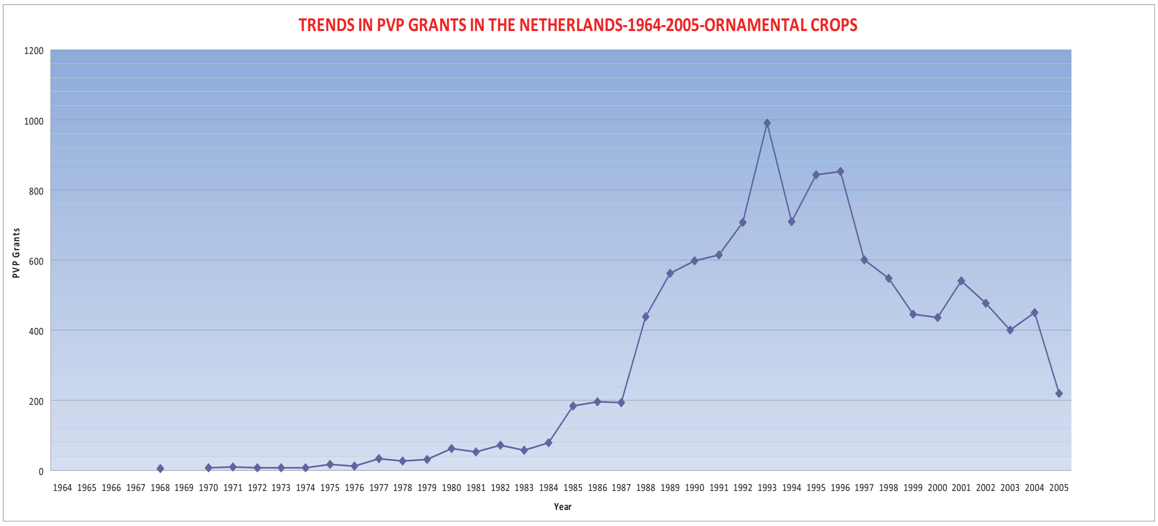

Figure 3.4 *Trends in PVP grants in the Netherlands for ornamental crops, 1964-2005.*

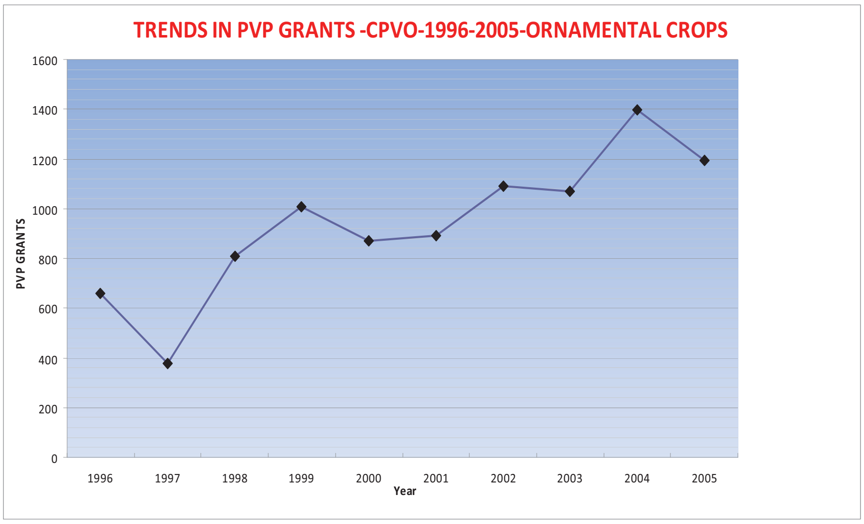

Figure 3.5. *Trends in CPVO grants for ornamental crops, 1964-2005.*

The number of PVP certificates granted to the various companies is shown in Table 3.5. The table is based on UPOV data about the allocation of plant breeder's rights by CPVO for the main crop groups. The names of the companies have been adjusted manually on the basis of the available information about acquisitions. This may have resulted in a slight overestimation of the diversity of the applicants.

The table shows that the number of applicants for European plant breeder's rights for cereals, oil seeds and vegetables decreases, resulting in an increase of the share of the top 5 companies in the total to above 50%. Ornamental crops and fruit, however, show an opposite trend: more applicants and a smaller share for the top 5. For these crops many companies or individuals have applied for one or two varieties only in both periods. Analysis of the number of plant breeder's rights certificates of the top 5 companies reveals that there are four dominant cereal breeders, two breeders of oil seeds, fruit and vegetables, and that the distribution for ornamental crops is more even. The table also shows that the largest companies at the global level (Monsanto, Pioneer, Syngenta, Limagrain/Vilmorin) are all represented in the European top. It is not certain that the number of varieties for which plant breeder's rights have been obtained is a solid measure of the innovative strength of a company.

Table 3.5. Spreading of PVP applications to the CPVO (Source: UPOV database).

	Number of applicants		Top 5 applicants (%)		Number of varieties	Top 5 companies (number of varieties)
	1996/2000	2001/2005	1996/2000	2001/2005	1996/2005	
Cereals	96	63	43	60	2563	SW-Seed (40) Ragt Seeds Ltd (126) KWS (153) Pioneer (265) Limagrain (279)
oil seeds	26	29	56	66	592	Limagrain (21) Syngenta (21) SaatenUnion (Raps gbr) (27) Pioneer (58 Monsanto (67)
Fruit	85	139	32	19	639	CIRAD (10 Driscoll (12) CRPV (14) INRA (20) Darnaud (22)
vegetables	152	112	40	52	2031	Bejo Zaden (68) Nunhems (Bayer) (68) Syngenta (76) Monsanto (143) Rijk Zwaan (152)
ornamental crops	559	759	19	12	9365	Anthura (122) Ball (128) Poulter Russell (144) Yoder Brs (150) Vletter & den Haan beheer (155)

3.4.3 Trends: Patents

The rise of biotechnology in plant breeding and the introduction of genetic modification resulted in an increasing interest in the application of patent rights as IP protection system. In Europe patent rights allow patents on plant *properties*, plants *per se* and numerous molecular plant *techniques* since 1998, the year in which the EU Biotechnology Directive was enacted. In 2008 the European Patent Office handled a total of 150,000 applications. The EPO annual report mentions 3000 oppositions and an average of 2200 technical appeal cases in 2007/2008[34]. The American patent office (USPTO) reports an annual increase in the number of applications of 7% during the last 4 years[35].

A limited analysis has been carried out to gain some insight into the use of patents as IP protection instrument in case of genetic modification[36].

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34 Annual report EPO: http://documents.epo.org/projects/babylon/eponet.nsf/0/7943587024b8e445c12575a00056831b/$file/epo_annual_report_2008.pdf.

35 Annual Report 2008 of USPTO: http://www.uspto.gov/web/offices/com/annual/2008/2008annualreport.pdf.

36 The patent data were extracted by Jos Winnink (*Octrooicentrum Nederland*); the data were analysed by Anthony Arundel, member of the Research Team.

Information about three types of plant patents was collected:

- EPO plant patent applications between 1980 and 2006; i.e., all applications, viz. directly ('First filings') to the EPO. Via priorities of national or PCT applications;
- USPTO plant patents between 1980 and 2004;
- USPTO plant patent applications between 2001 and 2007.

Plant patents usually fit into one (or more) of the following categories[37]:

- A011H1 to A01H4: this category comprises *processes* for changing genotypes and phenotypes, as well as plant reproduction via tissue culture techniques;
- A01H5 to A01H17: this category comprises *products* such as new varieties. This category is frequently used in the USA;
- C12N15/82, /83 and /84: this category comprises recombinant DNA/RNA or other *technologies* (such as vectors) that are used for the genetic modification of plants.

The analysis focused on patents for processes and genetic modification techniques (i.e. not categories A01H5 to A01H17).

A total of 4,048 EPO patent applications for processes and genetic modification were submitted between 1980 and 2006; an annual average of 300 over the last 10 years. In the USA 5,506 such patents were granted between 1980 and 2006, and 5,070 between 2001 and 2007. (Patent application data for the USA have only been included from 2001 because information about earlier applications was not released.)

Private sector

The analysis shows that the dominant players in the field of plant patents are in particular companies with their head office in the USA. Of the 3,049 applications to the EPO in the period 1980-2006, 41% were made by American companies, 41% by European companies, and 18% by companies from other countries. The American supremacy is even stronger when looking at the 3,786 *USPTO* patents granted between 1980 and 2006, where American companies accounted for 75% of the patents, European companies for 15%, and companies from other countries for 10%.

Table 3.6 presents the patent applications by companies in these categories. The number of companies applying for, and being granted, patents increased over time. The number of companies filing applications in Europe increased from 36 companies between 1980 and 1984 to 252 companies between 2000 and 2004. The number of companies that patents were granted to by USPTO increased from 57 between 1980 and 1984 to 235 between 1995 and 2005. The decrease in granted patents in the period 2000-2004 is not reflected in the number of patent applications between 2003 and 2007, with 274 companies responsible for 2,962 patent applications.

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[37] These are the so-called *IPC* categories. The *International Patent Classification* system is a classification system for patents set up by the *WIPO (World Intellectual Property Organisation).*

Table 3.6. Percentage plant -process-GM patents by leading companies: 1980 – 2007.

	Number of companies	Number of patents	Share all patents Top company	Top 5 companies	Top 10 companies
EPO patent applications					
1980-1984	36	63	9.5%	31.7%	54.0%
1985-1989	100	248	5.6%	22.6%	40.7%
1990-1994	134	442	6.7%	28.3%	44.4%
1995-1999	219	939	10.5%	32.3%	45.9%
2000-2004	252	1008	9.4%	31.4%	44.1%
2005-2006	105	349	12.1%	42.4%	55.3%
USPTO patents granted					
1980-1984	57	135	8.8%	31.6%	47.8%
1985-1989	107	474	9.7%	35.7%	50.4%
1990-1994	137	875	13.0%	36.7%	54.4%
1995-1999	235	1705	24.2%	49.6%	61.1%
2000-2004	56	597	55.6%	80.5%	87.1%
USPTO patent applications					
2003-2007	274	2962	28.4%	63.2%	71.7%

Source*: EPO patent applications, USPTO granted patents, USPTO patent applications. The results do* not *include the public research sector, the private non-profit sector, and individual patent holders.*
Remarks*: (1) Restricted to patents from IPC classes A011H1 to A01H4 and/or C12N15/82, /83 and /84, ánd to patents for which full information was available about the identity of the patent holder/applicant; (2) The company with most* USPTO *patent applications between 2003 and 2007 is Dupont Pioneer Hi-Bred, followed by Monsanto, Syngenta, BASF and Ceres, which last company is involved in the development so-called energy crops.*

Contrary to the growing number of companies that submitted at least one patent application to EPO or USPTO, or companies awarded at least one patent, the number of patent holders is decreasing, in particular of *USPTO* patents. The top 5 patent applicants in Europe submitted 22.6% of all process-GM patent applications for plants between 1985 and 1989, and 31.4% of all applications between 2000 and 2004. The concentration is even stronger in the United States. Between 1980 and 1984 the top 5 companies accounted for 31.6% of all granted patents, a figure increasing to 49.6% from 1995 to 1999. The concentration level is even higher for the more recent *USPTO* patent application data. Between 2003 and 2007, the top company accounted for 63.2% of all these patent applications, and the top 10 companies accounted for 71.7%.

Table 3.7 shows the top 10 companies that account for most of the GM patent applications. This concerns applications to EPO and USPTO between 2003 and 2007.
The share of the top 10 companies in the United States is no less than 75.1%. The concentration level in Europe remains lower, with 42.5% of all patent applications.

Table 3.7 Top 10 applying companies for process-GM-plant patents between 2003 – 2007.

USPTO patent applications (total 2992)			EPO patent applications (total 1220)		
Company	Number	Share	Company	Number	Share
Pioneer Hi-Bred	843	28.5%	Pioneer Hi-Bred	107	8.8%
Monsanto	728	24.6%	BASF	105	8.6%
Syngenta	167	5.6%	Monsanto	101	8.3%
BASF	128	4.3%	Bayer CropScience	57	4.7%
Bayer CropScience	89	3.0%	Crop Design	36	3.0%
CERES INC.	74	2.5%	Syngenta	28	2.3%
Mertec LLC	58	2.0%	Unilever	23	1.9%
Anix Corporation	49	1.7%	Icon Genetics	22	1.8%
Dow AgroScience LLC	48	1.6%	Novartis	21	1.7%
Delta and Pine Land	39	1.3%	Mendel Biotechnology	18	1.5%
Total	*2223*	*75.1%*		*518*	*42.5%*

NB: Ownership of a company is allocated in the year of acquisition. Crop Design was acquired by BASF in 2006, Icon Genetics was acquired by Bayer in 2006, Delta and Pine Land was taken over by Monsanto in 2006.

The results of this analysis point towards a large backslide in the number of companies that can utilise biotechnology for the development of new plant varieties and that patent positions are concentrating in a smaller number of companies.

Public sector

The public research sector (universities, government bodies, and private non-profit organisations) continue to play a major role in the development of plant based patents. Between 1980 and 2006 the public sector submitted 23.8% of the patent applications to EPO, public bodies were granted 21.9% of the patents in the United States, and submitted 24.9% of the patent applications to *USPTO* between 2001 and 2005. This is considerably more than the contribution of the public sector to all types of patents, as estimated by Graff *et al.*[38] at only 2.7% of the *USPTO* patent applications between 1981 and 2000.

The contributions of the public sector to patent applications and grants showed a peak at the end of the 1990s (Figure 3.6). It is unclear whether this is the result of the fall in investments in the public plant breeding sector or of a policy change – especially in the USA – to stop applying for patents, possibly in view of studies that showed that only few universities gain a net profit from the management of their protected knowledge. In Europe, this fall in the share of the public sector, incidentally, is much lower.

[38] Graff, GD, Cullen SE, Bradford KJ, Zilberman D, and Bennet AB. (2003), The public-private structure of intellectual property ownership in agricultural biotechnology, *Nature Biotechnology*, Vol. 21, pp. 989 – 995.

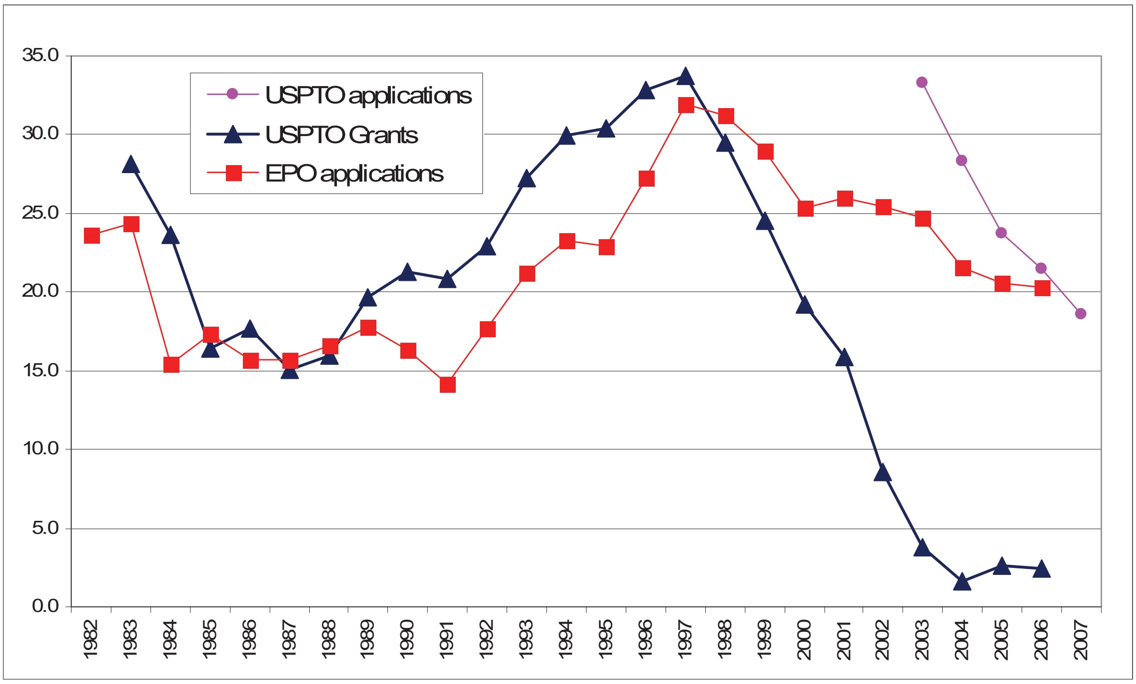

Figure 3.6. *Share of the public sector in applied and granted patents (in %).*
***Source**: EOB and USPTO data. The results are three-year averages.*

3.4.4 Analysis of the trends in the use of the patent system

Numbers

The success of patent rights in general terms and in biotechnology in particular is reflected by the rapid increase in the numbers of applications and grants in the 1980s and 1990s.
The numbers do not seem high relative to the total number of patents applied to the EPO (about 200,000 per year). In view of the fact that patents are valid for 20 years, however, and that many patents cover a large number of applications and crops, it still is a significant number that should be taken into account by plant breeders. Another important fact is that new players in the field, such as China, Brazil and India, are expected to produce ever increasing numbers of patents. This puts a high pressure on the patent offices that need to assess all applications for novelty, inventiveness and applicability. Assessment of novelty as well as inventiveness requires a accurate comparison with the 'prior art'. This results in large backlogs at the patent offices and a loss of patent quality. Opposition against trivial patents is complex and costs time and money. In the annual report 2008 the president of the EPO mentions 'growing mounds of unprocessed patents' and the need to improve efficiency, the quality of the applications, and improvement of the inventiveness assessment[39]. Until a few decades ago biotechnology consisted of a field with new developments but a growing part is now 'state of the art'.

Public sector

In the past research carried out by public research organisations was published in scientific journals and publication was the standard against which scientists were judged. This has partly changed because public-private collaboration is considered as a way of knowledge valorisation. The term "valorisation" is used to mean an increased use of knowledge in society as well as for the creation of income for the university[40]. For such collaborations patent

39 Annual report EPO: http://documents.epo.org/projects/babylon/eponet.nsf/0/7943587024b8e445c12575a00056831b/$file/epo_annual_report_2008.pdf.

40 Jonge, Bram & Niels Louwaars, 2009. Valorising science: whose values? EMBO Reports 10 (6), 535–539. http://www.nature.com/embor/journal/v10/n6/pdf/embor2009113.pdf.

protection is considered essential by research funders as well as universities. The correlation between commercial interests of universities and their public objectives is, however, often obscure. Public institutions make large contributions to the numbers of patent applications (Figure 3.6) and important developments, such as, e.g., the 'particle bombardment' method for transformation, developed by Cornell University, are not freely available because these have been given in exclusive license.

Patent quality

The way in which patents are granted and the way in which patent rights are exerted is increasingly criticised. Patents should meet the three criteria of novelty, inventiveness and applicability but lack of clarity of the description, accuracy of the boundaries, and validity of the claims are growing problems.
The degree of inventiveness (as for DNA sequences) and whether 'essentially biological processes' can be patented are main issues in plant breeding patents. An important function of a patent description is that it is clear to the reader what the applicant has invented, what is covered by the claims, and –in particular– what is not covered by the claims. Patents in biotechnology are often unclear on these aspects and the Netherlands Patent Act as well as the EPO allow the applicant much room for formulating the applications. This results in broad claims extending to matters never investigated by the applicant, so-called 'reach through' claims on material that is developed by using the invention, etc. This results in patents being granted with poorly defined boundaries that are creating uncertainties for scientists and companies operating in an area close to the patent.
This is enhanced by the creation of patent portfolios of overlapping or adjoining patents that may in practice obstruct progress, the so-called 'Patent Thickets'[41]. It also happens that companies are in particular investing in innovation 'around existing patents' which does not contribute much to true innovation. This may disturb the balance between the rights of the patent holder and the value for society resulting in the patent system restricting rather than stimulating innovation[42].

The effect of these developments is not the same for all players in the field. Patent positions restrict access to the sector for new players. The legal, technical and financial possibilities to deal with the complexity and the costs of the patent system are a great advantage to larger companies. In the end, strategic patenting results in society benefiting less from patenting than desired.

The quality of patents already is an important issue in the breeding sector. The ISF (International Seed Federation) as well as ESA (European Seed Association) did in 2008 and 2009 start consultations with patent experts of the European Patent Office to exchange views and for organising joint workshops with examiners[43].

41 Reitzig, M., 2004. The Private values of 'Thickets' and 'Fences': towards an updated picture of the use of patents across industries. Econ. Innov. New Techn. 13(5): 457 – 476. And specifically for genetic inventions: Bobrow, M. & S. Thomas, 2000. Patents in a genetic age. Nature 409: 763-764.

42 Heller, M., & R. Eisenberg, 1998. Can patents deter innovation? The anticommons in biomedical research. Science 280: 698-701.

43 Added information for the english translation: In February 2010, ISF and the Amserican Seed Trade Association organized a meeting with examiners of the USPTO, similar to the workshops in Europe with EPO.

3.5 Trends regarding policies and use of genetic resources

3.5.1 Trends: biodiversity policy

International policy with regard to genetic resources started in 1983 with the adoption of the 'International Undertaking on Plant Genetic Resources for Food and Agriculture" of the UN Food and Agriculture Organisation (FAO). This agreement primarily treated such genetic resources as a 'Heritage of Mankind' that should be freely available for all. The Convention on Biological Diversity (CBD) which came into force in 1993 put genetic resources under the sovereignty of the nations where such resources have obtained their distinctive character. Countries can – since then – make access to their genetic resources subject to mutually agreed terms.

Countries differ in their implementation of the CBD and in their policy regarding access to genetic material. In some countries it is very difficult to gain access, e.g., because consent of the farmer, the land owner, the local community leader, local administrators and national authorities is required (e.g. Philippines). A recent example is the unsuccessful attempt by Dutch vegetable seed companies to gain access to a tomato collection from Ecuador.

Such problems led to the development of the 'International Treaty for Plant Genetic Resources for Food and Agriculture' in 2001. An important novelty of this International Treaty is the multilateral system that should facilitate both and the sharing of benefits originating from the use of the resources. This applies to almost all crops and forages important for global food security. Ornamentals and most vegetables, however, are not included. Materials of crops to which the Multilateral System apply that are under the control of the signatory governments are available under a single Standard Material Transfer Agreement (SMTA). The terms of the SMTA include a mandatory payment of 1.1% of the value of the seed sales (with a 30% discount to cover taxes etc)in case a crop variety is produced using genetic resources from the Multilateral System, and if that variety is not freely available for further research and development. Alternatively, breeders can contribute a flat rate of 0.5% of their gross sales for use of all genetic resources of the crop. The Netherlands have been very active in the development of the International Treaty and has (until October 2009) been chairing the FAO Commission that has prepared the Treaty.

3.5.2 Trends: Genetic diversity in the field

The selection of uniform varieties from a wide diversity and the resulting fear of global genetic erosion led to the establishment of international, national and corporate genebanks. In the context of the current study it is relevant to investigate whether the organisation of the breeding sector, notably the consolidation of breeding programmes, may have an impact on genetic erosion.

Genetic diversity of crops is characterised by a number of historical bottlenecks, i.e. critical moments diminishing this diversity. The first bottleneck is the result of domestication of crops in which only a subset of a the diversity of the wild species remains after repeated selection for desired traits, e.g., non-shattering, plump seeds[44]. This may be followed by a dispersal bottleneck which arises when only a subset of the crop is exported to another region, in which diversity is further reduced through adaptive selection to the new conditions[45] . This led to the famine in Ireland caused by potato blight exerting its disastrous effect as result of the narrow genetic base of the cultivated potato in comparison with those in the Latin American areas of origin. The 'modernisation bottleneck'[46] is the result of scientific plant breeding that replaced genetically diverse landraces by uniform varieties. This was the case with the introduction of 'Acquitaine' wheat in France around 1870 and the introduction of 'IR8' rice in large parts of Asia during the Green Revolution in the 1970s.

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[44] Tanksley, S.D. & S.R. McCouch, 1997. Seed banks and molecular maps; unlocking genetic potential from the wild. Science 277: 1063-1066.

[45] Zeder M.A., E. Emschwiller, B.D. Smith & D.G. Bradley, 2006. Documenting domestication; the intersection of genetics and archeology. Trends in genetics 22: 139 – 155.

[46] Van de Wouw, M., C. Kik, T. van Hintum, R. van Treuren and B. Visser (in press) Genetic erosion in crops: concept, research results and challenges. Plant Genetic Resources: Characterization and Evaluation.

Van de Wouw, however, identifies a second modernisation phase (footnote 45) where the access by breeders to genebanks increases the use of exotic material and thus the genetic diversity at the allelic level. This, combined with modern techniques, enables an effective and efficient use of genes of such distant material. Transformation technology may even make the diversity of other species available for plant breeding. And marker technologies enable more specific selection for certain regions and purposes, creating larger numbers of varieties. A meta-analysis of 44 published studies, mainly in Europe and North America, indicates that after the modernisation bottleneck the diversity in the major food crops has increased until the end of the last century.

These trends over the last decades indicate that plant breeding currently contributes to the diversity at the allelic level and not necessarily at the level of number of available varieties of agricultural crops in Northwest Europe. Given that the data cover a period until 2000, it may be concluded that during the first consolidation phase in the seed industry (starting in the 1970s) genetic diversity has increased. Whether this positive trend will continue will depend on a number of issues.

First, technological developments determined to a large extent the opportunities for increasing genetic diversity in crops so far. The refinement of such technologies will almost certainly support this trend in the future.
Secondly, the quoted analyses has been carried out at regional level (Northwest Europe, North America, etc.). When consolidated breeding programmes will cater for the needs of both regions, then diversity in each region may be enhanced at the same time when diversity at the global level decreases. The breeding of specifically adapted varieties may be reduced in case consolidation leads to reduced competition levels in the seed market.

When more benefits can be obtained through 'trait breeding', i.e. introducing a new trait in an existing variety through genetic modification or repeated backcrossing in combination with the use of markers, genetic diversity could decrease. Where in the past conventional breeding introduced a much wider genetic load when farmers' varieties or wild relatives were used to introduce such traits, a much more precise introduction of the desired trait alone is now possible. This may lead to a narrower genetic base of crops.

This means that the results of the studies of Van the Wouw cannot simply be extrapolated to the future. Whether future analyses of genetic erosion will add a 'molecular bottleneck' or a 'corporate bottleneck' to the 'domestication', 'dispersal' and 'modernisation' bottlenecks, remains to be seen. It is however important to identify such risks in time.

3.6 Trends in developing countries

Plant breeding of the major food crops in developing countries is strongly dependent on public investments in the centres of the Consultative Group on International Agricultural Research (CGIAR). These provide varieties or half-bred materials to the national public institutes and universities, and research results also reach the private sector in developing countries as well as elsewhere. The private seed sector in developing countries focuses on a limited number of crops, notably maize, cotton and some hybrid crops, and particularly in Asia also on vegetables. The lack of private investment in other crops can be explained by the dominance of the public sector on the one hand and the low purchasing power of the majority of farmers and the lack of effective protection on the other.

The WTO TRIPS Agreement (1994) spurred the upgrading of patent systems and the development of breeder's rights in many countries. The least developed countries, however, obtained considerable time to meet all requirements of TRIPS. Most Latin American countries responded by joining UPOV under its 1978 or 1991 Acts. Most Asian countries developed systems that are close to UPOV (but did not join) or combined breeder's rights with aspects of politically important Farmers' Rights because these are considered insufficiently protected by UPOV. In Africa, few countries are member of UPOV (South Africa, Kenya – and Tanzania has applied), a large number is still developing a PVP system, and the francophone countries are preparing for joining as a group. The level of implementation of breeder's rights legislation differs widely. A major concern in developing countries is that under UPOV, farmers are not allowed to exchange seed of protected varieties, and that only for specific crops farmers may be allowed to reuse their own seed. This is opposed to traditional seed handling practices by farmers and exchange is an important tool in preventing seed shortages among poor farmers. During the Green Revolution, the local exchange of seed was stimulated in order to increase access to better varieties.

With regard to patents, many countries have adapted their legislation to the requirements of TRIPS. For example, in 2007 India expanded the protection of methods to products, deleted its ban on the protection of pharmaceuticals and ‘methods of agriculture’ and now includes the protection of biotechnological inventions. African counties however, expressed in the WTO their great concern about the patenting of living organisms.
Apart from TRIPS, bilateral or interregional trade negotiations put pressure on developing countries to upgrade their IP systems beyond the minimum standards of TRIPS, e.g. the protection of pharmaceuticals and plants and animals, and the development of an effective ‘sui generis’ system for the protection of plant varieties. Countries are sometimes asked to become a member of UPOV in exchange for trade agreements and sometimes they are asked to introduce patent rights for plants and even plant varieties. This puts developing country policy makers who are aware of the importance of local seed exchange among farmers for basic food crop seeds in a difficult position. Ethiopia tries to find a way in this dilemma with assistance of the Royal Netherlands Embassy in Addis Ababa through a combination of high protection levels for commercial crops (without the right to replant seeds) and full Farmers’ Rights for the basic food crops produced by smallholder farmers. UPOV recognises an exemption for private and non-commercial use, but this is interpreted by many as to be valid only for farmers who consume all of their crop within the family. Since almost all farmers take some surplus grain to the local market, this strict interpretation does not help much and is not likely to lead to UPOV membership for countries like Ethiopia. It must be clear that the patent system does not allow for any reproduction of seeds by farmers. The only exception is the farmers’ privilege that has been explicitly introduced in the European Biotechnology Directive for rights on patented inventions that extend to plant materials. This experience may be an interesting example for developing countries.

4. Stakeholder views

Stakeholders have different views and interests. These may be useful in assessing whether it would be beneficial and necessary to take steps in the sector. Farmers and growers stress the free choice of varieties and the vicinity of breeding programmes; breeders stress plant breeder's rights, biotechnologists both IP systems, and policy makers the need of ongoing innovation.

4.1 Interviews with stakeholders

Following the meeting of the Advisory Board in July, PlatumNL and Niaba have been asked to provide names of stakeholders in the sector in the broadest sense to be approached for an interview. A number of more general interviews have been held as well. The names of the interviewees are listed in Annex I. In this section we present the results of discussions with interviewees. Statements have been anonymised and cannot be traced back to an individual.

Plant biotechnologists

There are two major types of products of plant biotechnology: traits and methods. Traits such as a disease resistance or product quality (e.g. increased antioxidant content) create value in the chain, for farmers, traders, through to consumers. Methods, such as molecular marker platforms and transformation techniques, create value in the process of breeding. A minority see 'open source' as the best mechanism to further biotechnology using the patent system to create freedom to operate for further innovation; mainstream thinking is that exclusive rights are necessary to create commercial value necessary to sustain research and development. For companies that have based their business model on the development and marketing of traits or marker platforms the protection through patents is essential. Biotechnologists working within the framework of seed companies also see opportunities to obtain a return on investment through 'staying ahead of the competition' in the seed market also if those traits are available for further breeding. Biotechnology research is then part of the investments in pre-breeding in traditional breeding.

Biotechnologists also mention the need to implement stewardship, which is related to both the responsible use of the inventions and the limitation/management of liability. Major companies consider the increasing role of lawyers in their companies as a natural effect of the professionalisation of the industry and a necessary contribution to biotechnological research.

Views in the public sector are diverse; the following arguments play a role in different combinations: patents are necessary to enter into public-private partnerships, to maintain freedom to operate for scientists, assist in the downstream utilisation of public inventions, and to obtain cash benefits for the institute facing increasing difficulties to secure public financing. All agree that the complex patent system requires significant legal capacity and investment. Companies with a lot of experience in the system argue that the idea of complexity resulting from patent landscapes is mainly the result of lack of experience in the public sector and small companies, and that the freedom of operation can be increased by, e.g., opposing patent positions of others, by estimating risks, and by improving license negotiation skills.

Plant breeders

Plant breeders are generally 'brought up' in the plant breeder's rights system, and recognise that these rights have provided an essential contribution to the innovation and the success of plant breeding. They also in general value the breeder's exemption, which allows them to use protected varieties for further breeding, which represents a significant value. Even if they would be ahead of the competition and would thus benefit from a restriction of the breeder's exemption they argue that for other crops, or at a different moment, they could benefit from the availability of the competitors' genetic resources. This generates a more stable income over time than a 'winner takes all situation' resulting from genetic material being 'locked' for 20 years. It is also suggested that the objective of plant breeding is to produce better varieties for farmers and growers – breeders are proud of their contribution to an efficient agriculture and food security. Investors' interests usually are not the breeders' first priority. The argument that the breeder's exemption may have to be restricted because technological development has reduced the development time of a new variety from 10 years to sometimes half, meets little response. The counter argument is that better molecular techniques provide a return on investment by decreasing the time and costs of variety development.

There are however different practices with regard to the breeder's exemption. In cereal breeding, breeders may pick up their competitors' varieties from the official field trials stage – in Germany this is only permitted from the last year of testing. Pioneer has in the International Seed Federation (ISF) proposed to introduce a time lock on the exemption, i.e. to agree that further breeding with commercial varieties would not be permitted for a certain number of years. Although European companies see the benefits of the breeder's exemption, it appears that in some crops the exemption is obsolete in practice. Maize breeders state that they do not use competitors' materials and use their own 'gene pool' only out of fear to – even unintentionally – use materials that are patented in the USA, where companies meticulously monitor the genetic content of all maize hybrids and undertake immediate action when their 'blood' has been used in the line of descent of competitors' hybrids, especially when these appear on the American market. The right to further breeding with material under PBR is widely used in all other cases.
In the USA, the plant breeder's rights system has generally less credit. This is not because of the breeder's exemption, but because of the wide interpretation of the farmers' privilege, which significantly reduces the opportunities to obtain revenues on self-fertilising seed crops. In Europe breeders can also claim licence income from self-produced seed of their varieties.

Farmers and growers

Farmers are interested in having regular access to new varieties that meet the changing requirements of cultivation practices and market. They stress the importance of having a free choice of varieties specifically adopted to their cultivation conditions, which may be limited either by demands in the chain or through conditional sale of pesticides and varieties. Neither of these cases are widespread in The Netherlands, but farmers' representatives are very wary. Apart from the free choice it is important that varieties are available for their specific conditions. These are not even uniform in a small country such as The Netherlands, particularly in open cultivation where differences in soil type, disease pressure between the coastal zones and inland are large. These specific submarkets have been bred for by the variety of seed companies that used to breed in The Netherlands. When the number of breeding programmes decreases, when the decision power on the breeding programmes in The Netherlands moves to foreign countries, and when eventually multinational seed companies centralise their breeding programmes abroad there are concerns that the value of the market in The Netherlands will decrease attention for Dutch farmers' needs. This is compared with the problem in Scandinavia where farmers need varieties that withstand long winters, but where the seed market is too small to generate the interest of the international breeding companies for specific programmes. Cereal farmers generally value the freedom to reproduce their own seed, which has been maintained in the latest revision of the UPOV Convention as well as in the Biotechnology Directive.

Processing industry and retail trade

Chain partners, be it processors or retailers, have a growing interest in the results of plant breeding, even though most have never explicitly been involved in actual breeding (Unilever being an exemption) but merely express their needs and preferences to breeders. They are however becoming more and more important in creating value to breeding products, such as hypoallergenic food products (e.g. apples) and novelties in vegetables (small cauliflower, yellow sweet pepper) and new flowers. Vertical integration from variety to shelf is, however, still rare (tasty Tom tomatoes being an exception).

Policy makers

Policy makers also have their own interest in the debate. A major objective is that the innovative strength of the sector needs to be sustained and maximised. This innovative strength provides tools for various policy objectives, such as the banning of certain pesticides. Plant breeding contributes to food security, cheap and healthy food, the development of a biobased economy, and a market position of The Netherlands in the world. And the sector is employing highly qualified staff which is an important element in the knowledge economy that The Netherlands pursues.

4.2 General findings from the interviews

License costs

Discussions with stakeholders often concern the importance of license conditions, and in particular the costs. These are contained in confidential contracts; this means that the team had no access to up-to-date data. One case has been described by the World Bank[47] where the licence costs for a Bt construct (insect resistance) for use in cotton in India were twice as high as hybrid cotton seed, resulting in a threefold increase of the final seed price for the farmer. This led to protests and government action. This price seems excessive but the value of this construct to the farmer is high if it means that fewer insecticide sprays are required per season. But the farmer must largely finance the expected profit in advance whereas he does face all the crop production risks of, e.g., drought. This is hard to accept in a developing country context.

During the interviews representatives of technology companies suggested that license costs are to be based on the added value for the farmer. This added values must be divided between licensor, licensee (breeder) and end user. For constructs that are very interesting to the market, such as resistance genes, without which a variety would be worthless, commercial considerations may, however, play a dominant role and a breeder will be prepared to pass on all added value in the form of a license fee to stay in the market. At worst, even part of the profit margin will be passed on to the technology owner, which may endanger the longer term existence of the licensee if this would result in lower investments in practical breeding.

Thicket of rights

A frequently heard and frequently opposed remark is that patent rights generates a ‘patent thicket’, impenetrable to biotechnologist or breeder. The complaint is that so many patents, so much uncertainty about the precise description of the protected subject matter and the boundaries of the rights as long as these have not been confirmed in an opposition, together with the large number of applications still awaiting handling by the patent office, make it impossible to establish with certainty whether certain techniques can be used. Experts with a lot of experience in patents argue that this fear of the patent system is mainly caused by inexperience and lack of knowledge, that risk assessments may well be made, and that ‘thickets’ do not exist. But for companies with little experience and insufficient capacity to acquire sufficient experience such a thicket is certainly a reality.

General conclusions

The picture arising from the discussions is that the patent system in plant breeding as such does not necessarily need to be problematic but that the execution by means of private contracts and the unavoidable inequality in negotiations between parties with different legal capacities creates large inequality. In addition, the stance taken by certain companies in the execution of their IPR seems to conflict with the collaborative model in which traditional plant breeding in The Netherlands is rooted. Together with the number, broad scope and lack of clarity of patent claims, this gives the IPR system a bad name. This concerns strategic patenting policies and aggressive licensing

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47 World Bank, 2006. Intellectual Property Rights. Designing regimes to support plant breeding in developing countries. Washington DC, World Bank Agriculture and Rural Development. Report # 35517, 77 p. (see: http://siteresources.worldbank.org/INTARD/Resources/IPR_ESW.pdf.

policies (licensing negotiations and conditions). One of the complaints is that the patent system does no longer perform its original task. The balance between the interests of the patent holder and public interests has disappeared because patent holders generate advantages via strategic use of the system while society has done little to oppose this by modernisation of the patent itself to restore the balance.

5. IPR in plant breeding, discussion

Preface

Chapter 5 discusses and analyses the main results of the study as these are described in the trend analyses in Chapter 3 and the stakeholder interviews in Chapter 4.

We restrict the discussion to the results concerning the relationships between IPR and the structure of the sector, IPR and technology development and innovation in plant breeding, and IPR and access to genetic variation.
The discussion takes place against the background of a number of important normative points of departure and the basic objectives of plant breeder's rights and patent rights.

This leads to the conclusion that patent rights as well as plant breeder' rights play a major role in supporting plant breeding and innovation. As regards patent rights, however, a clear distinction needs to be made between patents on technologies for plant breeding and patents on genetic properties of plants.

This study shows that granting patent rights for genetic traits is conflicting with plant breeder's rights, the breeder's exemption in particular. The analysis reveals that access to genetic variation is so crucial to further innovation in breeding that a form of breeder's exemption within patent rights is required.

5.1 Normative choices

The research team has formulated a number of normative points of departure after analysis of the trends in the plant breeding sector and the way the sector puts the different forms of intellectual property into practice as emerged during the different interviews. This is the background against which this chapter discusses the findings as prelude to the conclusions and policy recommendations. The team has formulated these points during the study. They are based on the interviews with stakeholders, discussions with the Advisory Board, and the independent study into various trends. The main points of departure are:

- Plant breeding should make a sustainable contribution to food supply and a sustainable agriculture and horticulture worldwide.
- Access to genetic variation is essential for breeding crops for the future.
- The innovative strength of the breeding sector must be preserved and even strengthened.
- The competitive strength of the sector must be safeguarded through a diversity of companies.
- The Dutch breeding sector must be enabled to safeguard its competitive position in a fair way.
- Good safeguards must be created for acquiring a decent and profitable market share.
- Intellectual property rights must stimulate innovative strength.

5.2 The two objectives of patent rights and plant breeder's rights

Despite the large differences between both systems, plant breeder's rights and patent rights have two fundamental, identical objectives.
On the hand, both rights systems ensure that the developer/inventor is recognised for his/her creation/invention by granting an exclusive right. For the proprietor this serves in practice a business-economic purpose that may provide the basis for a good return on investment (ROI).
On the other hand, plant breeder's rights as well as patent rights include an important socio-economic objective, by disclosing information on the patentable invention and by making a plant variety under PBR available for further breeding ('breeder's exemption'). This offers possibilities to build on such inventions and may stimulate further innovation by others, including competitors, with serves the public objective of economic development.

Assessment of the way in which plant breeder's rights and patent rights are applied in plant breeding needs evaluation of their true contribution to both objectives. This will be done in this discussion.

5.3 The role of plant breeder's rights in innovation

It is generally recognised that the plant breeding industry is a very innovative industrial sector in which a large-scale development of new breeding techniques is ensuring a continuous supply of new plant varieties; it should be noted that large differences do of course exist in the development of this sector on the various continents and in the various countries, while differences between the various subsectors in arable farming and horticulture, and between companies exist as well. High-quality research in plant genetics and in breeding research provides The Netherlands with a very strong knowledge infrastructure[48]. At the same time, and stimulated by this strong knowledge base, the country also traditionally harbours a strong commercial R&D sector, the development of new varieties and the production of high quality propagation material (seeds and planting materials) with high investment levels in R&D (15% to even 25% of turnover).

Especially the interviews with employees of breeding companies reveal that the drive to innovate in new breeding methods and the development of new varieties is based on the motivation to find creative solutions for problems in farming and in the value chain that can capture a market segment. Entrepreneurship and specific expertise play a major role. Protection of Intellectual Property in plant breeding is not the primary driver to develop new, innovative varieties but it is an adequate tool to protect the new varieties in the market against (illegal) reproduction and sales.

For many decades plant breeder's rights, specifically developed for the protection of IP in plant breeding, have been used for this purpose. The proposition that obtaining plant breeder's rights is not the prime drive of innovation but in particular serves to facilitate protection is illustrated by the fact that for many new (particularly vegetable) varieties plant breeder's rights are not applied for and that nevertheless a decent market share is acquired with an appropriate profit margin. This has to do with the specific introduction speed and turnover of varieties in the market. 'Open innovation' was in fact a practice 'avant la lettre' in plant breeding because all plant breeders have always used new varieties with the latest properties, whether the varieties were protected or not.

Interviews in the ornamental sector made clear that the breeder's exemption is of direct significance for survival of this sector. It was also argued that the breeder's exemption lowers the access barrier in this sector making it still possible for starting companies, in particular in the ornamental sector, to acquire a position in he market.

The large number of new varieties that are being developed, the increasing numbers of varieties for which plant breeder's rights are requested, and the positive way in which stakeholders speak about the breeder's exemption allow the conclusion that the breeder's exemption plays an essential role in innovation in practical plant breeding. The combination of IP protection and breeder's exemption makes that plant breeder's rights are perfectly satisfying both objectives formulated above.

5.4 The role of patent rights in innovation

Since the introduction of modern plant biotechnology in the 1980s many new (in particular molecular) technologies have been developed that are important for plant breeding, which enables, e.g., speeding up of the breeding process and the discovery of genetic information. These technological breakthroughs have led to major changes in

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[48] Hans J.M. Dons and Raoul J. Bino, 2008. Innovation and Knowledge transfer in the Dutch Horticultural Sector. Chapter 6 in W. Hulsink and H. Dons (eds.), Pathways to High-tech Valleys and Research Triangles: Innovative Entrepreneurship, Knowledge Transfer and Cluster Formation in Europe and the United States, Springer, 119-137.
http://library.wur.nl/frontis/research_triangles/06_dons.pdf.
Colja Laane and Koen Besteman eds., 2009. Partners in the Polder, A vision for the life sciences in the Netherlands and the role of public-private partnerships. Den Haag, Netherlands Genomics Initiative.
http://www.lifesciences2020.nl/documenten/partners%20in%20de%20polder_DEF.pdf.

plant breeding and the development of molecular breeding. If these new techniques meet the criteria of novelty, inventiveness and industrial applicability, they can qualify for a patent being granted. After the patent has been granted, the inventor has the option to use the patented technology himself or to let this be used under licence by others, dependent on other rules such as those governing market access of GMOs. And because the patented technology is published it contributes to the public knowledge and stimulates further innovations in breeding. Such use is in full accordance with the objectives of patent rights.

Patents are not only granted for new technologies but also for genetic properties of plants (so-called trait patents). The strong increase in knowledge about plant genetics has led to patenting of an increasing number of genes that are coding for interesting properties. This gives the patent holder an exclusive right to commercialisation of those plants. Similar to plant breeder's rights, patent rights on plant properties can also lead to a return on investment. Plants with these new properties, however, are not available for practical breeding and (dependent on the claims) products developed further down the chain may also fall under the scope of the patent.

The trend analyses and the interviews with stakeholders reveal concerns about the way in which patents are granted, the scope of the claims, and the way in which patented findings are handled.

- There is much debate about the question whether the discovery of new genetic properties that are present in plants do meet the criterion of inventiveness, certainly when techniques are used that have meanwhile become 'state of the art'.
- Important subjects in the interviews with stakeholders were the acquisition of licences, the costs of licences and the licensing conditions. Companies that depend on licenses on important traits may as result of high licensing costs loose part of their profit margin on seeds that their own innovative R&D is endangered, which further increases their dependence.
- Plant breeding is a special sector building on the work of 10,000 years of farmers' selection and some generations of breeders. New varieties are created by making use of the total genetic information that is present in a gene pool. Access to that genetic variation is required to achieve variety improvement.
- If a patent on a certain breeding technique stretches to genetic traits and into further links in the innovation and production chain (down to end product) this may restrict practical variety development if insufficient licenses are granted or if their price is too high.

The interviews also showed that acquiring a patent on a new technology or new property is often seen as a bonus on the prolonged and high investments in research for development of the technology, and thus as a method to obtain a good ROI. This, however, disregards the fact that investments and duration are no criteria for acquiring a patent.
As said in the discussion of plant breeder's rights, acquiring patents should not be the main 'driver' for innovations in plant breeding but an instrument to protect market positions. Other important motives were mentioned during the interviews. Prolonged and costly research lines were also set up in plant breeding in a time that patenting in this sector was not yet possible; motives were the breeder's interest and the prospect to be first with the introduction of an improved crop, thus establishing a quality brand for the company.

The relationship between patent rights and technology development has been the subject of many studies. Comparison of technology areas seems logical, in particular for industries that are also investing in plant breeding. In the agrochemical sector innovation has for some decades been restricted to improvements in the formulation of substances and very few new substances are being developed. This is probably associated with the high registration costs and the risks associated with market introduction (comparable to the authorisation of GMOs), but 'evergreening' may also play a role. This is the system under which *de facto* a prolongation of the patent protection of substances is obtained by patenting a new formulation of the same chemical. Innovation in pharmaceutical research is more significant but these companies are also striving for prolongation of expiring patents. Most innovation in this sector is accounted for by small companies, especially start-ups that supply (or are acquired by) large companies that have good facilities for final product development, registration and marketing. Such an innovation system may function properly as long as sufficient start-up companies are set up; this is not the case in plant breeding as result of the high access barrier.

5.5 IPR and genetic modification of plants

Genetically modified crops (GMOs) have a special position in the total field of IPR and plant breeding. We should be aware of the large differences between countries and continents, between developed and developing countries, and between the different sectors (arable, vegetable and ornamental crops) in this field.
IPR play a major role in genetic modification, in technologies developed for application in breeding programmes as well as for the introduction of specific genetic information coding for new traits. Although the basic technologies and the genetic analyses have mainly been developed on the basis of concepts within public research organisations several companies have built up a strong and extensive patent portfolio. Also here, the analyses show a very strong concentration. Only a few companies are owning by far the largest part of the modification-related patents.

The heavy requirements for market admission of varieties are specific for GMOs. The dossiers that need to be submitted in this process are protected by copyright and they are confidential. This means that when a company withdraws a registration, e.g. because am improved version of the technology is available, others cannot apply the old technology. In the US it occurs that GM technology is withdrawn just before expiry of the patent to make a restart with a marginally different version (in particular in Bt technology). Rights to the dossiers can in this way be used for effectively prolonging the IPR on the technology (evergreening).

5.6 IPR and access to genetic variation

Access to genetic variation is a major issue in the discussion about innovation in the breeding sector. The development of new plant varieties depends on access to and use of genetic variation. Natural genetic variation is another important source of variation for the breeder. The last twenty five years have seen a lot of attention for the way in which access can be granted to this form of natural variation while taking the rights of the countries in which this variation has developed into account. This illustrates that genetic variation is the breeder's most important source of innovation.

Plant varieties are exempted form patentability in the European Patent Convention (EPC). Plant varieties can be protected via plant breeder's rights and the genetic variation remains available for further breeding. As set out above, plant varieties can be patented indirectly by patenting breeding methods but especially by patenting properties of plants. 'Abusive' use of patents on breeding techniques and properties (too easy approval, obstructive licensing strategy etc.) can have a negative effect on the further innovation in the sector when patent rights stretches to a plant that can be used as parent in breeding. This is more the case for patents on 'traits' and less on breeding methods such as new marker systems. This is enhanced by an essential difference in business model between seed companies and 'trait' companies where the income model of the latter is not based on selling seed but on royalties. Such protection of intellectual property of genetic variation clearly reduces the availability of genetic variation for further breeding. This may lead to a decrease of the genetic diversity used in plant breeding and thus to a restriction of the diversity in varieties being made available to farmers and growers.

There is prominent place for compulsory licensing in the Biotechnology Directive. This instrument should increase the accessibility of genetic material. In practice, however, this instrument has not yet been used. The conditions for compulsory licensing in Article 12(3) of the Biotechnology Directive make effective use of this instrument very difficult. Proving that the invention (e.g. trait) constitutes 'significant technical progress of considerable economic interest' when it can be used in the variety of company X, cannot be demonstrated *a priori*. In more general terms (i.e. also in other sectors) it is difficult to demonstrate that one has in vain addressed the patent holder to obtain a license. Article 12(3) of the Directive in this respect not even refers to obtaining a license under 'reasonable conditions', a term already difficult to apply in legal practice. A positive effect of compulsory licensing on patents and plant breeder's rights cannot be demonstrated.

5.7 IPR and the structure of the sector

Intellectual property rights also have a strong effect on the structure of the sector. Before the introduction of IPR seed companies depended on their good name based on the quality of their seed and reliability of supply. Varieties could simply be copied, which led to low profits and to the establishment of many new companies.
After the professionalisation of breeding, the introduction of compulsory inspection of seed, and the introduction plant breeder's rights (in The Netherlands in 1941) the number of new entrants decreased due to the greater demands on knowledge level and professionalism and the fact that market positions could be protected. This professionalisation certainly raised the access barrier to the seed sector.

The increasing investments and R&D costs by the introduction of new technologies in plant breeding considerably raised the access barrier for new companies and led to major changes in the structure of the sector. Some companies have organised the need for access to knowledge and technology by entering into strategic alliances with technology companies, others have developed the technologies themselves or obtain them via licences. On the other hand pharmaceutical and agrochemical companies that have biotechnological capacities have acquired seed companies in view of the expected synergy in the application of biotechnologies. This illustrates that different factors have led to the current concentration trend in the sector; IPR is one of these.
The new breeding techniques not only require considerable investments in equipment but also demand specific technological knowledge of skilled staff, and the associated knowledge of legislation and regulations. And driven by this new technology, responsibilities in the field of biological safety and liability (in particular for genetic modification) are increasing as well. This too drives the concentration in the breeding sector.

Another important aspect of the relationship between IPR and the structure of the sector has to do with the costs of acquiring and keeping rights. Some IP systems, such as trademark law and plant breeder's rights, can simply be used by small companies but patent rights are different. No lawyers are required for an application of PBR, a system that has very little room for interpretation, resulting in very few court cases (except possibly in the field of derived varieties, new varieties with a phenotype very close to the original variety). Patent applications, however, require specialised patent attorneys to describe the invention and to formulate the claims. It may take years before rights are granted and the value of a patent may not become clear until it has been opposed, which may lead to long legal procedures. The legal costs of such a procedure may cause a financially weaker party to surrender already after a threat with a court case. All these arguments give room for the strategic use of patent rights, which is impossible under plant breeder's rights.

The costs of maintaining a patent portfolio and of determining freedom to operate should in the end be recovered from the market. It was impossible for the team to get insight into the expenditure on legal assistance in relation to the expenditure for research and development by the companies that were visited. Earlier discussions, however, indicate that large American companies spend more on legal council than on R&D. This justifies the question whether the current patent system yields the best added value for society in the plant breeding sector, assuming that innovative R&D and not lawyers are coming up with solutions for policy challenges such as food security, protection of the environment, adaptation to climate change etc.

Companies can use the patent system for protecting their own findings and for restricting the room for competitors via strategic patent policies. This may even lead to what is called a patents arms race where companies build their retaliation force against obstructions[49]. The exclusive right makes it possible to favour or obstruct parties in the market[50]. Strategic patent use also includes the development of a 'Patent Thicket'. The complaint is that the multitude of patents around the same theme creates a lot of obscurity about the precise description of the invention and the boundaries of claims, which makes it in fact impossible to determine what is freedom of handling and how far protection is reaching. Experts with much experience in patents, however, argue that the fear of the patent system is mainly caused by inexperience and lack of knowledge, that risk assessments are easily made, and that

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49 Granstrand, Ove, 2006. Patents and innovations for Growth and Welfare. Summary and policy recommendations of a government policy study. CIM report 2006:1. http://www.ip-research.org/articles/files/Publications/(99)others/sou2006-80summary_en.pdf.

50 http://www.reuters.com/article/pressRelease/idUS169979+16-Jun-2009+PRN20090616.

patent thickets do not exist. For companies with limited experience and insufficient capacity to build up this experience, however, this thicket certainly is a reality. Too broad and too easily obtained rights in the hands of few weigh heavily on the structure of the sector.

Referring to the original objectives of patent rights (mentioned in the first section of this chapter) it is clear that such forms of 'strategic' use of patents do fall under business economical objectives but are certainly not in rapport with the socio-economic objective of patent rights.

5.8 Other options for IPR?

There is an interaction between plant breeder's rights and patent rights in the plant breeding sector. The objective of this study is to investigate the interference between both systems in breeding in relation to developments in the sector. There are other forms of dealing with IPR which have hardly been activated within plant breeding.
So-called 'patent pools' can, e.g., create good possibilities for parties to make use of each others' technologies[51], which is positive as long as parties outside the pool can exert their right on licences thus avoiding competition problems. But patent pools are not operating very easily in a market with unequal players, as is the current situation in plant breeding. One step further, the patent system may also grant access to new technology for all who are endorsing the 'open source' rules. This is successfully applied in copyright (Linux) where this led to major innovations in which even the largest computer companies are cooperating, but until now this strategy is hardly successful in plant biotechnology despite a number of initiatives (Cambia – BIOS, PIPRA www.pipra.org).

The effect of IPR on the sector is closely interwoven with competition law. Too wide protection may lead to monopolistic behaviour. Competition law and intellectual property right can be considered as two sides of the innovation medal. In case, however, the level of IP is carefully chosen and guarded, both systems can lead to healthy competition. This will be the case when IP does not obstruct future innovation[52].

5.9 Conclusions

IPR in plant breeding is a complex, wide-ranging and important issue although it can be said that acquiring IPR as such is not the driving force for innovation in breeding. Fact is that new varieties have for more than a hundred years been developed in a professional fashion because there is large need for creating crops that better meet the requirements of producers and consumers, and the development of good varieties enables breeders to acquire a good market share.
Analysis of the role of patent rights in plant breeding requires a clear distinction between patents granted for the development of a new technology and the discovery/development of new genetic traits of plants.
The protection of new techniques often concerns breakthrough technologies that may disclose or create new genetic variation, thus making an important contribution to innovation in plant breeding. It is obvious that it must be possible to grant patents for such techniques, provided that they meet the criteria. The study nevertheless reveals that the method of acquiring patents, as well as the exertion of the exclusive right needs strong improvement. These are discussed extensively in this report and include:

- Too wide and vague formulation of the protection scope of patents (the claims), where through broad claims, functional claims and 'reach-through' claims – in particular on genetic material – matters that would have to fall beyond the patent scope are wrongfully claimed.
- The development of large patent portfolios of more or less overlapping claim files ('Patent Thickets').
- The protection of technologies that in fact fall under the essentially biological processes and should therefore not be patentable.

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[51] WIPO, 2009. Sharing technology to meet a common challenge. Navigating proposals for patent pools, patent commons and open innovation. WIPO Magazine, April 2009 –p. 4-7.

[52] John Vickers, 2009. What's mine, what's yours; When should firms be required to share their intellectual property with rivals. The Economist, May 28th.

Both forms of IPR, plant breeder's rights and patent rights, are also used for the protection of the market position of the developer of a plant with new properties. PBR protects the new plant variety while patent rights protects the genetically determined property in a variety. A number of problems are also associated with the granting of patent rights on properties. These include:

- Patents on genetic properties of plants are too easily granted through careless application of the criteria (the inventiveness test in particular).
- DNA sequences for functional genes can still almost automatically be patented whereas the technique has meanwhile become state of the art and hardly contains innovative elements.
- Too broad formulation of the protection scope of patents (the claims), where through broad claims, functional claims and 'reach-through' claims – in particular on genetic material – matters that would have to fall beyond the patent scope are wrongfully claimed.

Too broad and too easily obtained rights in the hands of few weigh heavily on the structure of the sector.

This study shows that the granting of patent rights for genetic properties conflicts with plant breeder's rights, the breeder's exemption in particular. Analysis shows that access to genetic variation is so crucial for further innovation in breeding that a form of breeder's exemption within patent rights is required.

6. Towards solutions – answers to questions and options for policy and stakeholders

Preface

Further to the discussion and conclusions in Chapter 5 this chapter first answers the questions of the Minister as formulated at the start of the study.

This is followed by a presentation of the policy options resulting from this study and a brief discussion of the possible legal consequences. Because policies dealing with intellectual property rights in plant breeding cannot be seen in isolation from the society in which they operate, some adjacent policy areas are discussed that need consideration when answering the questions.

6.1 Answers to the questions raised

The Netherlands Minister of Agriculture, Nature and Food Quality (LNV) has formulated four (groups of) questions about the future of plant breeding in the light of developments in the field of plant breeder's rights and patent rights. These are briefly discussed before policy recommendations are formulated.

1. *Present a review of the trends in the different plant breeding subsectors and the production of plant propagation material and in plant biotechnology. What is the situation of the concentration of the companies and the role of intellectual property in this? Who are the main patent holders in plant breeding?*

It is important to establish that plant breeding continues to remain important for the policy objectives of the ministry of Agriculture, Nature and Food Quality (LNV), including emerging priorities such as biobased economy and climate change. The sector experiences enormous technological developments with a leading role for progress in molecular biology and biotechnology. Molecular breeding has strong effects on the sector through the introduction of marker-assisted breeding, availability of a broader genetic diversity for use in breeding, and the development of genetic modification. These biotechnological developments in plant breeding will continue; there will be new innovations and the technologies will find ever increasing application in the various sectors (arable farming, vegetable and ornamental crops) and this is necessary to hold on to the current competitive position of The Netherlands.
The concentration in the industry by acquisitions and mergers, which started in the 1970s, seems to continue. Many traditionally Dutch companies have meanwhile become part of large multinationals. The rapid growth of the global market of seeds and planting materials is levelling off with a considerable increase in the market share of the largest companies at the same time. Besides globalisation and technological developments, intellectual property rights - and patent rights in particular - significantly reinforce this trend. The contributions of the different forces, however, are not easy to quantify.
Traditionally, plant breeder's rights played an important role in the protection of intellectual property while contributing to continuous innovations in the form of new plant varieties, with an important role for the breeder's exemption. Patent rights entered plant breeding via the introduction of biotechnology. Patents play an important role in IP protection in the field of new technologies as well as in the field of genetic traits of plants. More than 50% of the patents in the field of genetic modification is held by two companies. PBR certificates are granted to a larger group of companies.

2. *What are the socio-economic consequences of these developments for the diversity of companies and adequate market competition? What are possible consequences for the (inter)national breeding sector, the role of Dutch companies, and for developing countries? What are the possible consequences for the use of genetic diversity, for food security and quality, and for the production of green raw materials (biobased economy)?*

The reduction of the number of companies in the market for seeds and planting materials in the subsectors where this trend is strongest (cereals, oilseeds, vegetables) is the consequence of the concentration in the industry. This is not compensated, as in some other industries, by new players entering the market. In practical plant breeding in Europe this only happens in the ornamental sector. The strong knowledge concentration in The Netherlands has until now prevented a significant loss of high-quality employment in the Netherlands as a result of this internationalisation of the sector. Most new owners maintain, or even strengthen, their research capacity in The Netherlands. Some companies, however, have moved the decision power about the direction of plant breeding abroad, which farmers and growers consider as a risk.
Developing countries are generally critical about the demands of trade partners for strengthening their IPR systems on living material.
The free availability of genetic diversity for breeding decreases when genetic materials are patented. There is, however, no evidence yet that this results in a decrease of the genetic diversity in the field.
In October 2009 the special rapporteur for the Right to Food reported about the relationship between IPR and food security in the general meeting of the United Nations[53]. This report also mentions competition and calls for 'open source' strategies.
Consequences of all these developments for food security, food quality, and for new developments such as biobased economy are connected with consequences of the sketched developments for innovation level and innovation direction in practical plant breeding. The study indicates that PBR makes a positive contribution to innovation and hardly causes restrictions. Patents on new technologies are also contributing to the necessary innovation. Patents stretching to genetic material (in 'trait patents' or 'technology patents' with claims that are too broad) have negative consequences for the availability of genetic material. This may restrict innovation in plant breeding with possible consequences for the mentioned policy objectives.

3. *Which positive and negative effects are to be expected for which parties as result of these developments and how could undesirable effects be restricted or prevented?*

Companies with a large research capacity and a large legal competence will benefit from the ongoing concentration. Their market power will expand, in particular in the global arable and vegetable crops. This may entail larger research investments in these crops as long as the concentration does not lead to monopolistic behaviour, but not necessarily to more innovation in practical plant breeding. Smaller companies see that their possibilities to keep their market share are shrinking by the current use of the patent system. The investments in the larger markets mean that farmers and growers in niche markets will see that fewer plant varieties will be specifically developed to meet their needs than in the past, and ongoing concentration of a sector will sooner result in markets becoming niche markets.
Proposals to prevent the undesirable effects are presented in the policy options. These consist of a combination of measures: in legislation and regulations, in the application of the criteria for patenting, and the way in which IPR is applied by the rights holder.

4. *Which legal aspects play a role when taking measures to prevent undesirable effects? Which different legal systems in the world play a role in this?*

Current use of patent rights contributes to the developments described above. The effects of this can be diminished by a change in the use of the right (less 'strategic' patent policy by patent holders); by a stricter interpretation of the patent requirements (novelty, inventiveness and industrial application) by the granting office, and by improving patent legislation itself. Amendments of patent regulations should take national, European and global (WTO-TRIPS) levels into account. In this internationally operating sector it is important that changes of policies and regulations are introduced

53 VN Special Rapporteur for the Right to Food Olivier de Schutter, 2009: Seed policies, and the Right to Food : enhancing agro-biodiversity, encouraging innovation. Report A/64/170, 64th session of the UN General Assembly http://www.srfood.org/images/stories/pdf/officialreports/srrtf2009_iprightsseedpolicies_en.pdf.

at least at European level, and preferably even wider. Restoring the balance between the rights of society and those of the inventor/IPR holder should be an important objective. Companies will increasingly face a society that expects them to take their public responsibility, also as regards the use of IPR. The proposed measures will not directly result in reversing concentration of the sector into a situation with a large number of smaller companies. They will, however, expand the possibilities for companies and thus stimulate competition in the market.
The policy options will also deal with a number of legal consequences. Apart from amendment of the patent system issues such as the role of competition law in preventing oligopolistic tendencies while a number of adjoining policy areas needs to be considered as well to arrive at a coherent policy.

6.2 Policy options

The discussion and conclusions show that IPR plays an important role in crop breeding. A clear distinction must be made between IPR on technology for use in plant breeding and IPR on genetic traits of plants. The conflict between plant breeder's rights and patent rights is in fact restricted to rights on and the availability of plant traits. Patents on genetic material, the way in which these are granted, and the way in which rights are handled are important causes of the decrease in diversity of breeding companies and threaten to obstruct innovation in plant breeding.
An important conclusion is therefore that amendments of the patent system are required for a sustained stimulation of innovation in the plant breeding sector. The policy objective for the internationally operating plant breeding sector must be the implementation of the required amendments at international levels.

Options for achieving the objectives are found at three levels: amendment of legislation and regulations, improvement of the quality of patents, and improvement of the handling of intellectual property.
Policy options can be proposed for all three levels. These are discussed in the following three sections.

6.2.1 Amendment of legislation and regulations

Targeted changes in legislation and regulations is recommended to improve the availability of genetic resources for breeding. There are the following options:

1. Exemption of patentability of plant traits. Patent protection of technological processes in support of plant breeding is possible but should not stretch to plants and their genetic traits.
2. Introduction of a full breeder's exemption in patent legislation, i.e., an exemption of the use in plant breeding of genetic material falling under the scope of the patent, and also of the commercialisation of the new varieties (plant propagation material) originating from such breeding.
3. Introduction of a restricted breeder's exemption in patent legislation, i.e., an exemption of the use of genetic material for plant breeding, but not of the commercialisation of the varieties originating from this activity when these varieties carry this patented trait.
4. Introduction in patent legislation of the possibility to allow breeders to cross with varieties that carry the patented traits but only with the intention to remove the patented traits from these varieties so that only the genetic background may be used for further breeding.

In view of the results of the study and the chosen principles options 1 or 2 are most logical. These options lead to reestablishment of the exemption of plant varieties as formulated in the European Patent Convention (EPC), which is now ineffective as a result of the patenting of plants and traits. These options restore the freedom to operate in plant breeding which stimulates the necessary innovation. Option 1 is a far-reaching option, clear in its scope (plants and their genetic materials cannot be patented). Option 2 allows room for innovation in plant breeding without affecting the patentability of plant biotechnological inventions. The choice between both options will depend on the legal consequences and on the political will at national and international level. These two aspects are not part of the current study; a first start is made in Chapter 6.3.

Options 3 and 4 are not supported by the analysis and the principles formulated in Chapter 5. Only the genetic background is made available in these options, i.e., those parts of the genome that have not been altered by the innovation. As long as the patent is valid, the patented genetic material is only available after a licence has been obtained. Material will not be available for the development of new varieties by others than the patent holder until after expiry of the patent (usually 20 years). Option 3 has a advantage for plant breeding in comparison with option 4. Because breeding with the patented material is permitted without a license by the restricted breeder's exemption, patented traits can become freely available for the introduction of new plant varieties directly after expiry of the patent protection. Under option 4, the effective protection is after 20 years prolonged by the development period of a new variety.

6.2.2 Improvement of the quality of patents

Many problems concerning plant breeder's rights and patent rights, as described in this study, originate from the numbers of patents and the associated uncertainties. These problems can largely be prevented by improving the way in which existing regulations are interpreted and executed. The objectives of the patent system would then also be better met, viz. creating an optimum balance between the rights of the inventor and public interests.

The quality of patents can be increased considerably by:

- a critical analysis of novelty;
- stricter criteria for the inventiveness of the invention ('inventive step');
- a wider interpretation of the concept 'processes of essentially biological nature'
- restriction in number and scope of claims;
- restriction of the possibility to *de facto* prolonging patent validity via new applications or other 'evergreening' strategies.

Improvement of the quality of patents in plant breeding will reduce the number of rights while at the same time stimulating true inventions. Such an approach can remove restrictions caused by obscure, not very inventive patents and broad claims. As regards patents being granted, this can partly be achieved by tightening the implementing orders of the relevant bodies, in particular the EPO, as regards inventiveness, novelty and the scope of claims. This may partly be achieved by directions from the relevant national ministries, but will only be effective if this is done in cooperation with other Member States. This already receives a lot of attention in the breeding sector. Initiatives to improve the quality of patents by tightening criteria have already been started: the ISF (International Seed Federation) as well as ESA (European Seed Association) did in 2008 and 2009 start consultations with the patent experts of the EPO and USPTO to exchange views on these matters in workshops with examiners. In the US the courts are taking the lead through cases for the 'Federal Circuit' *re Kubin* (lack of 'non-obviousness'), *Ariad v. Eli Lilly* (inadequate description)[54] and the current case *ACLU vs Myriad genetics* (among others: novelty)[55].

Decisions about the quality of patents can also be tested by the 'Technical Boards of Appeal' of the EPO. The decisions of these Boards are guiding but the final decisions on dealing with these decisions are taken autonomously by national judges. This provides a wide playing field for national jurisprudence.

6.2.3 Dealing with intellectual property

The PBR system as developed for plant breeding has contributed to the diversity of companies and has stimulated innovation in this sector. Entry of the patent system into the sector contributes to the concentration and reduction of the diversity of companies, thus contributing to a decrease of the innovative capacity.
Alternative models for the exertion of patent rights as these apply in other industrial sectors, such as 'patent pools' in combination with FRAND (Fair, Reasonable and Non Discriminatory) - licences, could lead to better access to genetic material and subsequently to more effective technological innovation. It would be interesting to investigate which are

[54] *Ariad v. Eli Lilly*, 560 F.3d 1366 (Fed. Cir. 2009).
[55] http://www.genomicslawreport.com/index.php/2009/06/04/aclu-v-myriad-genetics-suit-legitimate-challenge-or-publicity-stunt/

the ‘drivers’ for the various ways of cooperation in other technological sectors and how these relate to plant biotechnology and breeding. Contacts with representatives from the industry in the sector revealed that relevant parties are interested in putting the current use of patent rights under debate. It is important that the sector itself comes up with solutions for the problems that arise, e.g., through establishing codes of conduct in the international organisations of the seed sector (such as ISF). A radical change in the utilisation of the patent system by companies, by refraining from strategic use in particular, will improve the public profile of the sector. Improvement of the use of patent rights is a responsibility of the industry. It is suggested that ISF and ESA are asked to formulate proposals to achieve this. In that case it would be desirable to put a deadline.

Another, also politically, interesting issue concerns the contribution of public research organisations to the patenting in the plant sciences. Current policy stimulates public research organisations protecting their findings via patent rights. It is worth investigating how current patent and publication policies –and their execution by those organisations- together with their licensing policies make a positive or negative contribution to the developments described in this report.

6.3 Legal consequences

Amendment of the regulations via the routes described in 6.2.1 requires careful consideration of the legal consequences. This study is not primarily a legal study. As soon as policy options lead to concrete actions a thorough study will have to be conducted into the legal consequences, where three levels are to be distinguished: national (Netherlands Patent Act), European (Biotechnology Directive), and international (TRIPS Agreement). The following remarks, however, are to be made:

Re 1. Restriction of patent rights such that genetic material of plants would no longer be patentable (option 1, mentioned in 6.2.1) is permissible under Art. 27, 3, b of the TRIPS Agreement (exemption of plants), but requires amendment of the Biotechnology Directive 98/44/EC. This requires a European procedure as well as amendment of patent acts in the Member States. This study has not analysed whether such an exclusion would have unintended effects on other sectors (other than plant breeding).

Re 2. Implementation of a full breeder’s exemption in patent rights (option 2, mentioned in 6.2.1) can, in the analysis of the team, take place at national level, and does not require amendment of Directive 98/44/EC. Implementation at European level is of course to be preferred from a harmonisation point of view but it is unmistakable that a national implementation would considerably advance these options elsewhere. The patentability of genetic material is not disputed. Genetic material of plants remains fully patentable, in all its possible applications, but third parties may always use this material for scientific research (by virtue of the already existing research exemption, Art. 53, 2 Netherlands Patent Act 95), for use in new plant varieties and for commercialisation of those varieties (by virtue of the breeder’s exemption to be implemented). Any other use requires permission of the patent holder, who can of course stipulate conditions for his permission. Option 2 may be considered by some as a too serious erosion of the right of the patent holder, which might be in conflict with the TRIPS Agreement. Consulted individuals, however, disagree on this point.

Re 3. The restricted breeder’s exemption can also be implemented in patent rights at national level (option 3, mentioned in 6.2.1). The main difference between options 2 and 3 is the freedom of the breeder to introduce his new variety on the market. This freedom is unrestricted under option 2, viz. without permission or license obligation; under option 3 he will have to negotiate with – and pay - the patent holder for the genetic material. Such restricted exemptions of model option 3 have already been implemented in France and Germany.

Re 4. The breeder’s exemption of option 4 can also be implemented at national level

Tightening of the practice of granting patents (as indicated in 6.2.2) requires instructions to, and consultations with, the national patent-granting bodies and, firstly, with the EPO. It is logical that this last action would be undertaken via the Netherlands representatives in the Administrative Council of the European Patent Convention, which is the competent body for directing procedural rules, tariffs, implementing provisions, etc. Action could also be undertaken via SACEPO. The European Patent Office itself is in fact already developing plans into this direction.

6.4 Adjacent policy areas

6.4.1 Economic policy: competition

The strong relationship between IP and the concentration in the seed sector raises the issue of the role of competition law as tool to tackle misuse of exclusive rights and monopoly positions that may or may not arise as result of patenting. The assignment did not include a request for describing and analysing the legal possibilities in this field. A case of suspected misuse of the market position of a company in the breeding industry is currently at hand in the US. We understand that this is a forceful instrument in the US, especially because companies that are subject of such investigation have to provide full disclosure. It is recommended to investigate whether application of current competition law would be meaningful considering the developments in the plant breeding industry in Europe.

6.4.2 Biodiversity policy: access to genetic resources and sharing the benefits arising from their use

The team argues that access to genetic resources is an important condition for a healthy, innovative plant breeding sector. The study in particular focused on the significance of access to advanced genetic resources as potential parent material in plant breeding. A policy aimed at improving the accessibility of such varieties via amendments in patent rights logically goes hand in hand with policies in the context of the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA) to advocate the broadest possible access to genetic resources.

6.4.3 Development policy

Patent policy should contribute to a proper balance between the rights and obligations of inventor/patent holder and society. This means that developing countries should also be able to determine this balance themselves. Bilateral trade agreements of the EU with developing countries often include strict requirements for developing countries to take their IPR to a higher plan than the minimum requirements of the multilaterally agreed WTO-TRIPS Agreement. In the light of this report it should be considered on a country-by-country basis whether these requirements serve the interest of the developing trade partners, in particular as regards breeder's and farmer's exemptions, where The Netherlands can take initiatives in UPOV and WIPO to make IPRs contribute better to agricultural development through plant breeding.

6.4.4 Knowledge policy

The policy of bodies that are financing public research such as NWO, STW, KNAW and relevant Ministries stipulate conditions for research programmes by public research organisations and public-private collaborations (e.g. FES) via agencies such as the Netherlands Genomics Initiative and the Technological Top Institutes. Patenting policies of universities and institutes are to a large extent determined by these funding conditions. It is recommended to consider this policy in the context of this report and to avoid public research contributing to a patent-governed restriction on innovation in plant breeding.
When restriction of patent rights would lead to a reduction of private investments in certain aspects of biotechnological research it is worth considering an increase in the public investments in such areas.

Annex I. Interviewees

Fr 4-9	Kees Noome	Limagrain – breeding arable crops
Mo 7-9	Richard Visser, Ton den Nijs, Ruud van den Bulk & Lidwien Dubois	Wageningen UR – public breeding research
Tu 8-9	Martin Robaard	Wiersum – breeding arable crops
We 9-9	Theo Ruys	Moerheim Roses – ornamental crops
	Piet Schalkwijk	AkzoNobel – IP expert – Member Advisory Board
Th 10-10	Orlando de Ponti	International Seed Federation / Genetic Resources Policy Committee of the CGIAR
Mo 14-9	Theo van de Sande	Ministry of Foreign Affairs – development expert
	Richard Schouten Kees of Bohemen	LTO – farmers' union ZLTO – farmers' union
Tu 17-9	Arie van Zanten Sjoukje Heimovaara	Royal van Zanten – ornamental crop breeding
	Leo Melchers Gerard Meijerink Rico Linders	Syngenta seeds – vegetable crop breeding
Fr 18-9	Paul van der Kooij	University Leiden – IP scientist – Member Advisory Board
Mo 21-9	Ben Tax	RijkZwaan – vegetable seed breeding
	Maarten Koornneef	Max Planck Institut – public breeding research
We 23-9	Rudy Rabbinge	University Professor Wageningen University – Member Advisory Board
Th 24-9	Arjen van Tunen	Keygene – breeding research
	Pim Lindhout Marleen van Balkom Henry Bosch	Monsanto – deRuiter Seeds – vegetable crop breeding