



Intellectual Property Rights and Native Traits in Plant Breeding

A quick scan of patents involving products of conventional plant breeding

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1. Summary

Intellectual property protection (IPR) in plant breeding encompasses two different systems: Plant Breeder's Rights (PBR), a system of IPR specifically designed for plant varieties, and Patent rights, a generic (industrial) IPR system. Most (> 90%) of the patent applications regarding plants concern GM-related inventions (i.e. transgenic plants). In the last two decades interest has risen in filing patent applications on products of conventional breeding as well. In the public discussion, traits involved have been named "native traits" as they usually were already naturally present as such in the progenitors of the novel plant line. Novelty lies in their recognition (or design of plant ideotypes) and/or combination into a useful trait in novel elite types of plants.

This "quick scan" explored "native traits" in relation to patents in plant breeding using two approaches: 1) an exploration of European patent applications potentially addressing conventional plant breeding, and 2) interviews with stakeholders about their experiences with and opinion on IPR and "native traits", in particular with regard to effects on access to genetic resources for breeding and innovation. The patent exploration was primarily aimed at obtaining an idea about the numbers of patents involving conventional breeding products, and about the crops and traits, and the claims concerned. Subsequently, we looked which questions could be raised with regard to access to plant genetic resources from the point of view of plant breeders/biologists. The exact scope of the claims can only be assessed by legal experts, but that was beyond the scope of this study.

We used international patent classification codes (IPC) for plant-related inventions to find patent applications involving conventional plant breeding. Obtaining a comprehensive overview of patents did not succeed in this way. In the end, we also scanned patents from breeding companies in order to assess whether we had not missed patent applications. As this list of companies may not have been exhaustive, we still may have missed some patents. The main problem was distinguishing applications involving conventional breeding from the applications targeting genetic modification, i.e. transgenic plants, which represent the bulk of plant patents. For instance, applications involving genes may use them both for transformation and for generating markers to be used in introgressing the genes, thus conferring native traits to elite plant material using marker-assisted breeding (MAB). To classify applications correctly, we studied the claims in more detail, which is the normal practice in the patent field. Patent applications contain claims that may not be granted, but the number of granted patents was relatively small as most patent applications were still in the examination phase.

The combined queries for European patent applications produced, up to the end of 2013, approximately 400 applications with an expected relevance to conventional breeding products. The total number of plant biotechnology-related patents was in the order of 6100 (Winnink 2012). This number of 400 needs to be addressed with care as in the above search strategy patent applications may have been missed. For 2014 and 2015 82 new applications were found in a less exhaustive scan. Of the 400 found, 50 applications apparently did not contain claims on plants and thus fell outside of the scan's focus in so far this was aimed at possible effects on access to plant genetic resources. The majority of the patent applications encompassed arable and horticultural crops; only relatively few ornamental species were represented. In addition, a few medicinal crops were encountered. In view of the time available, 200 applications could be reviewed in more detail for traits, crops and types of claims. The 200 applications studied in more detail included as much as possible vegetable crops, as they represent an important part of the activities of the Dutch breeding sector, plus other crops, covering as wide a variety of traits as possible, but due to the combination of a wide variation of traits and crops, figures can only be indicative. Claims in applications may not all be granted, but analysis of claims granted was only possible to a limited extent as most applications were still in the examination process.

A steady growth in number of patent applications per year was observed from the 1980s up until the present day: of the 200 analysed, 5 were from the period of 1983 to 1992, 51 from 1993 to 2002 and 144 from 2003 to 2012. The percentage granted was about 60% in the first two decades. No conclusions can be drawn for the last period of 2003 to 2012 as often the examination procedure was still ongoing. The traits involved are familiar with breeders efforts as known from scientific literature. The largest part of the applications concerned product quality (48%), encompassing traits for the grower (5%) and for the consumer (42%). For the grower, these are for instance improved yield and plant architectures

adapted to efficient harvesting. For the consumer, improved shelf life and taste or improved compositions with regard to (secondary) metabolites, such as glucosinolates and carotenoids in vegetables or fatty acids in oil crops like oilseed rape. Resistances against pathogens and pests had a share of 30%, among which against viruses, bacteria, fungi, oomycetes, nematodes and insects. Another part of the applications (15%) entailed traits related to F1 hybrid variety production, particularly male sterility (MS) and/or matching fertility restorers, the most common form being cytoplasmic MS (CMS).

Patents could contain claims that were primarily "product-based", i.e. referring to plants with a specified set of traits, or primarily "process-based", i.e. a method by which a trait is introduced into (elite) plants (e.g. MAB). In the latter case, the products (plants) could be claimed as well, but that was not always the case, as mentioned above for the 50 applications not further examined for that reason. Methods could also be incorporated in the product claim, e.g. 'obtainable by process x', where they serve as a circumscription enabling reproducing the production of the plant ("product-by-process"). For patents granted, sometimes process claims were granted but the product claims not, or the other way round. The trend of the last two years seemed to be an increase in product-by-process claims, possibly as a consequence of the procedure on the Tomato and Broccoli cases at the Enlarged Board of Appeal of the EPO, who decided in 2015 that "essentially biological methods" of crossing and selection, including when supported by technical means such as marker-assisted breeding (MAB, see below), were not eligible for patenting. The products (plants) resulting from such a process of an "essentially biological" nature are eligible, if conforming to the usual patent law demands of novelty, inventiveness and applicability (G2/12 & G2/13).

"Native traits" is a term used in the public debate, but it is not a term used in patent applications or classifications. In order to obtain an overview of patent applications relevant with regard to native traits, we performed a broad search for applications containing claims related to conventional breeding products, that is, excluding genetic modification in the sense of plant transformation and producing transgenic plants that are outside the scope of this scan. Conventional breeding leads to varieties that breeders in Europe freely use for further breeding under PBR. Subsequently, we have looked at the relevance of the applications found for "native traits" by looking at the techniques used and the characteristics of the plants produced. With regard to the techniques used to produce the plants that carry the trait, the most basic is classical crossing and selection that are not eligible for patenting as mentioned above. Crossing and selection use genetic variation found in the crop species and cross-compatible wild relatives, such as found in genebank collections. Cell fusion (somatic hybridization, 5 of the applications analysed) is a more advanced biotechnological method that may enable interspecific hybridizations that are very hard to achieve by other means. The plants produced will contain new combinations of naturally occurring traits that in some cases also could have been brought together by conventional crossing.

Using mutagenesis (38 of the applications analysed), mutations are experimentally induced at higher frequency by treatments of a technical nature. Nevertheless, mutations arise as randomly as under natural conditions and desired traits are selected for by the same selection techniques as spontaneous mutations. In many cases, induced mutations in plant products cannot be distinguished from spontaneous mutations that are underlying natural variation ("native traits") found in genetic resources. One needs to know the underlying methods by which the plants were generated, to determine whether the trait came from an existing plant source.

The limited breeders exemption recently put in place enables the use of patented plant materials without permission from the patent holder, but plants developed still containing proprietary traits can only be marketed after obtaining a license. Thus, breeders will likely screen material for proprietary traits before using them in their own programmes. For assessing germplasm for the presence of proprietary traits, the traits descriptions in the claims will be analysed. These descriptions may be adapted according to assessments during the examination procedure. Descriptions could be based on phenotypic and/or genotypic characterizations. The seemingly most straightforward genotypic category, desirable alleles of specific genes identified, encompassed about an eighth of the patent applications analysed. A number of phenotypic traits may be part of basic measurements in normal breeding practice (e.g. fruit shape or colour). Traits that are described as, for instance, levels of a compound higher than a particular value or percentage, or as compared to a reference plant without the new trait, may be laborious to assess. However, they may be based on relatively simple modes of inheritance, i.e. loci or genes. On the other hand, disease resistance, often bred through R genes/loci, may also be based on combinations of QTLs

(quantitative trait loci), thus more complex in the genotypic description. Complex cases where semi-quantified descriptions were combined with polygenic/unknown or unspecified inheritance were found less commonly than with genes, loci or QTLs. Without a more detailed inquiry, it is difficult to estimate to what extent additional efforts would be required to identify proprietary traits when incorporating new germplasm into a breeding program.

Overall, two fifths of the patent applications analysed encompassed marker-assisted breeding (MAB). DNA markers are an important innovation of the last two decades and have increased the efficiency of introducing new traits significantly. In the first instance, the necessary investment to develop markers meant an incentive for strengthening IP protection through patents, as methods cannot be protected through PBR. On the other hand, applying markers leads to higher efficiency of selection and thus also to cost reduction for developers of new varieties. At the same time, a competitor may now also be able to more quickly introduce a trait that was originally difficult to obtain, such as a pathogen resistance from a wild relative, into his own elite materials for developing new varieties.

More than half of the patent applications involving MAB concerned introgression of QTL (quantitative trait loci). QTL are detected by a statistical association of a desired phenotypic trait with markers across a region on a genetic linkage map. This association described in the claims may extend to various numbers of markers in the chromosomal interval that are associated with the trait. Other desirable, yet undetected traits may be localized in or around the same chromosomal interval, since such chromosome intervals easily harbour large numbers (hundreds) of genes. In practice, hot spots of various types of QTLs may be found in genomes. This may raise the question whether any interference could occur with the use of such a genomic area for other traits when the proprietary QTL (i.e. the phenotypic trait) may still be identifiable. Due to its relative novelty, still few patents have been granted in this field.

The interviews indicated that “native traits” were often regarded as part of a wider discussion about biotechnology, including transgenic plants, and access and benefit sharing of plant genetic resources. From the NGO’s point of view, the position of smallholder farming was pivotal. This included access to native traits conserved in landraces over generations, independently of whether they had become patentable by their definition and being engineered into elite cultivars. Among scientists, the freedom to operate or “open source” approach of PBR was appreciated, but in the end, the main point would be what would serve society at large the best, i.e. a responsible innovation process. Complex trait introgressions, particularly from wild species, were perceived by all companies as demanding large investments and thus providing a strong incentive for IPR protection. This is particularly so when they entail traits such as resistances that will quickly gain a large part of the seed market. Companies further varied in their preferences for IP protection of native traits through either PBR or patents. This depended on their appreciation of which IPR system gave the best balance between investments and revenues.

Other aspects included transparency about which material contained proprietary traits and the advantage provided by PBR of “freedom to operate” with germplasm. Companies with a preference for patenting of particular traits sought a solution to some of the criticisms in increasing transparency. This could be achieved through e-licensing, i.e. offering proprietary materials on their websites with standard licensing terms available to all interested parties. Vegetable companies have been negotiating a licensing platform, which would also improve transparency about proprietary traits, the International Licensing Platform (ILP) Vegetable. In addition, the PINTO database initiative of ESA (European Seed Association) is filled by patent assignees on a voluntary basis and links patents to plant varieties marketed. The database contains a limited number of patent (application)s until now.

2. Introduction

The increasing pace of innovation in the plant breeding industry is reflected in an increased interest in the ways intellectual property can optimally be protected. Ideally, by IP protection the innovator should be able to obtain sufficient revenues to be able to sustain continued innovation. At the same time, optimal availability of genetic resources to breeders, both small and large companies, is essential for continued innovation. Intellectual property rights (IPR) in breeding have become an issue in discussions on the best ways to achieve global food security and these discussions also have extensions into considerations about ethics concerning living beings. Thus, IPR in breeding has caught attention of society at large.

In IP protection in plant breeding, various systems play a role: trademarks, image rights, Plant Breeders' Rights, and Patents. A separate system of Plant Patents for asexually propagated crops exists, amongst others, in the US, but that is not relevant to the situation in Europe. Plant Breeders' Rights (PBR, enacted for sexually propagated crops under the Plant Variety Protection Act (PVPA) in the US), a system of IP protection specifically designed for plant varieties, and Patent rights, a generic (industrial, or 'utility' in the US to distinguish it from the Plant Patents mentioned above) IP protection system, are the main systems. The present use of both systems side by side is the subject of discussion in Europe. Briefly, for plant breeders' rights (PBR), plant varieties are the basic unit of protection with regard to marketing and propagation. The varieties need to fulfil the conditions of novelty, and of distinctiveness, uniformity and stability (DUS). The protection is standardised, and it does not extend to the use of varieties in new breeding programmes, so germplasm in the form of varieties protected by PBR remains free for other breeders to use for breeding and commercialising new varieties (this is often referred to as the breeder's exemption). Patent protection is for inventions that are defined as being novel (i.e. not part of the state of the art), inventive (or non-obvious), and industrially applicable. The applicant needs to describe what the invention entails, i.e. formulate claims defining for which elements of the invention protection is desired. These claims may include methods of production or use, and the products made using the invention. Patents also contain a detailed description of the invention, which can be used by third parties for further innovation and development. However, direct use of the patented material is only allowed with permission (a license) from the patent holder, except for a research exemption, which entails testing for the usefulness or presence of the invention, and a recently enacted limited breeders' exemption, which is only applicable in some European countries (see below).

Plant varieties can be protected through PBR, but they are not eligible for industrial patent protection in Europe. In contrast, plants that contain an invention that is industrially applicable and can be introduced and perform its function in other plants or plant varieties, are eligible for patenting in Europe. Using such plants freely in further breeding, as is allowed in the case of protection by PBR, is possible only when an explicit exemption is included in patent law. This has been the subject of discussions in Europe for many years. France, Germany and Switzerland have a limited exemption for plant breeding, which was recently followed by the EU in its 'unitary patent' and The Netherlands (33 365 (R1987) "Wijziging van artikel 53b van de Rijksoctrooiwet 1995 in verband met de invoering van een beperkte veredelingsvrijstelling"). With the introduction of the limited exemption for plant breeding, breeders are allowed to use patented biological material for breeding and developing new plant varieties. For commercialization of the newly bred variety, however, a license of the patent holder is required when the proprietary trait is still present in the plant material. There are ongoing discussions about a broad exemption, in which also commercialization would be allowed.

In both the TRIPs Agreement and European patent law (the European Patent Convention (EPC) and the EU Directive 98/44/EC on the legal protection of biotechnological inventions), an exception (exclusion) exists with relevance to plant breeding. That is the exception for "essentially biological processes for the production of plants or animals", which are not eligible for patenting (Article 53(b) EPC and Article 4(1)b 98/44/EC). "Essentially biological processes" refer to the basic breeding methods of crossing and selection (Rule 26(5) EPC and Article 2(2) 98/44/EC). These issues around the parallel existence of PBR and patents have been reviewed by Louwaars et al. (2009) and the ongoing discussion between stakeholders about how to handle PBR and industrial patents in plant breeding in practice in the Netherlands was the topic of the Trojan report (2012).

The patentability of conventional plant breeding products with regard to the interpretation of this exception (exclusion) was the subject of a recent decision of the Enlarged Board of Appeal of the

European Patent Office (the so-called “broccoli” and “tomato” cases, G 2/12 and G 2/13, respectively). The decision confirmed that “essentially biological processes” of crossing and selection remain excluded from patentability¹. The decision further indicated that plant products were eligible for patenting, if conforming to the normal conditions of novelty, inventiveness and applicability, even when the underlying methods are not under the EU Biotech Directive 98/44/EC.

Industrial patenting in plants is common when it concerns genetically modified (GM) crops. Transgenic constructs can be relatively straightforwardly identified as inventions, while various techniques regarding plant transformation have been patented from the 1980s onwards. Indeed, at this date, the great majority (>90%) of patents regarding plants concern GM inventions. Possible effects of GM (transgenic) plant patents on accessibility of germplasm in Europe are small at this moment as very few GM crops made it into commercialisation due to explicit GM regulations. GM (transgenic) plant patents are outside the scope of this study.

In the last decades, interest is rising in filing patent applications on products of conventional breeding as well (Louwaars et al. 2009). Here, inventiveness is based on the recognition, definition and/or combination of (gene variants underlying) traits into a useful trait in novel elite types of plants. Partly as distinction from GM traits, such traits have been named “native traits”, as they are, so to speak, natively (naturally) present in germplasm. Patenting of conventional breeding products has been stimulated by novel technology that led to higher investments in breeding research. This was particularly so with the advent of marker-assisted breeding (MAB). The use of DNA markers significantly increased the number of native traits that could be introduced into new plant varieties, and/or the speed by which native traits could be introduced or combined.

The term “native traits” refers to traits already existing in germplasm, including wild relatives of crop species, or that can be produced by recombination of existing traits. Unfortunately, the term has not been defined exactly, and therefore stakeholders may have somewhat different views on what represents a native trait. In addition, it is a relatively recent term, up to now little used in the scientific literature and in patent filings. To our knowledge, no extensive public overview exists in scientific literature about the types of conventional breeding products and/or native traits that are the subject of patenting in practice, and the nature of the claims in these patents. There are some reports of collections and discussions of patents on conventional breeding by NGOs, e.g. Then & Tippe (2009, 2013, 2014) and Hammond (2011). Winnink (2012) recently provided an overview of numbers of plant breeding patent applications and companies/institutions involved, in which all types of biotechnology, including GM, were taken together.

This report is a quick scan to explore “native traits” in relation to the parallel existence of the two main types of IPR in plant breeding in Europe. This exploration was performed by two approaches: 1) an exploratory inventory of European patents potentially addressing conventional breeding products, and 2) interviews with stakeholders about their experiences with and opinion about PBR and patents in relation to “native traits”. Clues provided by the interviews were used to focus the analysis of the patents on elements that could be relevant to the question of primary importance to breeders, namely, to what extent may patents involving native traits affect the use of genetic resources in breeding new plant varieties. We specifically looked at the following questions:

- Can we estimate how many European patent applications involve conventional breeding products in plants? In searching for such patent applications, they need to be distinguished from patent applications involving genetic modification (i.e. referring to transgenic plants). Subsequently, we looked into the relevance of the patent applications found for “native traits”.
- What types of traits and techniques, and in which crops, are the subject of these patent applications?
- What sort of claims do we find in these patent applications?

¹ “a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability...”

- How is the “(native) trait” described and/or quantified and what may this mean for the efficiency by which they could be identified by breeders in plant material that they consider for use in a breeding programme leading to a commercial plant product?
- Do the claims for conventional breeding products lead to specific questions with regard to the use of plant genetic resources in breeding?

We performed this analysis on patent applications. It was not possible to do this on the same scale on granted patents as many patent applications are relatively recent and still in the examination phase. We note that there may be substantial differences between the claims in a patent application and those that are finally granted. In cases in which the patent has been granted, we could compare these, and where appropriate observations on differences are included.

The scan was done in detail for patent applications found up to the end of 2013, more recent applications and granted patents will be briefly mentioned. It should be noted that the exact scope of claims can only be assessed in discussion with legal experts, and in the end may only be settled in court, but this was not part of this study. Hence, all numbers of patents and on traits in tables can only be taken as indicative. We touch upon GM traits with regard to their delimitation from native traits, but we do not address issues about GM (transgenic) crops themselves and their IP protection.

In the interviews our focus was on the following topics:

- How do stakeholders assess the impacts of patenting and PBR on “native traits” and what are in this context their opinions on the parallel existence of patenting and PBR?
- What experiences do stakeholders have with concrete cases about access to and use of native traits in plants, and how could (possible) restrictions in this context be addressed?

While this study was being carried out, there were ongoing societal discussions, such as on limited or broad breeders’ exemptions, and alternative solutions have been proposed and/or put in place by stakeholders to find the balance between innovation efforts and revenues, access to germplasm and transparency. Our study aims to facilitate these discussions by exploring and providing relevant data and biological insights.

3. Approach

The study consisted of two parts: exploration of patent applications and interviews with stakeholders.

3.1. Exploration of patent applications on native traits

Patent applications were searched using the database Orbit (Questel). The searches were limited to European patents (EP numbers). "Native traits" was not a common term or keyword in plant patent applications, even though a few applications did include the term as keyword. Underlying breeding methods would be a better starting point of this search, i.e. (in the context of PBR and patent discussions,) conventional techniques. A complicating factor is that for breeders in the European context, conventional methods usually refer to a series of techniques other than genetic modification (i.e. recombinant DNA technology/transgenic plants) that is under regulatory scrutiny of Directive 2001/18/EC (cf. van de Wiel et al. 2010). Some of these conventional techniques are of a more biotechnological nature than crossing and selection. Thus, mutagenesis and cell fusion (defined as genetic modification in the 2001/18/EC Directive, but specifically exempted from regulation) are classified with plant transformation in International Patent Classification under mutation or genetic engineering IPC codes C12N 15/01 and C12N 15/02, respectively (specifically C12N 15/05: plant cells). In addition, conventional methods of producing changes in chromosome number are coded separately as A01H 1/08 under processes for modifying genotypes (mutagenesis has A01H 1/06, hybridisation and selection A01H 1/02 and A01H1/04, respectively). On the other hand, crossing and selection are increasingly supported by (molecular/DNA) marker use (marker-assisted breeding or selection, MAB or MAS), which may be classified under C12N 15/09 (recombinant DNA technology). In addition, IPC codes appear not to be used consistently (see below).

For obtaining an overview as comprehensive as possible for further discussion, we have in the first instance targeted patent applications not involving genetic modification/engineering *sensu stricto* (i.e. involving transgenic plants). After presenting the results, we will further discuss the relevance for "native traits". Thus, IPC codes were used as follows:

- A01H5+ (new plants: angiosperms) NOT C12N15/82 (genetic engineering with plant cells as hosts), to find patent applications involving plants but excluding those involving genetic engineering. The patent applications found were expected to cover conventional breeding methods and were therefore screened for their relevance to "native traits". A part of them still proved to be based on genetic engineering/plant transformation, and these were removed. On the other hand, there are several reasons why this query did not completely cover patent applications related to conventional breeding:
- A01H1+ (processes for modifying genotypes) may also contain claims on the products (i.e. plants) achieved by these processes. In particular claims on plants, and/or traits selected for, bear relevance to the question of the possible impact of IP protection on the use of genetic resources. Therefore, an additional search was performed with this IPC, excluding the above two categories.
- The above excluded C12N15/82 (genetic engineering with plant cells as hosts) may in practice cover more than just GM *sensu stricto*, i.e. transformation of plants, for the following reasons:
 - Patent applications addressing characterized plant genes may claim both applications using GM (i.e. transformation) and applications using marker-assisted breeding or selection (MAB or MAS). MAB by itself can also be categorized under C12Q1/68 (tests involving nucleic acids). However, because of the large number of applications of such tests also in microorganisms and in medicinal technology, searches using this IPC produced an unmanageably large number of results. A feasible variant was a search with a combination of C12Q1/68 AND A01H1 OR A01H5, which, although in principle redundant compared to the above searches, did produce additional patent applications.
 - As mentioned, IPC codes appeared to be not always consistently attached to applications, i.e. C12N15/82 where C12Q1/68 would have been more applicable, or mutagenesis without code A01H 1/06 and/or C12N 15+ codes missing with mutagenesis.
- An additional search using A01H4 (tissue culture, which is an important supporting technique in conventional plant breeding) did not yield additional patent applications. A search using A61K (medical preparations) did produce a few additional patent applications.

As a check whether patent applications with relevance to conventional breeding were missed, searches were also performed using specific breeding companies as term (list in Annex). Results were also cross-checked with the ESA (European Seed Association) PINTO database (<http://pinto.azurewebsites.net/>). The PINTO database is a recent initiative that links marketed plant varieties to patents and patent applications. The database is filled by patent holders on a voluntary basis. The detailed search comprised patent applications up to the end of 2013. A less exhaustive search was performed for 2014 and 2015, which included the use of the patent listing of the recently established International Licensing Platform (ILF) Vegetable (see interviews and Discussion).

Subsequently, the patent applications found were categorized based on crop species, breeding method and traits. Breeding methods encompassed basic crossing & selection, selection methods, modifying ploidy levels, etc. Traits involve for instance disease resistances, cytoplasmic or nuclear encoded male sterility (CMS or NMS), and more complex quality characteristics, such as shelf life (keeping quality).

Claims were categorized according to the manner by which complex traits were described: morphological/plant architecture – qualitative (e.g. colour) or quantitative (e.g. internode lengths), physiological (e.g. hormonal tests), biochemical (e.g. levels of specific metabolites), and the genetic basis: locus (e.g. “classical” R gene-based disease resistance), QTL, gene, mutants, polygenic/not described. An attempt was made to distinguish between levels of precision in quantifying traits, e.g. absolute measures of quantities of a substance, or levels relative to those in a reference (breeders lines, plant line, known variety, deposited seeds).

Patent applications were also followed in time, i.e. we noted dates of application and dates of granting, and dates of divisional applications when applicable. Published applications for patents were included since breeders may need to reckon with all claims as long as the patent is not finally granted. Indeed, patent applications not yet granted can also be found in the PINTO database mentioned above. For some claims with potential relevance to the use of genetic resources, such as whether more than one crop species was involved or with respect to the use of markers, we were able to compare the claims in the granted patent to those in the published application. In such cases we specifically noted claims that did not make it to a granted patent and/or for which a divisional application was filed. However, only a small number of patents has been granted so we only make a few qualitative observations by comparing the first published applications with the respective granted patents. Intermediate steps and the correspondence regarding claims during examination and/or opposition were not studied, as this study was meant as an exploration of a range of patent applications in this field, not as an in-depth study of particular patent applications.

3.2. Interviews with stakeholders

Interviews were carried out by Erik de Bakker and Clemens van de Wiel with seven stakeholders from the following fields:

- Science (2)
- Breeding companies (4)
- NGO (1)

The questionnaire used can be found in the Annex.

Because the interviews were held in Dutch and the reports have been circulated for feed-back with the interviewees in Dutch, this part of the report is in Dutch.

4. Results

4.1. Exploration of patent applications

The combined queries for patent applications produced approximately 400 European applications with an expected relevance to conventional breeding products up to 2013. In a less exhaustive search for 2014 and 2015, 82 additional patent applications were found. The total number of applications for plant breeding innovations between 1980 and 2008 established by Winnink (2012) was 9456 through WIPO or EPO and 6106 through EPO exclusively. The applications included involved breeding methods counting as classical/conventional/traditional as opposed to genetic modification involving transgenic plants (e.g. Van de Wiel et al. 2010). Thus, applications referring to genes only counted when they were used in marker-assisted breeding (MAB), i.e. in introgression by classical (“essentially biological”) methods of crossing and selection using DNA markers based on the gene sequences. In practice, such applications were often combined with use of the genes in GM, which made it more difficult to distinguish them from applications purely referring to GM. A small group combined GM traits with “native traits”, e.g. stacking of transgenes using conventional crossing or inducing infertility in GM plants by classical means (9 applications). Some techniques of a more biotechnological nature, such as protoplast fusion and mutagenesis, were included as the traits produced using these techniques are found in conventional (non-regulated) varieties which can be used by breeders as normal variation to be combined with other traits into new varieties using classical breeding techniques. Their relevance with regard to “native traits” will be discussed later on. Three applications found addressed oligonucleotide-directed mutagenesis, a novel genome editing technique with as yet an uncertain regulatory status with regard to genetic modification. These were not included in the analysis (for more details see the Discussion).

We primarily focussed on claims on plants with specified traits as we were interested in possible effects of IP protection on accessibility of identifiable plant genetic resources. Often applications that primarily involved methods (process-based) for selection of specified traits, also contained a claim on plants; these were also included. However, process-based applications without direct claims on plants may still be relevant as to the traits themselves. This will be touched upon in the more detailed discussion below of claims. Using these criteria, 50 of the applications were process-based filings that apparently did not contain direct claims on plants and about 350 applications remained that contained claims on plants. Because of time limitations, 200 of these were studied in more detail. The primary focus of this subset was on applications in crops that are important to the Dutch breeding industry, i.e. vegetable crops, tomato, pepper, cucumber, melon/squash/watermelon, lettuce, potato, onion, leek, *Brassica* spp., also including the smaller crops such as pea, carrot, eggplant, rucola, celery, cichorium, corn salad, radish, and strawberry. For *Brassica* spp., also some oilseed crop applications were included, as was the case for sunflower, mainly comprising a range of fatty acids traits. Likewise, examples of traits such as carbohydrate, protein and/or secondary metabolite compounds as well as resistances against abiotic and biotic stressors were included for maize, wheat, grasses, sugar beet, soybean and other crops. Finally, a few applications in ornamentals and pharmaceutical crops were included in the selection. In this way we aimed to encompass the diversity of traits as well as possible in the subset of 200 patent applications. Thus, notably, a number of patents in arable crops were not included in the analysis, and so the numbers below must be taken as indicative.

4.2. Patent applications: types of crops and traits, and techniques

The (crop) plant species occurring in the subset of 200 applications are shown in Table 1. Major arable and horticultural crops are represented, and a few ornamental species. In addition, a few medicinal crops were encountered. Among the arable crops, the cereals maize and wheat, the oilseed crops oilseed rape and sunflower, and the protein crop soybean are represented. There are fewer applications for sugar beet and potato, which may reflect the relatively later developments in the use of biotechnology and/or the higher complexity of breeding in these crops. Among the horticultural crops, the largest numbers of applications are for the vegetable crops lettuce, cucumber, pepper, tomato and *Brassica oleracea* (cabbage, cauliflower, broccoli etc.). These may reflect the large investments in biotechnology in vegetable crop breeding in the last twenty years, particularly in MAB (see below).

Table 1. Crop species in the 200 patent applications studied in more detail.

Cultivation types	Product types	Crop species	Cultivar group	#	
Horticultural	Vegetable	<i>Brassica oleracea</i>	Broccoli	12	
			cauliflower	4	
			Kohlrabi	4	
			Cabbage	1	
			radish <i>Raphanus sativus</i>		1
			celery <i>Apium graveolens</i>		1
			<i>Cichorium</i> vegetable		3
			lettuce <i>Lactuca sativa</i>		15
			corn salad <i>Valerianella locusta</i>		1
			rucola <i>Eruca sativa</i>		2
			leek <i>Allium ampeloprasum</i>		2
			onion <i>Allium cepa</i>		3
			carrot <i>Daucus carota</i>		1
			eggplant <i>Solanum melongena</i>		1
		pepper <i>Capsicum</i>		13	
		tomato <i>Solanum lycopersicon</i>		25	
		cucumber <i>Cucumis sativus</i>		13	
		Fruit	melon <i>Cucumis melo</i>		7
			squash <i>Cucurbita</i>		4
			watermelon <i>Citrullus lanatus</i>		5
	strawberry <i>Fragaria x ananassa</i>			1	
Arable	Protein	pea <i>Pisum sativum</i>		2	
		soybean <i>Glycine max</i>		9	
	Cereal	maize <i>Zea mays</i>		10	
		wheat <i>Triticum aestivum</i>		7	
	Root crop	sugar beet <i>Beta vulgaris</i>		1	
		potato <i>Solanum tuberosum</i>		3	
	Oil seeds	sunflower <i>Helianthus annuus</i>		5	
		white mustard <i>Sinapis alba</i>		1	
Brassica (napus)/oilseed (canola)			22		
Other	Fodder	ryegrass <i>Lolium perenne</i> , <i>L. multiflorum</i> , <i>L. hybridum</i>		1	
	Amenity grass	fescue <i>Festuca</i> spp		1	
	Ornamental	<i>Impatiens walleriana</i>		1	
		<i>Pelargonium</i>		2	
		<i>Petunia (Calibrachoa)</i>		2	
		<i>Verbena</i>		1	
	Medicinal	<i>Cannabis sativa</i>		1	
<i>Catharanthus roseus</i>			1		
Other	plant (crop) species		10		
Total				200	

Table 2. Traits in the 200 patent applications studied in more detail.

Trait types: assessment	Trait types	Detailed traits	#
	Interspecific hybridization	Several traits	4
Morphological involving observations and/or measurements	Quality traits: morphology	Architecture (new form, taste, yield)	4
		Colour vegetable	4
		Ornamental: flower architecture/colour pattern	6
	Quality traits: cultivation/harvesting efficiency	Architecture	7
Biochemical involving quantifying substances	Quality traits: compounds	Protein	1
		Fatty acid composition	16
		Carbohydrates	5
		Sucrose	3
		Secondary metabolites: pigments, glucosinolates etc.	10
		Lignin/fibre	1
		Vitamins	1
		Taste combination	4
		Combination of oilseed qualities	1
		Pharmaceutical	1
Physiological involving tests	F1 hybrid variety production	Cytoplasmic male sterility CMS	15
		Nuclear male sterility NMS	7
		Others such as incompatibility, heterosis, flower morphology	8
	Quality traits: seedless fruits	Parthenocarpy	14
	Quality traits: physiology	Shelf life	9
		Physiological disorders	2
		Tissue culture	1
	Quality traits: processing	Several traits	2
	Resistance biotic stress	Viruses	12
		Bacteria	1
		Plasmodiophorids (clubroot)	2
		Fungi	19
		Oomycetes	17
		Nematodes	2
		Insects	6
	Tolerance abiotic stress	Drought/nutrient stress	4
	Resistance herbicides	IMI, glyphosate	5
Yield	Yield	2	
	Combinations of traits	Several traits	4
		Total	200

The traits for which applications were found are presented in Table 2. A large group (48%) of patent applications involved traits related to product quality (output traits as opposed to the input traits related to cultivation). Among these are fatty acid composition in oilseeds and starch in cereals. In vegetables, levels of secondary metabolites, such as flavonoids, carotenoids and glucosinolates, were represented. Also combinations of metabolites and/or morphology improving taste were found. Quality traits relevant for the grower, such as improved harvesting efficiency, encompassed 5%. Other types were improved processing and shelf life characteristics. The few ornamental applications also addressed output traits, such as flower architecture and/or colour patterns.

Furthermore, 30% concerned resistances against pathogens and pests. Resistant plants were often the result of more or less complex interspecific crossings. Most applications addressed viruses, fungi or oomycetes; some targeted insects. Only a few applications concerned abiotic challenges to plants, such as drought and nutrient deficiency, which only recently became popular breeding goals. Herbicide tolerance was also represented, mostly tolerance to imidazolinone herbicides attained by mutagenesis or selection of spontaneous mutants. Finally, some applications addressed plant architecture improved for ease of harvesting.

Fifteen percent of the applications was comprised of traits useful for F1 hybrid variety production, particularly male sterility and/or matching fertility restorers, the most common form being cytoplasmic male sterility (CMS), which in some crops originates from a cell fusion with other species (e.g. the Ogura cytoplasm from radish into *B. oleracea* and *B. napus*).

Table 3. Techniques in the 200 patent applications studied in more detail.

Methods	#	Comments
Breeding method	4	
Selected plants	10	
Crossing & selection	66	
MAB/QTL	74	Of which 42 QTL
Polyploidization	3	
Mutagenesis	38	Of which 20 mutation detection by sequencing
Somatic hybridization	5	
Total	200	

With regard to the breeding techniques used, most classical techniques (for an overview see Van de Wiel et al. 2010) were represented (Table 3): interspecific crossing including sophisticated methods such as embryo rescue, ploidy level manipulation, with either haploidization or polyploidization, and tissue culture-related methods. Also mutagenesis and cell fusion were represented. Techniques involving modifying chromosome sets, such as addition or substitution lines and translocation breeding, were rarely encountered. Such techniques (including ploidy manipulation) often involve (bio)technological treatments, different from classical crossing and selection.

While a few patent applications focus on particular, apparently more difficult interspecific hybridizations (4 in Table 2), most applications relate to the introgression of a desired trait from exotic germplasm of the primary gene pool or another species from the secondary gene pool. Introgression of the desired trait can be difficult, also with regard to the removal of the accompanying linkage drag. A similar problem may also occur when combining particular traits from elite germplasm, such as taste and keeping quality, when they are genetically closely linked. This is reflected in the types of selection methods used; 74 applications (37%) involved MAB and/or QTL (quantitative trait loci) (see Table 3). Also with part of the mutagenesis applications, molecular-genetic methods were used for mutation detection (e.g. sequencing, TILLING). A special variant of this use of biotechnology for introgression of desirable traits from other species is protoplast fusion (somatic hybridization, Table 3), which is mostly used for the introduction of cytoplasmic male sterility (CMS).

Table 4. *Distribution over time of patent applications and patents granted (checked up to 2015) in five- and ten-year periods for the 200 patent applications studied in more detail.*

Periods	Applications	Granted	Decades	Applications	Granted
1983-1987	1	0			
1988-1992	4	3	1983-1992	5	3
1993-1997	19	14 ^a			
1998-2002	32	15 ^b	1993-2002	51	29
2003-2007	60	27 ^c			
2008-2012	84	11 ^d	2003-2012	144	38
Total	200	65		200	65

a) 2 revoked after opposition; b) 2 revoked after opposition, 1 opposition ongoing; c) 4 revoked after opposition; d) 1 revoked after opposition, 3 opposition ongoing

4.3. Patent applications: development over time

Table 4 shows the steady growth of the numbers of published applications and patents granted over the years, from the early 1980s up to 2012. In the first two decades, about three out of five published applications were granted. This proportion may be lower for the last decade, but it is difficult to predict how this proportion will be in the end, as recent applications may still be granted in the coming years. One case was found in which a patent was granted after 14 years.

4.4. Patent applications: product or process-based

Even though there is considerable variation among applications in the way claims are composed, a few general patterns could be discerned:

- Applications primarily claiming plants with a specified set of traits (“product-based” (IPC A01H5) or “product-by-process”). These may be described phenotypically or genotypically, in the latter case by loci, associated molecular (DNA) markers, QTLs and/or genes. Frequently, reference is made to representative seed samples from the plants claimed or sometimes from the plants from which the traits originated. These concerned samples that were deposited as obliged at collections of one of the International Depository Authorities (IDA such as NCIMB, ATCC). Subsequently, additional claims may be listed:
 - The breeding method by which the plants were produced. This is not frequently done, which may be related to the exemption of classical crossing and selection methods from patentability (“essentially biological processes” in EU patent law).

Alternatively, there may be other method claims:

- Methods using the plants claimed, such as propagation, cultivation/harvesting/processing, producing hybrid varieties, performing further crossing for introgressing other elite traits or transformation, genotyping using DNA markers.
- Applications primarily claiming a method to introduce a trait into (elite) plants (“process-based”, IPC A01H1). This encompasses a broad field, including marker-assisted breeding/QTL identification, mutagenesis, somatic hybridization. Subsequently, the products of the methods, the plants, are often claimed as well, as above, or as obtained or obtainable by the methods claimed.

For this study, in the first instance the applications containing plant claims were analysed in more detail as we were interested in possible effects on the use of genetic resources. Process-based applications that targeted general breeding methods such as doubled haploids, often did not contain any claims referring to specific traits. Such applications were left out of the more detailed analysis. Other process-based applications referred to the selection of (combinations of) traits. These may not claim the traits as such, but for instance with claims on the use of MAB (see below the section on MAB/QTL), they may be

relevant for breeders working on these traits. However, such process-based applications will likely have no direct effect on the use of genetic resources and therefore were also no part of the detailed analysis.

There are indications that in recent applications primarily involving plant (product-based) claims, separate method claims are disappearing. This may be partly related to simplify the application, e.g. to avoid having to file a divisional later to fulfil unity of invention (either process or product emphasis). At the same time, method circumscriptions are increasingly incorporated into the descriptions of traits of the plants claimed, where they serve as a circumscription enabling reproducing the production of the plant (product-by-process). This may be related to the patentability of plant products of an inventive nature despite the exception for “essentially biological processes” (methods of crossing and selection), as was recently confirmed in the decision on the interpretation of the exception for “essentially biological processes” in the broccoli/tomato cases by the EBA of the EPO. Comparing the last two decades, there appears to be a trend of a relatively higher number of product-based applications as compared to process-based applications (see Table I in annex). In some cases, process-based applications were changed into product-based patents during the examination procedure. In other cases involving gene sequences, method (process) claims both for use in MAB and for use in genetic modification (transformation) could be combined with product claims for the GM versions of the plants only. The latter could sometimes also be seen only in the granted patent, when in the application product claims were made both for MAB-based and GM-based versions of the plants.

4.5. Patent applications: trait descriptions

The claims varied widely in the way traits were described and the level of complexity in descriptions varied with the type of trait. For exploring which germplasm may contain proprietary traits, it is necessary to get a hold on the exactness of descriptions in order to be able to identify the trait unequivocally. There are various ways by which descriptions could be categorized in order to assess their levels of complexity. An obvious distinction is between phenotypic and genotypic descriptions.

Phenotypic descriptions were (tentatively) categorized in three types (see Table 2 for the relationship with individual traits):

- (i) Traits related to biochemistry, i.e. desirable compounds (output traits) such as fatty acid or starch compositions or levels of sugars, vitamins, carotenoids, or glucosinolates. Applications quantified amounts of the desired component in terms of M/w or w/w (fresh or dry weight of e.g. fruits) or relatively to other components, e.g. % saturated of all fatty acids in oilseeds or ratios of different glucosinolates. Alternatively, levels were compared to those of a specified plant standard or a plant not having the trait/wild type, and/or reference was made to the seed deposits at an IDA.
- (ii) Traits related to plant architecture (morphology), such as head form of broccoli or branching patterns of an ornamental. Salient characteristics could be quantified, e.g. numbers of branches, leaf forms, internode lengths, colours with reference to standard colour charts or, as a last resort, a drawing or photograph.
- (iii) Traits related to plant physiology, such as resilience against “yellowing” or “hollow stem” or keeping quality/shelf life. These were usually described by performing tests, e.g. ethylene treatments with description of expected plant responses, or in the case of shelf life, periods of time (days, weeks) in which e.g. a fruit should keep a specified firmness or colour. Tolerance to abiotic stresses such as drought, also fell under this category. Finally, some common traits that were also assessed using testing, were included: male sterility (22 applications in Table 2), in most cases located on cytoplasmic (mitochondrial) genomes, and resistance to biotic stresses. A large part of the applications addressed resistances against pathogens and pests (a total of 59 in Table 2) and many of these were not described in quantitative terms in claims but often were in the method descriptions in the patents, e.g. using scales, particularly in the case of MAB/QTL (see below). Again, as with morphology and biochemistry, plant references were often applied in several ways.

Genotypic descriptions varied with mode of inheritance and the way this was detected, which could be classified as follows:

- (i) Traits with a polygenic or unknown inheritance.
- (ii) Traits based on one or more loci that follow Mendelian inheritance. Qualitative resistance to pathogens based on classical R genes is a common (dominant) example.
- (iii) Traits based on quantitative trait loci (QTL), in practice formulated as markers for parts of genetic linkage groups that were associated with a specific complex plant characteristic, such as yield.
- (iv) Traits based on specifically identified genes.
- (v) "Rest" categories were polyploidy and mutants. The mutants referred to molecular-genetically uncharacterized ones from phenotypic screens or mutagenesis. The basis of locus- or gene-related traits usually is an allelic variant having one or more mutations compared to "wild type" plants.

The complexity of genotypic and phenotypic descriptions did not correlate with each other. Traits that were complex from a phenotypic point of view could be based on relatively simple modes of inheritance, i.e. loci or genes. For instance, one mutated gene may confer conspicuously different growth habits or leaf morphology (e.g. indented vs straight), i.e. a trait complex in phenotypic descriptions. On the other hand, disease resistance, often bred through R genes/loci, could also be based on combinations of QTLs, thus more complex in the genotypic description. Table 5 represents an attempt to present numbers of descriptions in the two dimensions, phenotypic and genotypic. The descriptions are categorized phenotypically across the rows as to the type (biochemical, morphological or physiological) and to the extent that traits were quantified in the claims, either absolutely (levels of a substance, lengths of plant part(s)) or by comparison to a specified control plant (line) or to similar plants or wild types not having the trait. Across the columns, the mode of inheritance is categorized. The most difficult to assess based on the descriptions in the claims will be the cases where qualitative/semi-quantified descriptions were combined with polygenic/unknown or unspecified inheritance. These cases were relatively rare, however (9 of 54 in column "polygenic/unknown inheritance"). More commonly, semi-quantified/qualitative was combined with information on genes (13 of 28), loci (39 of 58) or QTL (24 of 42). The most straightforward genotypic category, genes identified encompassed about one eighth of the applications (28 of 200).

Biochemical traits were mostly quantified as levels of specific compounds or levels relative to those of other compounds. In about two third of the cases, quantification was in terms of higher or lower than a specified percentage or a specified quantity, e.g. microgram per gram biomass (13 and 10, respectively out of 35 applications). The remainder compared levels to plants not having the trait or was semi-quantified, usually with a reference to plants (seeds) deposited along with the patent application. Most of these applications were based on genes. Most of the morphological traits were quantified absolutely or in comparison to a specified plant line instead of plants not having the trait. There were also a few qualitative ones, but their determination may not need to be a problem with morphological traits such as flower colour. The morphological traits descriptions were based more on loci than on gene sequences.

Most of the descriptions that may be relatively difficult to assess, were encountered with the physiological traits, i.e. those containing no specific genotypic information combined with tests that need to be performed in comparison to plants not having the traits or without specified references. Most were based on genes, loci or QTLs, and most of the qualitative ones comprised disease or pest resistances. Many of the resistances that were not further specified/quantified in the claims, were provided with detailed scoring methods and/or disease scales in the descriptions or examples of the patents. This could be of importance with e.g. QTLs as they may not produce the described phenotype in all genetic backgrounds. The special genotypic category with claims based on QTLs will be discussed separately in the section on marker-assisted breeding (MAB) below.

Table 5 provides a very general idea of the sort of observations or tests that may be needed to assess the presence of proprietary traits. In order to obtain a more concrete idea of the sorts of observations or tests that may need to be performed, we will discuss the patent applications in two crop species, tomato and lettuce, in more detail in the following section.

Table 5. Phenotypic and genotypic circumscriptions of traits in the 200 patent applications studied in more detail. Numbers are number of patents; the total numbers add up to over 200 because some applications involve a combination of more than one type of trait circumscription.

Trait types	Genetic basis	gene	locus	QTL	mutants (unspecified loci)	polygenic/unspecified	polyploidy	mitochondria (CMS)	total
morphology	quantified in absolute terms	1	5	1		11	1		19
	quantified compared to reference plant/line						1		1
	quantified compared to reference plant without traits or wild type	1	2			1			4
	semi-quantified without specified ref		1			1			2
	Qualitative		1			3			4
	Total	2	9	1	0	16	2	0	30
biochemical/compounds	quantified in absolute terms	7	2	2	6	18			35
	quantified compared to reference plant/line		1						1
	quantified compared to reference plant without traits or wild type	1							1
	semi-quantified modified levels without specified ref	6		1					7
	no quantification								0
	Total	14	3	3	6	18	0	0	44
physiological	quantified in absolute terms	1	6	3	2	7			19
	quantified compared to reference plant/line			3	1	1			5
	quantified compared to reference plant without traits or wild type	2	1	6	2	3			14
	semi-quantified modified levels without specified ref*	1	1	15	1	3			21
	qualitative*	6	36	8	2	2	1	10	65
	Total	10	44	35	8	16	1	10	124
phenotypes complex	many traits			3					3
methods (involving specific traits & plants)	interspecific hybridization, etc.	2	2		1	4			9
Total	Overall	28	58	42	15	54	3	10	210

4.6. Patent applications: examples of assessing traits – tomato and lettuce

In the previous sections, a broad overview has been given of traits and the ways they were described. In order to obtain a more concrete idea about what traits a breeder may have to assess to screen germplasm for possible proprietary traits, we have compiled, from the 200 patent applications, the data regarding two example crops, namely tomato and lettuce.

Assessing whether the use of a plant may be affected by a claimed invention will mean testing for the presence of the traits whenever new lines enter a breeding programme, which is something that breeding companies may do on a regular basis nowadays (see interviews). For tomato we analysed 25 patent applications plus 3 applications for a wider array of crops that included tomato. Of these, 5 were granted by EPO, of which one was revoked and another lapsed, 4 were withdrawn and one refused. These 7 were excluded and the remaining 21 applications were examined for phenotypic and genotypic traits to be assessed and the plant material where traits originated from (Table IIa in the annex). Likewise, for lettuce we analysed 15 patent applications plus 4 applications for a wider array of crops that included lettuce (2 overlapping with tomato). Of these, 7 were granted by EPO, of which 3 were undergoing an opposition procedure and another expired, and 2 were withdrawn. The remaining 16 applications were examined for phenotypic and genotypic traits to be assessed and the plant material where traits originated from (Table IIb in the annex).

Many phenotypic traits will be part of basic measurements in normal breeding practice (except e.g. for metabolites or mechanical tests, and specific disease resistance assays). For 17 of the 21 applications “alive” in tomato and 7 of the 16 in lettuce, relatively efficient molecular (DNA) tests could be performed to trace traits claimed.

As a first step for assessing any possible effect of patents on the use of public germplasm, we looked at the origins of the traits mentioned in the claims. A number of wild accessions were mentioned as origins, including some from genebank collections. In tomato, the most commonly used crossing populations used for introgression into elite material, involving wild parents *Solanum pennellii* LA716 and *S. habrochaites* LYC4, were derived from published research by Eshed & Zamir 1995 and Finkers et al. 2007, respectively. In lettuce also a number of wild accessions were mentioned as origins of traits in the applications, including some from genebank collections, in particular from CGN. Among them are crossing populations with wild parents *Lactuca virosa* CGN04683 and *L. saligna* CGN05271 published by Eenink et al. (1982) and Jeuken et al. (2004), respectively. Also a number of wild accessions of *L. serriola*, *L. saligna* and *L. virosa* deposited at NCIMB were listed in patent claims as sources of the traits involved.

4.7. Patent applications: the case of marker-assisted breeding (MAB) and quantitative trait loci (QTL)

About forty percent of the patent applications analysed encompassed marker-assisted breeding (MAB), i.e. selection for and introgression of desirable traits with the aid of molecular (DNA) markers genetically linked to loci of interest (74 of 200, see Table 3). Here too, descriptions of claims vary widely, from simply the use of MAB in the first applications of the late 1990s to detailed descriptions of markers used and positions on genetic linkage maps in more recent applications. Many of these applications address disease resistances.

A special case is the introgression of so-called quantitative trait loci (QTL) enabled by MAB (42 of the 74 MAB applications mentioned above). QTL refer to regions on a genetic linkage map that show a statistical association with the occurrence of a particular phenotypic trait, such as higher yield or a quantitative disease resistance. QTLs can be described using several aspects. Basically, one can specify one or more mapped markers associated with the trait to be selected for. This may also be termed a marker 'linked to' or 'flanking' a trait, or the trait may be 'indicated by the presence of a marker. In some cases other markers are associated with linkage drag and so they should be selected against in order to maintain existing qualities of the elite material to be bred. Further possible refinements included describing intervals flanked or enclosed by markers (chromosomal or genomic regions). Claims on sequences, in particular probes or primers, may be accompanied by homology specifications, such as percentage sequence identity (usually of the order of 70-90%). This may be necessary to include sequence variation without significant effect on the trait of interest but relevant to the molecular detection methods. All such marker claims are conditional upon association with the trait of interest. As these QTL applications are relatively recent, many of them are still in the examination phase.

5. Interviews with stakeholders (in Dutch)

Note: Because the interviews were held in Dutch and the reports were circulated for feedback with the interviewees in Dutch, this part of the report is in Dutch. The interviews were held in Spring 2013.

In mei en juni 2013 zijn zeven interviews afgenomen met verschillende belanghebbenden uit de wetenschap (2), het bedrijfsleven (4) en de samenleving (1). In totaal is met 11 mensen gesproken (zie de bijlagen voor de vragenlijst en lijst van geïnterviewden). In deze (semi-gestructureerde) vraaggesprekken is uitvoerig ingegaan op de impact die de verschillende beschermingssystemen van octrooieren en het kwekersrecht hebben op de omgang met en toegang tot Native Traits, welke voor- en tegenargumenten worden gezien voor beide beschermingssystemen in het kader van duurzame innovatie (economisch, sociaal, ethisch), over juridische procedures en ervaringen en hoe het beste is om te gaan met de omgang en toegang tot Native Traits. In elk interview werd benadrukt dat het hier om een verkennende studie ging die zich louter beperkt tot de kwesties die spelen rond 'Native Traits' en dat de bredere discussie over de balans tussen octrooirecht en kwekersrecht buiten het bestek van dit onderzoek valt. In de praktijk bleek echter dat de materie van Native Traits zich moeilijk 'apart' liet bespreken (zie ook de conclusies). In dit hoofdstuk presenteren we onze bevindingen aan de hand van de verschillende clusters van onderwerpen zoals die in de gesprekken naar voren kwamen.

5.1. Het begrip Native Traits

Bij twee van de vier bedrijven (Syngenta en Royal Van Zanten) en bij Oxfam Novib, werd langer stil gestaan bij de term Native Traits: wat is hieronder te verstaan? Hoewel je Native Traits in simpele termen kunt typeren als veredelingswerk zonder knip- en plakwerk van biotechnologische aard, waarbij je bepaalde eigenschappen 'vindt of ontdekt' maar niet door menselijk ingrijpen 'uitvindt', is dit onderscheid volgens deze twee bedrijven in de praktijk soms lastig te maken. Men spreekt dan over een grijs gebied waarbij het een discussie is welk soort recht hier van toepassing is of zou behoren te zijn.

Oxfam Novib benadrukt dat Native Traits van nature voorkomende eigenschappen zijn, die vaak door generaties van boeren door kruisen en selectie naar boven zijn gehaald, en die derhalve ook buiten elk octrooirecht zouden moeten vallen, ook wanneer deze met behulp van allerlei technologie worden gebruikt en toegepast om meer bruikbare landbouwgewassen te krijgen.

5.2. Kwekersrecht of octrooirecht?

Vanuit de wetenschappers wordt naar voren gebracht dat octrooieren vooral in het voordeel lijkt te zijn van grotere bedrijven, wat als nadeel kan hebben dat kennisvermeerdering op slot wordt gezet wanneer er monopolies worden uitgeoefend. De Ponti, mede sprekend vanuit zijn ervaring in het bedrijfsleven, is zonder meer een voorstander van het kwekersrecht omdat plantenveredeling volgens hem bestaat bij de gratie van *access*: kwekersrecht is "open source" intellectueel eigendom *avant la lettre*. Hij ziet bij bedrijven een neiging tot 'flauwekul-octrooien' en bovendien dat grote bedrijven kwekers in ontwikkelingslanden kunnen imponeren waardoor deze kwekers niet eens doorhebben welke ruimte ze hebben om met beschermd uitgangsmateriaal te werken. Koornneef ziet evenwel dat het kwekersrecht voor bedrijven die veel in veredeling investeren nadelen kan hebben. Voor hem is de vraag uiteindelijk niet zozeer kwekersrecht of octrooirecht, maar met welke vorm van bescherming het publieke belang het meest gediend is. Onder publiek belang is hier enerzijds te verstaan de boer en tuinder die goede zaden nodig heeft om goed en veilig voedsel te kunnen produceren, het proces van innovatie dat daarbij hoort en bescherming tegen kopiëren, anderzijds de consument die goedkoop en veilig voedsel wil hebben.

Ook Oxfam Novib benadert de discussie kwekersrecht of octrooirecht vanuit een meer algemene vraag: welke vorm van bescherming is het meest rechtvaardig en houdt rekening met de "Farmers' Rights" van boeren in ontwikkelingslanden. Het octrooirecht, en tot op zekere hoogte het kwekersrecht staan op gespannen voet met het recht van boeren ('farmers' rights') om geproduceerde zaden te bewaren, hergebruiken, uitwisselen, en verkopen (International Treaty on Plant Genetic Resources for Food and Agriculture). Het UPOV verdrag over kwekersrecht biedt landen de keuze om een dergelijk recht

(Farmers' Privilege) te respecteren dan wel in te perken, met name door boeren niet toe te staan om hun zaden te verkopen.

Bij de bedrijven zien we verschillende opvattingen. Enza en Syngenta zien in de toekomst een grotere rol weggelegd voor octrooirecht, om er voor te zorgen dat veredelaars hun langjarige investeringen in innovatieve planteigenschappen kunnen voortzetten met uitzicht op een redelijk financieel rendement. Royal van Zanten en Rijk Zwaan blijven in de toekomst een belangrijke rol zien voor het kwekersrecht (vanwege toegankelijkheid en de overtuiging dat dit uiteindelijk beter werkt voor innovatie, het voorkomt ook verdere juridificering). Ondanks deze principiële voorkeur voor het kwekersrecht, staan ze er pragmatisch in: ook zij zullen, als het erop aankomt, meedoen met het aanvragen van octrooien om niet geblokkeerd te raken door octrooien van derden.

De meningsverschillen over kwekersrecht of octrooirecht zijn voor een deel ook terug te voeren op de inschatting of percepties van (individuele) bedrijven in hoeverre de door introgressie verworven Native Traits (waaraan kosten en investeringen zijn verbonden) zich terugbetalen. Sommigen zijn van mening dat een optimale "first to market" strategie met rassen (op basis van kwekersrecht) de 'return on investment' voldoende borgt, anderen vinden dat de aanvullende revenuen via octrooieren hier beter werken. Deze percepties, zo kan men stellen, hangen weer samen met opvattingen over monopolies die innovaties zouden kunnen afremmen. Tegenstanders van het octrooieren van natuurlijke eigenschappen stellen dat een voor iedere teler belangrijke eigenschap zoals ziekteresistentie ("killer application"), die via introgressie is verworven en al snel tot 100% marktdekking leidt, bij het systeem van octrooieren tot onwenselijke monopolies zou kunnen leiden. Ook wijzen ze in dit verband op het ongewenste effect dat bij een groeiend aantal octrooien veredelingsbedrijven genoodzaakt zijn al het plantmateriaal van buiten op mogelijk geoctrooierde eigenschappen te onderzoeken; dit zou dan allerlei extra kosten met zich meebrengen, vooral als de eigenschappen moeilijk te detecteren zijn of de scope van de claims moeilijk is vast te stellen.

Voorstanders van octrooieren stellen dat octrooien een middel zijn om kennis, tegen een redelijke vergoeding, te kunnen delen. Monopolies zijn in de plantenveredeling volgens hen vrijwel niet mogelijk omdat de uiteenlopende markten en klimaatzones om een zeer gedifferentieerde genetische basis vragen; geen enkele veredelaar heeft die in z'n totaliteit. Het licenseren van innovatieve eigenschappen, maar dan wel op basis van meer vereenvoudigde procedures, zou in deze visie voor alle partijen voordelig kunnen werken.

5.3. Ervaringen juridische procedures m.b.t. Native Traits

Drie van de vier benaderde bedrijven hebben juridische procedures meegemaakt naar aanleiding van octrooiclaims en oppositie tegen claims. Het aantal juridische zaken waarvan melding gemaakt wordt, is echter relatief gering te noemen. Wel is hierbij op te merken dat oppositie tegen octrooiclaims vaak niet zonder succes is.

Met name de respondenten van het bedrijf dat nog geen concrete ervaring hiermee had opgedaan (Royal van Zanten), spraken hun vrees en verwachting uit dat ook zij gedwongen zouden zijn om mee te gaan met de 'octrooitrend' en dus ook de inschakeling van meer juristen en advocaten. In het algemeen is er bij de bedrijven een besef dat een zekere juridificering van de verdelingspraktijk en een toenemend juridisch steekspel omtrent octrooien, onvermijdelijk zijn. Waar het kwekersrecht nog meer op de coöperatieve gedachte zit (grotere toegangsmogelijkheden tot uitgangsmateriaal voor alle kwekers), is het octrooirecht harder en zakelijker te noemen.

5.4. Derde wegen?

5.4.1. E-licensing als bemiddelende weg naar open toegang tot octrooien

Om de problematiek van toegang, die vooral voor kleinere bedrijven kan spelen, te ondervangen, is er door Syngenta een systeem van E-licensing (genaamd TraitAbility) geïntroduceerd.² De filosofie achter dit systeem luidt: 'Free access, but not access for free'. Het komt er kort gezegd op neer dat de deelnemers aan E-licensing toegang hebben tot de planten waarin de geïntroduceerde traits zitten, zodat ze ermee kunnen werken, maar dat het wel zo is dat er licenties moeten worden geregeld en royalties afgedragen op het moment dat een nieuw product commercieel wordt gemaakt waarin nog geldige geïntroduceerde onderdelen zitten. Daarnaast zou Syngenta graag industriële patent pools ('licensing-platforms') realiseren. Deze zouden volgens Syngenta zowel kleinere als grotere bedrijven tot voordeel kunnen strekken omdat men snel en transparant met elkaar tot overeenkomst kan komen over het gebruik van Native Traits en niet steeds opnieuw in onderhandeling hoeft te gaan. In de periode van de interviews was het onduidelijk of een dergelijk licensing-platform niet op problemen zou stuiten, omdat andere bedrijven en ook de EU dit wellicht zouden kunnen zien als concurrentievervalsing. Maar inmiddels hebben een aantal groentezaadbedrijven een gezamenlijk (internationaal) licensing platform gerealiseerd (zie de laatste sectie van dit hoofdstuk)³.

5.4.2. Reacties op het 'bemiddelende alternatief' van E-licensing

De reacties op E-licensing liepen uiteen. ENZA, dat ook een systeem van E-licensing heeft, deelt de mening van Syngenta en geeft er ook sterk de voorkeur aan dat de industrie zelf regelingen/systemen opzet om de beschermingsystemen van kwekersrecht en octrooien goed te laten samengaan; dat wordt als meer praktisch gezien dan de oplossing zoeken in nieuwe regelgeving en wetten.

Royal van Zanten en Rijk Zwaan zijn beiden in principiële zin voor het kwekersrecht vanwege de "open source"-vorm die deze biedt tot de genetische bronnen. Kwekersrecht is naar hun mening uiteindelijk de beste weg voor innovatieve ontwikkeling in veredeling (en het voorkomt verdere juridificering). Maar ondanks deze voorkeuren wijst Rijk Zwaan een oplossingsweg om een pragmatische balans te vinden tussen voldoende "open toegang" (tot genetische bronnen) en octrooirecht zeker niet af. Hier zou wellicht een derde partij, denk aan een instantie met deskundigen en verschillende vertegenwoordigers uit de branche die over partijen heen denkt, een mediërende rol kunnen spelen. Ook de politiek zou hier een rol kunnen spelen, maar dat kan lastig zijn vanwege de complexiteit van deze materie, en nieuwe regelgeving is vaak ook een heel moeizame weg.

5.5. Conclusies uit de interviews

- Bij Native Traits bestaan er zowel verschillende meningen over (i) de feiten (hier: de impact van de verschillende beschermingsystemen in de vorm van kwekersrecht of octrooien) als over (ii) de waarden/doelen die rond Native Traits het richtsnoer moeten vormen. Dit maakt het tot een lastig onderwerp. We zien ook dat betrokkenen verschillende *frames* hanteren om hun ervaringen en meningen in te kaderen. Waar voor een maatschappelijke organisatie als Oxfam Novib de context van 'farmers rights' essentieel is, kijken bedrijven vooral vanuit een markteconomisch perspectief. Echter ook binnen het frame van een markteconomisch perspectief kwamen variaties naar voren in hoe smal of breed men de discussie over Native Traits trekt.
- Voor bedrijven is de voorkeur voor het ene of het andere beschermingsstelsel verbonden met verwachtingen/percepties van de impact, met de positie die men in het economische krachtenveld inneemt, en met de visie ten aanzien van het eigen verdienmodel. Hoewel niet alle

² Zie voor meer details de websites www.traitability.com en <http://www3.syngenta.com/global/e-licensing/en/e-licensing/Pages/home.aspx>.

³ International Licensing Platform (ILP) Vegetable gelanceerd 13 November 2014, Wageningen.

bedrijven even actief bezig zijn met Native Traits octrooiaanvragen, wordt ook bij de bedrijven die er momenteel nog relatief weinig mee bezig (zoals in de siersector) terdege beseft dat het een belangrijk onderwerp is dat grote impact kan/zal hebben op toekomstige activiteiten en ontwikkelingen in de zaadveredelingsindustrie.

- Momenteel zijn er 'derde wegen' in ontwikkeling om octrooieren meer acceptabel/transparant te maken (het voorbeeld is hier E-licensing). Een aantal bedrijven zoeken hier naar een pragmatische oplossing. Ook bedrijven met een voorkeur voor het kwekersrecht lijken nu meer te zien in dergelijke pragmatische oplossingen. Voor een maatschappelijke organisatie als Oxfam Novib moet deze discussie dan wel een brede ingang hebben (waarin bv. ook 'farmers rights' een plek hebben).
- De meest belangrijke conclusie is dat het onderwerp zich in alle gesprekken lastig liet afbakenen van bredere vraagstukken die spelen rond technologische innovatie, zoals kansen in ontwikkelingslanden en Noord-Zuid-problematiek, concurrentieverhoudingen en monopolisering. (Zie voor een recente studie naar de ethische en maatschappelijke vraagstukken rond intellectueel eigendom Timmerman 2013.) Ook deze interviewreeks waarin vier bedrijven zijn opgenomen, bevestigt wat in de eerdere verkennende interviews ook al naar voren kwam. Discussies over Native Traits worden ervaren als een onderdeel van een bredere discussie over octrooieren en biotechnologie. Het loskoppelen van de problemen van Native Traits van deze bredere discussie is met het oog op de beleving van deze discussie in de praktijk derhalve lastig. Bij de partijen die geneigd zijn de discussie breder trekken, kan dit zelfs geforceerd overkomen. Wil men alle belangrijke stakeholders betrekken bij de discussie rond Native Traits, dan lijkt het raadzaam dit bredere verband te erkennen.

5.6. Algemene slotopmerking uit de interviews: wat is het algemene belang?

Een aandachtspunt dat verhelderend is om de verschillende posities en standpunten die naar voren worden gebracht te kunnen begrijpen en plaatsen, zijn de verschillende wijzen waarop het 'algemene belang' kan worden omschreven of begrepen. Grofweg is hier een onderscheid te maken tussen 'eerlijke verdiensten', 'eerlijke concurrentie', 'eerlijke verdeling' en 'voedselzekerheid (ook voor de toekomst)'.

'Eerlijke verdiensten' houdt in dat bedrijven die in innovaties investeren hun investeringen ook terugbetaald zien door een zekere vorm van juridische bescherming. Anders zouden marktpartijen zeer geremd zijn om nog te innoveren.

'Eerlijke competitie' houdt in dat alle bedrijven eerlijke kansen hebben om te concurreren en dat ervoor gewaakt moet worden dat bepaalde bedrijven vanuit een monopolie de markt bepalen. Monopolies kunnen innovaties afremmen vanwege bedrijfsbelangen.

'Eerlijke verdeling' houdt in dat er rekening moet worden gehouden met de Noord-Zuid-problematiek, met ongelijke machtsverhoudingen waardoor de kans bestaat dat boeren en ondernemers in ontwikkelingslanden minder kansen hebben om hun natuurlijke bronnen voor hun eigen profijt te benutten en te gebruiken.

Waar Syngenta het accent legt op het algemene belang van 'eerlijke verdiensten', wijst een maatschappelijke organisatie als Oxfam Novib vooral op een 'eerlijke (mondiale) verdeling'. De andere partijen die zijn geïnterviewd nemen hier tussenposities in, waarbij voor de minder grote veredelingsbedrijven vooral 'eerlijke competitie' een cruciaal punt is.

'Voedselzekerheid (ook voor de toekomst)' kan tenslotte worden gezien als een 'gedeelde' eindwaarde die door geen enkele partij ontkend zal worden, maar waarbij de meningen dus verschillen via welke weg of wegen deze bereikt zal worden.

6. Discussion

This quick scan explores patent applications involving conventional breeding for the crops in which they were filed, the types of techniques and the traits involved. The aim of the quick scan was to facilitate discussions on the use of patents in conventional crop breeding in relation to the alternative IP system of PBR. Here we will first discuss views of stakeholders, mainly breeding companies, based on interviews. We then discuss how we collected published patent applications potentially relevant with regard to conventional breeding products. Subsequently, we looked into the relevance of the patent applications found for “native traits”. Based on the patent applications found and the claims they contain, we looked into several aspects of the question of what effects they may have on the use of germplasm for breeding.

6.1. Views of stakeholders on native traits in relation to parallel existence of PBR and patent rights vary

The interviews with stakeholders showed that breeding companies vary in their appreciation of the dilemma between adequate protection of IPR and facilitated access to genetic resources for future innovation in breeding. They all recognized that laborious introductions of native traits from exotic sources (e.g. wild species) into elite material while getting rid of linkage drag, demand high investments. In addition, a successful introgression of a highly desirable trait such as a disease resistance against a common pathogen can be seen as highly valuable (a “killer application”, i.e. it will quickly gain high market coverage). This also applies to varieties containing such trait. The choice for patent protection or PBR is dependent on the valuation of the effectiveness of recuperating the investment. Patent protection may effectively extend the protection beyond the commercial life span of individual varieties containing the proprietary trait. In these appraisals of the effectiveness of either IP system, modern marker-assisted breeding (MAB) plays a more or less paradoxical role. On the one hand, it requires investments in the supporting DNA techniques, on the other hand it leads to more efficient selection, thus simplifying complex introgressions. Some companies argued that the fact that MAB can be used by their competitors to quickly introduce a novel introgression from a wild species into their own elite varieties, means that these competitors now can produce such competing varieties within a relatively short period of time. Other companies argue that such competition has always existed, and that the period in which the innovative variety has a large market share is still sufficient.

Companies favouring patents for IP protection propose to address potential problems with access to plant genetic resources through e-licensing and/or patent pools, such as the recently established International Licensing Platform (ILP) Vegetable, in order to increase transparency on the patent claims attached to specific plants/seeds. In addition, the PINTO database initiative of ESA (European Seed Association) links patents to plant varieties marketed. The database is to be filled by patent assignees on a voluntary basis and up till now contains a limited number of patents. This is partly due to the focus on varieties, as only patents or patent applications are included that involve traits present in commercial varieties on the market. Also, not all companies have their patents or applications submitted to the database (yet). Indeed, these initiatives will assist breeders in identifying plants having proprietary traits produced by the patent holders themselves. The interviews namely also indicated that patents on native traits incited close scrutiny of new germplasm introduced into a company for the possible presence of any proprietary trait, which may come with additional costs. This will be further discussed in the next section.

6.2. How to obtain a comprehensive overview of patent applications in conventional breeding?

It proved to be not straightforward to obtain a comprehensive overview of patents involving native traits. Basic international patent classification codes could not be used by themselves as the codes for plant product and for process (A01H/5 and A01H1, respectively) include genetic modification (transgenic plants), and the number of patent applications involving genetic modification in plants is much larger than the number of patent applications regarding conventional breeding. Excluding genetic modification by using IPC code C12N15/82 (genetic engineering with plant cells as hosts) meant that a number of relevant patent applications were incorrectly excluded. Incorrect exclusion of patents was due to several reasons. An important reason was that applications involving genes may use them both for

transformation and for generating markers to be used in introgression (marker-assisted breeding, MAB, so classical crossing with selection supported by DNA markers). For assessing whether conventional breeding methods were involved could only be ascertained by scanning all claims of the application, and when this did not suffice, checking the methods used. A few special cases combined transgenic and native traits or selected for native traits improving transformability or improving expression of transgenes. In addition, IPC codes appeared to be not always used consistently. For instance, the C12N15/82 code was sometimes also used with mainly MAB-related patents whereas the C12Q1/68 code (tests involving nucleic acids) would have been more appropriate.

In order to assess whether we had not missed patent applications, we additionally scanned patent applications from companies that we knew to be active in breeding. As this list of companies may not have been exhaustive, we still may have missed some patents here. For breeders it may be easier to obtain a comprehensive overview of relevant patented traits, as their searches would likely be targeted to a specific crop species, although it may take some effort to identify the patents and patent applications involving “native traits” in crops in which many patent applications, including those on GM, exist, e.g. in maize or to a lesser extent in a large vegetable crop such as tomato. In addition, some process-based patent applications may target a large number of crop species, e.g. ones focussing on desirable alleles of a gene that is universally present across plant species and for which it is not immediately apparent which particular crops may be involved. However, patent claims across crop species were only infrequently found in the final granted version of the patent; often, divisional applications were filed in such situations.

Patent searches and assessments form a special expertise that innovative (bio)technological companies, including small ones, are used to invest in. However, they are relatively new to breeders used to PBR and may add costs for assessing material for proprietary traits, as mentioned in the previous section. Small breeding companies could decide to outsource patent searches to specialized agencies, in particular patent agents. Alternatively, they could co-operate with other small parties to share costs of patent watches. It is difficult to estimate the accompanying costs, amongst others because part of assessments for the presence of proprietary traits will belong to the routine screening of germplasm for breeding programmes (see also section 7.4 below). Other possible contributions to more transparency are the e-licensing and/or patent pools mentioned in the previous section.

Finally, it should be noted that patents may also be attractive to small (biotechnological) start-ups in breeding, in order to protect their position when they have not yet developed marketable varieties, and to research institutes to valorise their (pre)breeding research results when they are not developing varieties themselves, or to be able to optimize the use of the invention, which includes controlling as well as stimulating usage.

6.3. What sort of patent applications involving conventional breeding can be found?

From the point of view of the normal practice of using all available germplasm not under GM regulations in further breeding, all patents involving conventional breeding may play a role in discussions on IP protection, as can be seen in the sort of patents present in the collections in the PINTO database and the International Licensing Platform. Although this may not be immediately apparent from the traits of the products involved, not all such patents could be simply said to comprise “native traits”. Native traits can be defined as traits that occur in nature (i.e., in the germplasm of a plant species or genus), and they could thus be associated with those traits introduced or (re)combined by crossing and selection, i.e. “essentially biological” processes that are excluded from patentability in the European Patent Convention. However, traits occurring in nature could also be (re)combined by techniques of a more biotechnological nature, for instance, cell fusion (somatic hybridization), which can lead to novel combinations of cytoplasmic and nuclear genomes. Cell fusion may enable interspecific hybridizations, and thus produce combinations of traits that are hard to achieve by other means. Products of cell fusion are exempted from regulation of genetic engineering in EU Directive 2001/18/EC, provided that they could also be achieved using alternative conventional techniques of crossing and selection. However, this concerns the introduction into the environment, and does not address IP issues. Even when the traits have been introduced by crossing and selection, techniques of a biotechnological nature can play a role: complex interspecific crosses sometimes can only succeed by techniques such as “embryo rescue”, i.e. cultivating the hybrid embryo separated from the plant on artificial media. So, products and traits from advanced

conventional breeding methods may be indistinguishable from those from the most basic crossing and selection methods without detailed knowledge of the techniques used.

Another case in which products (traits and their genetic basis) are in many cases indistinguishable from those that could be obtained by crossing and selecting among naturally occurring/spontaneous (“native”) variants in existing germplasm, is mutagenesis. Mutagenesis, which is used since the 1930’s, involves the random induction of mutations by agents of a technical nature, such as chemicals or irradiation, to increase the amount of genetic variation in existing germplasm. Selection of desirable genetic variation is performed as in normal screening and crossing in existing germplasm, and may need backcrossing with elite plant materials to remove other induced mutations affecting plant performance. The desired variation generated by mutagenesis can be novel, but may also occur somewhere in existing genetic resources. An example may be the dwarf growth habit in cereals that has been successfully generated using mutagenesis and applied in many varieties produced in the Green Revolution in the 1960’s. The dwarf growth habit is based on loss-of-function alleles in hormonal biosynthesis pathways (gibberellins). Recently, “green revolution” mutations have been found in natural populations of *Arabidopsis thaliana* (Barboza et al. 2013), implying that novelties may already exist in nature, but may be very difficult to find. Comparable cases are modifications of ploidy levels, addition/substitution lines and translocation breeding, as they are generally inducing or accelerating phenomena that also may occur spontaneously.

Transgenic plants (not part of this quick scan) remain the most clearly recognizable category, as the transgenic construct is clearly recognizable as a human invention as it is an artificial combination of DNA sequences. That distinction may be complicated by the new breeding concept of cisgenesis where traits from cross-compatible plant species (i.e. species with which classical crossing and selection is basically possible) are introduced using transformation (Jacobsen & Schouten 2007). In this case, only the new location of the cisgene in the genome, and a small part of border sequences around it, remain features that distinguish the trait in a cisgenic variety from native forms in the germplasm.

Recently, novel genome editing techniques, such as oligonucleotide-directed mutagenesis and zinc finger nucleases have been developed, for which a few patents were encountered as side-product of our patent searches. It is likely that more could be found with a targeted search. The number of patent applications for these techniques is expected to increase in the near future as a result of the quickly increasing use of the CRISPR-Cas variant of genome editing (Bortesi & Fischer 2015). Genome editing may be used for directional mutations, i.e. non-randomly altered nucleotide sequences at specific sites according to the investigator’s design. Directional changes in the genome are deemed eligible for patenting as not falling under the exemption of “essentially biological processes” by the Decision by the Enlarged Board of Appeal of the European Patent Office of 9 December 2010 in the consolidated cases, “broccoli” and “tomato”, G 2/07 and G 1/08, respectively. At the same time, without prior knowledge of their origin, the directional mutations may be indistinguishable from spontaneous mutations or those generated by mutagenesis.

In conclusion, techniques that are eligible for patenting with regard to the exclusion of essentially biological processes, can lead to plant products that without prior knowledge, may be indistinguishable from those from crossing and selection, using genetic resources of the crop as source of the trait. Yet, the methods by which they were made may differ significantly in the underlying degree of biotechnological interventions. Thus, the natural occurrence of a particular trait may not preclude the possibility of patenting of novelties integrated into elite plant materials. Taken together, this may complicate the use of a concept of “native traits” in a discussion on (delimitation of) patentability in breeding, also in the light of continuous developments with the ongoing introduction of new biotechnological methods.

6.4. May there be effects of patented traits on the use of publicly available germplasm?

The genetic resources for which usage may be affected by a patent involving particular native traits, can be broadly divided into two types of germplasm:

- (i) varieties marketed by the breeder/patent holder (or their progenies) that contain the traits involved in the plant claims in the respective patent. This situation appears to become more transparent

because of actions of breeding companies, e.g. e-licensing and patent pools, such as the ILP Vegetable (International Licencing Platform Vegetable). An interesting example of increased transparency is ESA's PINTO database coupling varieties to patents. There is as of yet a limited number of patents represented in this database (28 in the most recent update on 01-07-2015); (ii) all other varieties, breeding lines, and accessions that may possibly contain the trait described in the patents claims, e.g. by being identical to or by common ancestry with the plants used as source for breeding the plants under (i), or an alternative source of the trait (e.g. a genebank accession).

Use of category (ii) plants or their progeny cannot be *directly* affected by claims on traits as the traits were already present in the material before the invention and thus have not been generated using the invention (Article 8 of Directive 98/44/EC). Could the descriptions laid down in claims on traits derived from e.g. genebank material affect in any way use of (parts of) this material in breeding for other traits? Genebanks are aware of this question around IP and access to resources as evidenced by distributing material under a Material Transfer Agreement containing an article about patenting and facilitated access to the plant material (see e.g. CGN: <http://www.wageningenur.nl/en/article/Patents-on-native-traits.htm>). Many breeding programmes make use of publicly available germplasm, e.g. accessions from genebank collections, usually of older date. We discuss two observations that may have relevance to this question, namely on complex quantitative traits and QTLs.

In patents, complex quantitative traits may be defined by physiological or biochemical tests. A physiological test applies for instance to reduced deterioration (e.g. yellowing) of plant products (keeping quality) or increased drought tolerance. A biochemical test could be the level of substances such as anthocyanins or glucosinolates. Quantitative traits may be laborious to assess when compared to a reference plant, such as a control plant without the trait, although there is always the possibility to refer to the seed deposits at an IDA. Such traits should be novel in elite plant material but might occur in other germplasm than the original or related accessions it was derived from, or in wild populations *in situ*. How many accessions might exist that already contain a level as has been claimed? What is the chance of this trait being introgressed along with breeding for other traits? In Brassica's some vegetable types have been bred specifically with higher levels of particular glucosinolates, whereas some oilseeds have been bred for low levels of glucosinolates, including cases where these levels were part of linkage drag coming with the desired trait (e.g. fertility restorers for CMS). The range of such traits found in a wide array of genetic resources will not always be known.

Introgressing desired traits is easiest if the allelic variants underlying the trait are known. However, most of the time the genes underlying desirable traits are not known or complex interactions between several genes may be responsible for the trait. A proxy is the QTL approach that detects a statistical association between markers for a part of the genome (chromosome) and a desired (native) trait. As compared to selection based on complex phenotyping, the advantage for the breeder is the possibility of efficient introduction of the trait by the markers whilst the same markers also enable to more precisely circumscribe/delimit the innovation in the patent. On the other hand, markers for a particular QTL may encompass an interval covering large parts of a chromosome. This is a consequence of the way QTLs are detected: the trait is statistically associated with a chromosomal interval, i.e. a specific part of a genetic linkage map flanked by particular markers, and the size of this interval and the statistical reliability (LOD score) may vary with the level of detail achieved by the availability of markers, the precision of phenotypic assessments (depending e.g. on field conditions and environmental variability), the number of progeny and the particular crossing parents used (e.g. Collard et al. 2005; Zhu et al. 2008; St.Clair 2010). Except for special cases, QTL usually show partial contributions to the trait, i.e. they explain only a part of the variation in the trait found in the crossing population(s) studied. The causal genomic basis may be a yet unidentified gene but it may also be a combination of genes and/or gene-regulating factors residing in this part of the genome. Upon further research, a particular QTL might turn out to be based on the net effects of a combination of genes, which may even partially have contrasting effects on the phenotypic trait of interest (see for example Den Boer et al. 2013). Such QTL may have different effects when introgressed in other genetic backgrounds or under different environmental conditions.

In the patent applications involving QTL, the phenotypic trait is claimed in combination with linked markers. Claims may involve various numbers of markers across the chromosomal interval associated with the QTL underlying a (native) trait, conditional on the presence of the proprietary trait. Chromosomal intervals may harbour large numbers of genes, and even hot spots, i.e. regions with QTLs for various types of traits, may be found in particular parts of genomes (e.g. Hartman et al. 2013). Thus,

it is conceivable that other desirable traits may be identified using a QTL approach in a region where a proprietary trait was already localized. One then may ask whether interference could occur. When for instance proprietary markers are detected in plant materials, when would one judge the associated proprietary phenotypic trait (QTL) to be absent? This will depend on the number of markers claimed and the exactness with which the trait is described, particularly in view of the usually quantitative nature of the trait and the variability of QTLs in various genetic backgrounds. Since QTL analysis is a relatively new topic in IPR, only few patents have yet been granted.

The next-generation large-scale sequencing techniques may be helpful in obtaining more background knowledge for looking further into these questions around QTLs and use of germplasm. They are already being used for comparing genotypes of core collections of germplasm, including cultivated and wild accessions from genebanks, in important crops, such as tomato, a species that we used as an example on what sort of traits and markers one needs to screen to know whether a plant contains potentially proprietary traits/sequences. Compared to QTLs, gene sequences may be more straightforward in claims on the use of specific allelic sequences. In patents that include gene sequences, the claims may extend to a wide variety of crop species as many genes have homologues (orthologues) across a wide variety of higher plants in which comparable types of alleles with accompanying traits could be selected for. Claims on plants across wide groups of species were usually not granted in single patents, but separated into divisional applications (e.g. for each plant species or for different combinations of plant species and their pathogen).

6.5. Final remarks

IP protection systems exist in order to stimulate innovation, which creates important benefits for society. It is clear from the interviews we held, from the public discourse on this subject, and from the political debates on breeders' exemptions, that stakeholders have different views on how to obtain suitable and sufficient IP for plant breeding when investments are rising. The concept of 'native traits' is an important one in these debates.

Patent analysis is normal practice in technical innovation but relatively new in the field of plant breeding. Smaller companies will lag behind larger companies in building up the required expertise. The initiatives towards self-reporting of patent applications by breeding companies (PINTO database) address the issue of transparency, and other industry initiatives such as patent pools (e.g. ILP Vegetable), aimed at facilitating obtaining licences, also address the transparency of the legal situation. From the side of the civil society Patent Watch groups also contribute to transparency by analysing patent applications and fuelling a public discussion.

The step beyond transparency is to determine the actual impact of the claims on breeding activities: what is restricted or needs a licence, and what is outside the invention and thus outside the scope of protection? This quick scan touched upon this subject, reasoning from biological/breeders knowledge. Notably, we asked ourselves whether patents involving quantitative characteristics and QTL may or may not affect the commercial use of gene bank accessions containing such traits. The answers to these questions will critically depend on the formulation of the claims, and how much room this leaves for others, which was beyond the scope of this review as we have not looked into the legal aspects *sensu stricto*.

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8. Annex

Names of companies used in patent application search

ABZ Seeds
Advanta Seeds
Agrico research
Agrisemen
AVEBE
Averis Seeds
Barenbrug
BASF
Bayer CropScience
Bejo Seeds
Biogemma
De Ruiters Seeds
Deutsche Saatveredelung AG
DLF-Trifolium
Dow AgroSciences
Du Pont De Nemours
East-West Seed
Enza Seeds
Erfurter Samen & Pflanzenzucht
Florimond Desprez
Fobek
Fresh Forward
GW Pharmaceuticals
"D.J. van der Have" or "SESVanderHave"
Hazera Seeds - Vilmorin & Cie
HM. Clause - Vilmorin & Cie
HZPC Holland
Keygene
Krishidhan Seeds Europe
KWS Saat AG
Limagrain
Meijer
Monsanto
Nickerson-Zwaan
Norddeutsche Pflanzenzucht
Nunhems
Pioneer Hi-Bred
RAGT Semences
Rijk Zwaan
Saaten-Union
Saka Ragis
Sakata
Semillas Fito
Seminis
Solana
Südwestdeutsche Saatzucht
Syngenta Seeds
Takii Europe
Tozer
Vilmorin
Western Seed

Table I. Numbers of patent applications filed with primarily process-based claims and those with product-based claims per time period for the 200 applications analysed. Patents granted checked up to 2015.

Periods	Applications process	Applications product	Applications total	Granted process	Granted product	Granted total
1983-1992	2	3	5	1	2	3
1993-2002	22	29	51	12	17	29
2003-2012	47	97	144	11	27	38
Total	71	129	200	24	46	70

Table IIa. List of traits involved in patent claims to be assessed in tomato.

Phenotypic:

1. Morphological measurements on
 - o Fruit size
 - o Fruit colour
 - o Fruit weight/plant
 - o Sympodial index
2. Physiological measurements
 - o Leaf wilting assay (drought test)
 - o Chlorosis by SPAD meter & yield (continuous light tolerance)
3. Parthenocarpy
 - o Assessing seedlessness of fruits
4. Metabolites
 - o Brix by refractometry
 - o Flavonols by HPLC
5. Shelf life
 - o Timing of fruit keeping quality
 - o Fruit wrinkling
 - o Mechanical measurement of fruit firmness by penetrometer etc.
6. Pathogen resistance assays
 - o TOTV virus
 - o TYLCV virus by field assay with infected whitefly
 - o Botrytis
 - o Phytophthora infestans
 - o Meloidogyne nematode

Genotypic:

1. Gene expression
 1. >2 genes flavonol pathway
2. Gene mutation sequence detection
 1. NOR gene
 2. SIARF9 gene
 3. SIPP2C1 gene
 4. SP3D & Psy1 genes (markers)
 5. HSK gene (no divisional application for tomato yet)
 6. DMR6 gene
3. Loci by markers
 1. 1 on LG4
 2. 2 on LG6
4. QTLs by markers
 1. 1 on LG9
 2. 5 (linked) on LG2
 3. 1 on LG4 LG5 LG12 resp
 4. 1 on LG1b LG6 LG9b resp
 5. 1 on LG4 LG6 LG9 LG11 LG12 resp
 6. 1 on LG4
 7. 1 on LG7
5. Loci only assessable on progeny of crosses:
 1. 2 for parthenocarpy
 2. 7 unspecified mutants

Accessions of wild species from which introgressions have been derived:

- *Solanum habrochaites*
 - 04TEP990312 (unknown origin 1 application))
 - LYC4 (2 applications)
 - TA517 (1 application using *L. hirsutum*)
- *S. pennellii*
 - LA716 (3 applications)
 - LA1926 (1 application)
- *S. chilense*
 - LA2884 (1 application, same as LA1926)
- *S. lycopersicon* var *cerasiforme*
 - LA1286 (1 application, same as LA1926 & 2884)

Table IIb. List of traits involved in patent claims to be assessed in lettuce.

Phenotypic:

1. Morphological measurements on
 - 1.1. Head colour
 - 1.2. Head leaf number/weight
2. Physiological measurements
 - 2.1. Ethylene seedling test measuring hypocotyl length, optionally Russet spotting & Yellowing on mature plants
3. Male sterility
 - 3.1. Assessing CMS
 - 3.2. Assessing NMS: detectable by flower heads remaining open longer & without pollen (Ms7)
4. Shelf life
 - 4.1. Reduced discolouration at wound surface as compared to control plant of which leaf disc when incubated between two sheets of wetted filter paper for 7 days at 5°C shows pink discolouration around the edges, optionally testing compounds involved in phenol oxidation (e.g. catechol) or inhibition by L-cysteine
5. Pathogen resistance assays
 - 5.1. Oomycete *Bremia lactucae* (seedling and/or leaf disk tests, and/or field trials; 6 applications)
 - 5.2. Aphid *Nasonovia ribis-nigri* (assay on 2-4 wk old plants after 1-2 wks, 3 applications)

Genotypic:

6. Gene mutation sequence detection
 1. HSK gene
 2. DMR6 gene
7. Loci/QTLs by markers
 1. 6 markers on 4 different LGs
 2. Marker linked to Ms7
 3. 1 QTL on LG8
 4. 1 QTL on LG2 & LG6, resp.
 5. Mitochondrial marker atp6
8. Loci only assessable on progeny of crosses:
 1. 3 for aphid resistance
 2. Unspecified mutants for reduced disease susceptibility

Accessions of wild species from which introgressions have been derived:

Lactuca serriola

- CGN05913 (IVT1308)
- 651554 (origin unknown, deposited as NCIMB 41488)
- 651738 (origin unknown)
- 10G.913571 (origin unknown, deposited as NCIMB 41776)
- Unspecified

L. saligna

- CGN05271
- CGN05315 (IVT1306)
- 650147 (origin unknown, deposited as NCIMB 41485)
- 650219 (origin unknown, deposited as NCIMB 41486)

L. virosa

- CGN04683 (IVT280)
- CGN05148 (IVT1538)
- CGN09365 (IVT1398)
- PIVT-280 (CGN04683) & PIVT-cd72723 > IVT 793202 introgression line released 1981
- 651968 (origin unknown, deposited as NCIMB 41489)

List of interview questions

1. Are you familiar with the debate about the impacts of the protection of intellectual property through patents and/or breeders' rights on access to and use of native traits in plants?
2. What are according to you the impacts of the protection of intellectual property through patents and/or breeders' rights based on native traits in plants on access to and use of germplasm for breeding?
3. Are you in favour of using patents or breeders' rights for the protection of intellectual property in the context of access to and use of native traits in plants?
 - a. What are your arguments for that position?
 - i. What are the pros and cons of either protection method?
 - ii. What is the importance of arguments about appropriate revenues sustaining innovation, including economic, social and ethical values?
 - b. If it depends on the situation/trait/crop, when would patents be preferred and when are breeders' rights to be preferred?
4. Are you aware of any concrete cases of problems about access to and use of native traits in plants?
 - a. (legal) disputes about claims
 - b. (legal) disputes about infringements
 - c. Uncertainty about the scope of claims on "native traits" impacting decisions about the use of particular plant materials
 - d. Did you ever experience difficulties in access to genetic resources yourself?
5. When access to and use of native traits in plants are restricted, how could these restrictions be addressed?
6. If needed, what kind of changes do you propose to the protection of intellectual property through patents and/or breeders' rights on access to and use of native traits in plants?
 - a. Do these revisions address changes in patent law/directives or in their interpretation or additional arrangements within the breeding sector?
 - b. Do these revisions primarily call upon action from public or private actors?
 - c. Do these revisions require additional knowledge on (trends in) the types of claims in patents on native traits and their scope/coverage in terms of germplasm/genetic resources?

List of interviewees

Maarten Koornneef (*em. Hoogleraar Erfelijkheidsleer Wageningen University & directeur Max Planck Institute for Plant Breeding Research*)

Orlando de Ponti (*voor pensionering Directeur Onderzoek bij Nunhems, daarvoor directeur IPO Wageningen*)

ENZA: Jeroen Rouppe van der Voort (*manager biotechnologie*)

Rijk Zwaan: Jack de Wit (*business support R&D*) & Kevin van den Hof (*innovation specialist R&D*)

Royal Van Zanten: Arie Veldhuyzen van Zanten (*divisiedirecteur*) & Sjoukje Heimovaara (*directeur R&D*)

Syngenta: Gerard Meijerink (*senior government relations advocate*) & Leo Melchers (*global head licensing*)

Oxfam Novib: Gigi Manicad (*Program Leader Biodiversity Management for Food Security*) & Sabina Voogd (*lobbyist for GROW: Oxfam campaign to grow more food more fairly and more sustainably*) (op persoonlijke titel)