Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)

Biopatents – A Threat to the Use and Conservation of Agrobiodiversity?

Position Paper of the Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection

(Translation of German original paper)

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Contents

1 Subject and background

The application of patent law to animal and plant breeding through the granting of biopatents has a growing impact on the conservation and use of animal and plant genetic resources.

Biopatents are intellectual property rights granted by the state for a limited period of time for inventions consisting of products made of biological material or processes with which biological material is produced, processed or used ('biological processes'). Biopatents can relate to plant or animal – or human – biological material and processes for its production. This paper solely addresses the patenting of animal and plant genetic resources.

A patent grants the inventor an exclusive right to use and market the invention for the duration of the patent. A patent prohibits others from using the invention without the permission of the inventor, who can demand a fee for granting a licence. In return, the inventor must fully disclose the invention in the patent application. In this way, a balance is sought between inventors' interest in exploitation of their inventions and the common interest in access to new knowledge. The overarching aim of patent law is to stimulate technical innovation without unduly obstructing its use by others (Krasser 2009; Schubert 2009).

The reproducibility of biological material presents a special difficulty when it comes to applying patent law to animal and plant breeding. Plant varieties and animal breeds are also defined in phenotypical, genetic and administrative terms. For plant varieties, the International Convention for the Protection of New Varieties of Plants adopted in 1961 under the International Union for the Protection of New Varieties of Plants (UPOV) laid down a dedicated system for the protection of intellectual property under which a breeder can be granted a breeder's right for a variety that is new, distinct, uniform and stable. The patent law requirement of invention disclosure is replaced here by a deposit mechanism. There is no parallel system for animal breeding, partly because distinctiveness, uniformity and stability cannot be demonstrated to the same extent for animal breeds as they can for plant varieties.

A further problem stems from the unpatentability of simple discoveries found in nature. From the 1970s onwards, patents were nonetheless being granted for biological inventions – microorganisms at first – and were confirmed in a series of court cases. It became dominant opinion that natural substances are patentable if isolated in a technical process. Patenting biological inventions presents certain practical difficulties, however. These include the fact that full disclosure is often not possible, the problematic distinction between invention and simple discovery, the scope of patent protection, particularly given the reproducibility of patented biological material and genetic information, and access for breeders and farmers to patented material.

Provisions on biopatents have been laid down in the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the 1992 Convention on Biological Diversity (CBD), the 1998 European Biopatent Directive, the 2000 revision of the European Patent Convention (EPC) and the 2005 revision of the German Patent Act (Patentgesetz or PatG). A series of patents subsequently applied for and also granted, notably by the European Patents Office, raise basic questions with regard to the conservation and use of animal and plant genetic resources. The problems at issue do not relate to patents for genetic engineering inventions, but patents for conventional breeding methods and for products resulting from them. These are classified in the legislation as “essentially biological processes” which are excepted from patentability. Crossing and selection are referred to in the legislation as “natural phenomena” and, like natural substances, are not patentable unless an inventive technical step is added. In patenting practice, however, there are major uncertainties as to the dividing lines.

This paper aims to highlight the problems of biopatenting from the perspective of the conservation and use of agrobiodiversity and to make recommendations for action.[1] It starts from the principle that the best way of conserving genetic resources *in agriculture* is to use them (conservation by use). This principle is enshrined in the Convention on Biological Diversity, in Germany’s National Strategy on Biological Diversity and in the European Biodiversity Strategy (BMELV 2007).

Emerging developments in biopatenting, however, could have a range of negative outcomes:

- Obstacles to the use of animal and plant genetic resources in the production of food and other agricultural outputs
- Partial diversion of research effort from improving genetic resources to the generation of patents
- Use of a narrower range of agrobiodiversity, thus fostering genetic erosion.

We will discuss these points in the following. We begin by reviewing the legal picture and the quantitative importance of biopatenting (section 2). We then explain the problems with reference to the three areas just mentioned. In doing so, we identify five problem areas: A shift in property rights (section 3.1), the effectiveness of specific legal provisions for farmers and breeders (section 3.2), implications for the innovation process (section 3.3), prevailing legal uncertainty (section 3.4) and patenting procedures (section 3.5). There follow a conclusions section (section 4) and a recommendations section (section 5).

[1] This position paper does not address the patenting of microorganisms.

2 Legal situation

2.1 Reasons for the introduction of biopatenting

Historically, patents have been justified as a means of protecting the rights of the individual, as an incentive to invent, and on grounds of fair play, allowing inventors to reap the fruits of their ideas. In the European Biopatent Directive, the focus is more on industrial policy considerations and investor protection: "The protection of biotechnological inventions will [...] be of fundamental importance for the Community's industrial development" (recital 1) and "In particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable" (recital 2). Financial resources are seen as a scarce factor in the development of biotechnology and genetic engineering, which "are playing an increasingly important role in a broad range of industries" (recital 1).

The business model behind these considerations stems from the pharmaceutical and chemical industry, where patents have long served as a means to recover heavy R&D spending on chemicals and processes. With the rise of biotechnology, the difficulty of protecting genetically modified plants using rules made for plant varieties and the UPOV regime led to a rise in patenting activity in the plant breeding sector. Once US case law opened the door to biopatents in 1985, successful pharmaceutical and agricultural chemical companies such as Monsanto, Syngenta and Bayer began acquiring seed companies and applying for seed patents. The commercial success of these companies is reflected among other things by significant global concentration in the seed sector (see LOUWAARS et al. 2009). They have strong incentives to safeguard this success by lobbying for greater patent protection. The TRIPS Agreement, in force from 1995, made minimum standards for the protection of intellectual property globally binding. The 1998 Biopatent Directive lays down far more detailed requirements for EU member states along with patentability criteria for biological materials and biological processes.

Making patents apply for a limited period tends to be in the common interest in the long term because knowledge disclosed in them helps others continue technical progress. This common interest can be harmed by 'evergreening', however, where patent owners use a range of strategies to extend the revenue stream from patents that are about to expire (Faunce 2008; Bansal et al. 2009). These include market strategies such as long-term licensing agreements with potential users of a patent, or even buying up copycat manufacturers and their products. Technical evergreening strategies include registering follow-on patents for process elements, applications and incremental innovations whose novelty, inventive step and added utility are often questionable (Faunce 2008: 222). In animal and plant breeding, the use and further development of patentable inventions depends on access to the genetic material. This fact presents biotechnology-specific opportunities for evergreening. The US administration began investigating possible anticompetitive behaviour by Monsanto in early 2010. The investigations relate both to licensing practices and to breeding strategies such as 'gene stacking' (Neuman 2010). By shifting the balance between the inventor's individual interest and the common interest, evergreening – if tolerated – can cast doubt over the legitimacy of the patent system.

2.2 Multi-level system of patent law

Biopatents are now an established legal institution at national, European and multilateral level. Any changes to national legal frameworks must therefore stay inside bounds set by European and international law.

After biopatents began to be granted under generic patent law from the 1980s, European and German legislators sought to clarify questions arising from the specific properties of biological material. This is defined in Section 2a (3) 1 of the German Patent Act as "material containing genetic information and capable of reproducing itself or being reproduced in a biological system". Defining features of biological material therefore include materiality and genetic information. This second characteristic brings biological material within the scope of intellectual property, which in Germany enjoys protection under Article 14 of the Basic Law for the Federal Republic of Germany and is also recognised under the First Protocol to the European Convention on Human Rights and the EU Charter of Fundamental Rights. The latter entered into force on ratification of the Lisbon Treaty amending the Treaty on European Union on 1 December 2009 (Article 6 (1) of the Treaty on European Union).

The following apply in Germany alongside the provisions of general law:

- The German Patent Act (Patentgesetz or PatG) as revised in 2005;
- Since 1973, the European Patent Convention (EPC), which as an international treaty has direct effect, as revised in 2000;
- Since 1998, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, referred to in the following as the Biopatent Directive. As a European directive, this does not have direct effect but is made binding through incorporation in national law.
- Since 1995, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This is part of the World Trade Organisation (WTO) international trade regime, which lays down binding minimum requirements for the protection of intellectual property. The provisions of the TRIPS Agreement are an integral part of the Community legal order and as such take precedence over the national law of EU member states (Eichholz 2008).
- The UN Convention on Biological Diversity (CBD), which came into force in 1993, makes access to genetic resources subject to national government approval. A protocol on access to genetic resources and the fair and equitable sharing of the benefits from their use ('access and benefit sharing') is planned to be adopted in the course of 2010. The CBD treaty complex is very important to the ability of breeders to use genetic resources in establishing new breeding programmes or in supplementing [2] or broadening [3] the existing gene pool. A key requirement for the breeding of ornamental plants, for example, is access to 'exotic' genetic resources. Under Section 34a of the German Patent Act, patent applications must include information on the geographical origin of biological material, if known. It is not possible to address issues relating to the CBD in greater detail here.

[2] By way of introgression, i.e. backcrossing a small number of genes lacking in the breeding pool as a short-run solution for specific problems.

[3] By way of incorporation and base broadening.

- The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) governs access and benefit sharing for most economically important agricultural crops in accordance with the UN Convention on Biological Diversity. ITPGRFA creates a multilateral system of publicly accessible seed banks, making sure a large proportion of existing agrobiodiversity stays in the public domain, accessible as a public good to breeders in member states.

Under the TRIPS Agreement, protection of plant varieties can alternatively be secured by an effective sui generis system. An alternative form of protection of this kind for intellectual property was codified in the International Convention for the Protection of New Varieties of Plants adopted in 1961 under the International Union for the Protection of New Varieties of Plants (UPOV). [4] The corresponding legislation in Germany is the Plant Variety Protection Act (*Sortenschutzgesetz*) in conjunction with Council Regulation (EC) No 2100/94 of 27 July 1994 on Community Plant Variety Rights.

Alongside biopatents and plant variety protection, other forms of intellectual property such as registered trade secrets can also play an important part. For owners, these can have an advantage over patents since the invention needs not to be disclosed.

2.3 Granting of patents: Requirements, exceptions and legal consequences

Table 1 gives an overview of the criteria for granting a biopatent under the various sources of patent law. As the table shows, biological processes and substances occurring in nature are expressly patentable under German and European law.

Patents can be granted for products or processes.

Where the invention is a product, "a person not having the consent of the patentee is prohibited from making, offering, putting on the market or using a product which is the subject matter of the patent or importing or stocking the product for such purposes" (Section 9, indent 1 of the German Patent Act). Biological material (egg cells, sperm), plants and animals have the added special feature that they can reproduce or be reproduced in a biological system. Under Section 9a, indent 1 of the German Patent Act in conjunction with Article 8 (1) of the Biopatent Directive, patent protection applies to biological material derived by reproduction or propagation as long as the biological material possesses the characteristics resulting from the invention (Deutsche Gesellschaft für Züchtungskunde e. V. 2009: 2). [5]

Where the invention is a process, a person not having the consent of the patentee is prohibited from "using a process which is the subject matter

[4] The 1991 revision of the UPOV Convention – chronologically in parallel with the negotiation of TRIPS – extended the scope of patent protection in plant breeding. To an extent, UPOV is in the process of being opened up to patenting.

[5] Under Section 9a (1) of the German Patent Act and Article 8 (1) of the Biopatent Directive, "The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics." Section 9a, indent 3 of the German Patent Act: "Where the invention is a product containing or consisting of genetic information, the effects of Section 9 shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function."

Table 1 : Criteria for biopatents

Criteria	German Patent Act	EPC	Biopatent Directive	TRIPS
Technical character	Section 1	Article 52 (1)	Article 3	Article 27 (1)
Novelty	Section 1	Article 52 (1)	Article 3 (1)	Article 27 (1)
Inventive step	Section 1	Article 52 (1)	Article 3 (1)	Article 27 (1)
Industrial application	Section 1	Article 52 (1)	Article 3 (1)	Article 27 (1)
Patents grantable in respect of living matter	Section 1 (2); German Federal Court of Justice 'Red Dove' decision (BGHZ 52, 74, 76/GRUR 1969, 672)	EPC Implementing Regulations R 26 (2) and R 27a	Article 3 (1) and (2)	Article 27 (1) ("all fields of technology")
Naturally occurring substances patentable if isolated in technical process	Section 1 (2) (second sentence)		Article 3 (2)	
Effective *sui generis* system permitted for plant varieties				Article 27 (3) (b)

source: Feindt (2009)

of the patent" (Section 9, indent 2 of the German Patent Act) and from "offering, putting on the market, using or importing or stocking for such purposes the product obtained directly by a process which is the subject matter of the patent" (Section 9, indent 3 of the German Patent Act).

A distinction is made between working processes and production processes. Unlike a working process, a production process results in a product – e.g. an article, a device, a substance or biological material. A patent for a production process covers the process itself and, under Section 9 (2) 3 of the German Patent Act and Article 64 (2) EPC, products directly obtained by that process (product-by-process protection). Patents for working processes have the same scope as patents for production processes except that there is no extension to products under Section 9 (2) 3 of the German Patent Act and Article 64 (2) EPC because working processes do not result in a product.

German, European and international law stipulate four exceptions from patentability (see Table 2):

Table 2: Exclusions from patentability

Exclusion criteria	German Patent Act	EPC	Biopatent Directive	TRIPS
Contrary to public policy or morality	Section 2 and Article 14 (1), second sentence of the German Basic Law	Article 53 (a)	Article 6 (1)	Article 27 (2)
To protect human, animal or plant life or health or avoid harm to the environment				Article 27 (2)
Plants and animals				Option to exclude under Article 27 (3) (b)
Plant varieties and animal breeds	Section 2a (1)	Article 53 (b); Implementing Regulations R 27 (b)	Article 4 (1) (a)	
Essentially biological processes	Section 2a (1); 2a (3), indent 2	Article 53 (b); Implementing Regulations R 26 (5)	Article 4 (1) (b)	Option to exclude under Article 27 (3) (b)
Processes involving cruelty to animals	Section 2a (2), indent 4		Article 6 (2) (d)	
Processes relating to multiple species/breeds patentable	Section 2a (2), indent 1		Article 4 (2)	
Microorganisms and microbiological processes patentable	Section 2a (2), indent 2		Article 4 (3)	Article 27 (3) (b)

source: Feindt (2009)

- Firstly, it is not possible to patent inventions whose use would be contrary to public policy or morality.
- Secondly, the 1973 European Patent Convention stipulated that plants and animals could not be patented. The provision to this effect in the 1973 EPC was however interpreted in more specific terms by legal practitioners and in subsequent case law as meaning only that plant varieties and animal breeds were unpatentable. Processes relating to multiple plant varieties or

animal breeds, on the other hand, are expressly patentable. Parts of plants and animals are likewise patentable. Animal and plant genetic resources and processes to produce them are therefore patentable above and below variety/breed level.

- A similarly narrow interpretation is applied to the patenting of "essentially biological processes". These are defined in the legislation as consisting "entirely of natural phenomena such as crossing or selection" (Article 2 (2) of the Biopatent Directive/Section 2a (3); indent 2 of the German Patent Act). Appeals currently before the EPO Enlarged Board of Appeal (the broccoli case and the tomato case) involve appraising whether the addition of a single technical step is sufficient to make an 'essentially biological process' patentable for breeding purposes.
- Finally, Article 6 (2) (d) Biopatent Directive excludes processes causing unproportional suffering to animals.

Socioethical objections to biopatenting are only indirectly incorporated in biopatent law by reference to patents contrary to public policy or morality. Ethical issues relating to biopatents are therefore difficult to address by legal means and instead are a matter for political debate.

2.4 Quantitative development of biopatenting

In the agricultural sector up to the late 1990s, biopatents were largely overshadowed by genetic engineering patents. The last decade has brought growing numbers of patent applications for conventional breeding methods and growing numbers of patent grants. Then and Tippe (2009: 16) counted over 500 patent applications before the European Patent Office relating to conventional plant breeding methods up to spring 2009. They also counted 70 granted patents relating to conventional plant breeding (conventional in the sense of not being based on genetic engineering) and 40 granted patents relating to conventional animal breeding. Non-genetic-engineering patents have thus grown to account for about 25% of all patents in 'green' biotechnology.

A recent development consists of patents that bring together genetic engineering with conventional breeding methods. 'Classic' genetic engineering involves introducing alien genes into a plant. The 1998 decision of the EPO Enlarged Board of Appeal in case G-01/98 NOVARTIS/Transgenic Plant, under which such processes are patentable if their technical applicability extends to more than one plant variety or animal breed, related to a process of this kind. These processes are distinguished from biotechnological processes in which genes are instrumental but which do not result in genetically modified organisms, such as selection methods using genetic markers. In both instances – processes designed to insert a gene and relating to multiple plant varieties or animal breeds, and biotechnological enhancements to conventional breeding methods – patents may have very wide scope due to product-by-process protection. In the second instance, however, only existing genetic diversity is used, making the patent law rationale for product-by-process protection appear questionable. The Advisory Board therefore considers that processes of this kind should be classified as working processes.

3 Implications for the use of animal and plant genetic resources

Numerous critical objections have been raised against biopatents (for a detailed review Feindt 2009). We will first look at implications for the use and then the protection of genetic resources for agriculture.

3.1 Shift in property rights

A first group of points concerns a shift in property rights relating to animal and plant genetic resources. Before the introduction of intellectual property rights, control of animal and plant genetic resources came about through actual or effective ownership of specific animals and plants. Genetic information was either common property or not even thought of as a category of ownership.

Patent law now provides a mechanism by which the presence of patented genetic information in a plant or animal can support a right to exclude others from using or marketing it. A patent has the effect of transferring the patented genetic information – for the duration of the patent and in the jurisdiction for which it is granted – from the public domain into the private property of the patentee. Three main aspects are important in appraising the practical significance of this transfer mechanism resulting in private ownership: The dividing line between discovery and invention, product-by-process protection, and the breadth of claims.

3.1.1 The dividing line between discovery and invention

Under patent law, natural substances are patentable if isolated in a technical process. In patent law terms, the outcome is then not a simple discovery, but a process invention that may confer derived patent rights on the isolated natural substance. In place of the often fuzzy borderline between discovery and invention, case law has increasingly tended to apply the criterion of 'technical character' in addressing questions of patentability.

As the German Federal Court of Justice clarified in its 1972 Imidazoline decision, the product protection conferred on chemically produced substances is absolute, not purpose-bound. This opinion was taken over by the European Court of Justice. Before enactment of the Biopatent Directive, the technical isolation of a gene sequence could therefore support a limited-term exclusive right of use and marketing. Article 5 (3) of the Biopatent Directive now stipulates that patent applications must disclose the industrial application of a gene sequence or partial gene sequence. Section 1a (4) of the German Patent Act stipulates for gene sequence patents that the specific industrial application must be disclosed in the patent claims. [6]

As Godt (2003: 7-9) argues, the criterion developed for chemical patents that a product must be

[6] Gene sequences have been patented in the USA, but recent case law is far more restrictive. A patent application for expressed sequence tags was turned down in 2005 as lacking novelty (In Re Fisher, 2005). A patent for a human gene sequence was rejected in 2009 as lacking an inventive step (In Re Kubin). See Louwaars et al. (2009: 29). The debate has also moved on in the natural sciences. Firstly, the definition of 'gene' used now differs from that used only a few years ago. Secondly, genes are no longer assumed to be capable of being matched with functions. It is therefore doubtful whether the disclosure of a DNA sequence can alone be considered a commercially applicable invention.

isolated in a technical process ceased in 1998 to be enough to support the patentability of DNA sequences in biopatents. Godt reasons that in contrast to the rule with chemical patents, isolation brings gene sequences within the scope of patenting but does not in itself make them patentable; patentability additionally requires a description of the function of the gene sequence and an industrial application. The information character of biological material plays a key role in this regard, as highlighted in Article 2 (1) (a) of the Biopatent Directive.

A change in patentability criteria from absolute to function-bound protection for gene sequences is supported by developments in biotechnology and a shift in the genetic paradigm (see Schneider 2003). Firstly, gene functions are now understood to involve multiple interdependencies with other gene sequences and with environmental influences (relational paradigm). Describing a gene sequence is therefore not generally enough to define the function of a gene. Secondly, technical advancement raises the bar for proving the presence of an inventive step (Straus 2001: 1019). This results in opposition to gene sequence patents on grounds that the technical barriers to discovering new genes have fallen considerably since the 1980s. It has been suggested, for example, that no inventive step is involved any more in automated gene sequencing (Krasser 2009: 237). It would therefore have to be argued in patent opposition proceedings that an invention based on this technique was obvious and comprised the state of the art. DNA sequences, too, increasingly count as prior art now that the genomes of key animal breeds and plant varieties have been decoded.
The criteria and limits of patentability are currently the subject of a number of appeals and opposition proceedings, as illustrated by the following example:

Example
Patent EP1506316 (Method for improving efficiencies in livestock production) claims a method of grouping parent animals, for the reproduction of offspring, according to specific genetic predispositions – in this instance, to form leptin (polymorphism in the ob gene linked to obesity). The patent is held by a Canadian breeder (Marquess, Foley Leigh Shaw Alberta, Toronto). An opposition notice filed by Greenpeace and Misereor casts doubt over whether a technical process is really involved and whether the industrial application is specified in sufficient detail. The ob gene is already known, and selection according to genotype follows the principle of marker-based selection, which is likewise already known.

3.1.2 Product-by-process protection

With regard to chemical inventions, it has become established practice to extend the protection conferred by a patent on a production process to products resulting from that process, and to natural substances isolated in a technical process. This principle has been expressly transferred to patents relating to animals and plants. Under Article 28 (1) (b) of the TRIPS Agreement, a process patent confers protection to the patented process itself and, at a minimum, to products obtained directly by it. [7] This provision leads to problems if applied verbatim to biopatents:

a) In biotechnology (as in chemistry and pharmacology), an isolated discovery relating to one substance often makes it possible to predict

[7] TRIPS Article 28 (1):
"1) A patent shall confer on its owner the following exclusive rights:
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

similar properties for others. This can lead to very broad patent claims. In the most recent case law from the German Federal Court of Justice, however, patent protection and the state of the art only relate to what is actually disclosed in the patent (BGH 2008: Olanzapin, especially paragraphs 25-29) .[8]

b) Subsequent generations: In animal and plant breeding, due to the biological reproducibility of animals and plants, a process patent (say for a breeding method) may be significantly devalued if animals and plants bred by the method concerned are used to reproduce subsequent generations. The European Biopatent Directive therefore extends product-by-process protection in Article 8 (2) to "any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics" (see also Section 9 of the German Patent Act, Article 64 (2) EPC and Article 28 (1) (b) of the TRIPS Agreement. Article 8 (2) [9] of the Biopatent Directive is to be read in conjunction with recital 46 of the Directive, which cites the aim of providing protection equivalent to that conferred by patents for non-self-reproducing material. The scope of protection therefore depends on an interpretation of what is needed in order to achieve equivalent protection. Also of relevance is Article 10 of the Directive which regulates the exhaustion of biopatents rights after transactions (Tvedt/Finckenhagen 2008: 219f).

The product-by-process provisions can potentially greatly extend the range of animal and plant genetic resources capable of being the subject of patent claims – i.e. of patent owners prohibiting others from using them. The reach of the provisions in the German Patent Act, the EPC, the TRIPS Agreement and the Biopatent Directive is disputed, however, and awaits final settlement in case law. A key aspect in the onward development of the law will be that of consolidating the incipient shift from absolute to function-bound protection, as advocated as early as 2000 for example by the Bundesrat, the upper house of the German parliament (Bundesrat 2000) (see Schneider 2003). Alongside an industrial application, patent grants could then also require a description of a gene's protein coding and function (see also GODT 2003). The Nuffield Council on Bioethics advocates (with regard to medical applications) granting product patents for DNA sequences only in rare instances and limiting patents for DNA sequences in certain areas to the described proteins (Nufield Council on Bioethics 2002: 47-66).

Product-by-process protection may pose special problems with regard to animal breeding since this generally encompasses the three steps of selection, crossing and selective pairing. Selective pairing can make animal breeding methods appear to be production processes, leading to a patent claim on the animals bred using them. The German Society for Animal Production (DGFZ) (2009) therefore advocate legislative clarification that animal breeding methods generally are to be classified as working processes.

[8] "What is to be determined is not therefore in what form a skilled person, for example with the aid of their knowledge in the field, is able to apply a given general teaching or how they might modify that teaching as needed, but solely what the skilled person infers from the prior-art document as the content of the given (general) teaching" (paragraph 25). "Modifications of and developments from this information are equally as little part of the disclosure as those conclusions which the skilled person might draw from the received technical information by force of their knowledge of the field" (paragraph 26).

[9] Article 8 (2) of the Biopatent Directive: "The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteri-stics."

Example

Patent EP1141418 (Selecting animals for parentally imprinted traits) owned by the University of Liège covers inheritance mechanisms in which desired properties relate to the interaction of multiple parentally imprinted quantitative trait loci. The patent's main claim is comprehensive and as such it may not be limited in scope to specific genes. In the subclaims, the claims are limited to the IGF2 gene and specific markers. The patent also includes a use claim for selection of the animals.

Analogously plant breeding processes consist of several steps: first the selection of parents (phenotypically or by molecular markers) according to specific desired traits to be combined in the offspring; second, the crossing of selected parents to produce offspring with new combined characteristics; third, the selection (by phenotype or molecular marker) of offspring which exhibit the desired traits; fourth, propagation of selected offspring. Selection in the first and third step are working processes; crossing and propagation are, however, production processes.

3.1.3 Very broad claims

In practice, some patent claims and granted patents tend to be very broad in scope (as with claims relating to all pigs in EP 1651777) or relate to the entire value chain. This is illustrated by the following examples:

Example

Monsanto patent application WO 2008140467 covers the use of over 260,000 single nucleotide polymorphisms (SNPs) in cattle, relating to various breeding objectives such as milk production, number of offspring and productive life. The use of SNPs to estimate breeding value is a long-recognised technology. The patent claim also extends to animals selected by this method. While the patent is listed as withdrawn in Europe since 2 October 2009, the unresolved underlying legal issues have not yet been clarified.

Example

The broccoli patent, EP 1069819, held by Plant Bioscience Ltd., UK, relates both to the production method and the resulting broccoli plants, their seed and all edible parts of the plant.

Example

Monsanto patent applications WO 2008143993 (maize) and WO 2008153804 (soy) each contain over 100 claims. Both patents claim "a library of nucleic acid molecules" and their use in statistical analysis.

Example

Patent EP 1257168 (Method of cryopreserving selected sperm cells), a patent held by US-based XY Inc. relating to gender-specific selection of sperm cells and artificial insemination in mammals, caused a stir because it expressly cites "for example, human, bovine, equine, porcine, ovine, elk, or bison sperm". The patent thus potentially includes a means of selecting gender in humans. [10] It is opposed by Greenpeace, Green Party MEP Hiltrud Breyer, and Monsanto. The opposition proceedings are still pending decision.

The combination of very broad direct claims with a derived claim on animals and plants produced using a specified process lies at the heart of disputes relating to biopatents in agriculture.

Example

The 'pig-breeding' patent EP 1651777 (use of a genetic marker in pork production; pig breeding using selection according to natural hereditary traits) was applied for by Monsanto in 2004. The application contained more than 30 claims, including DNA sequences (oligonucleotides). Only a patent on the screening method was ultimately granted in 2008 (European Patent Office 2009). The patent, held originally by Monsanto and then by US-based Newsham Choice Genetics, was opposed in 2009 by a number of parties including the German Catholic Rural Association (VKL), Friends of the Earth Germany (BUND), the German Farmers Union (DBV), the German State of Hessen, and various individuals. After the patent owner failed to file observations in response to the opposition,

[10] See the European Parliament resolution on patents for biotechnological inventions, P6_TA(2005)0407.

the EPA withdrew the patent on 23 April 2010 (European Patent Office undated). The underlying legal issues were therefore not properly clarified.

The patent application related to the selection of breeding pigs according to naturally occurring allelic variants and therefore covered applications for all breeds of pig. Under Article 8 (2) of the Biopatent Directive, the protection conferred by a process patent extends "to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics". The claim could therefore potentially cover all pigs produced by the process concerned, including subsequent generations. It might not be easy to tell in a given instance if a pig was produced by a new patented process or by a previously existing, 'old' method. Because the patent related to many different phenotypic traits, questions of this kind may not be answerable by looking for clear genetic differences between pigs produced by the new method or by other breeding methods.

Example

Monsanto patent application WO 2009011847 (Methods of improving a genomic marker index of dairy animals and products) is based on analysis of single nucleotide polymorphisms (SNPs). The patent extends both to bovine animals identified by analysis and to isolated bovine semen. This broad claim could give the patent owner wide-ranging rights relating to future cattle breeding.

Patent EP 1330552 "concerns the identification and isolation of a certain form (allele) of the DGAT-1 gene, which is associated with increased milk yield in cows, and its prevalence in dairy cattle. It includes the sequence of the allele concerned, transgenic bovines in which that sequence has been inserted as a transgene, and a test kit for detecting the sequence in the animals' DNA. The patented invention does not relate to naturally occurring, non-transgenic animals" (European Patent Office 2010). The patent was applied for by Belgian and Dutch breeders in 2001 and granted in 2007. Parties opposing it include the Federation of German Milk Livestock Producers (BDM), Misereor and Greenpeace Germany. The opponents question the presence of an inventive step and also point to the unpatentability of processes involving cruelty to animals under Article 53 (a) EPC read in conjunction with Rule 28 (d) of the EPC Implementing Regulations and Article 6 (2) (d) of the Biopatent Directive. The oral proceedings before the EPO's Opposition Division were held in March 2010.

Overall, there is not only the possibility of naturally occurring genetic resources and genetic resources in the public domain being taken into private ownership by means of patent law. There is also potential for conflict with previously existing property rights in agriculture. To serve agricultural interests, farmers and breeders should be granted special access to patented genetic resources and the patenting of "essentially biological processes" should be banned. This is the subject of the next section.

3.2 Restriction of patent protection by specific arrangements for agriculture

3.2.1 Access for breeders (extended research exemption)

In Germany, Section 11 (2) of the German Patent Act permits "acts done for experimental purposes relating to the subject matter of the patented invention" (the research exemption). This wording originally left it unclear whether the permission extended to research with the subject matter of the patented invention, as would be necessary for plant breeding. Since 2005, Section 11 (2a) of the German Patent Act has expressly exempted from patent protection the use of biological material for the purpose of breeding, discovering or developing a new plant variety. Under Section 9a (3), however, breeders of new plant varieties containing one or more patented components can be prevented from marketing them by the patent owner, or the patent owner can claim a licence fee. A corresponding provision applies for animal breeding.

3.2.2 Access and fees for farmers (farmers' exemption)

Like plant variety protection law, patent law allows cultivation of protected varieties under specific conditions (for use on own farm only, information to be provided by the farmer and payment of a license fee; art. 14 Directive (EC) 2100/94). An exemption from the right of patent owner to prohibit cultivation altogether is provided by Section 9c (1) of the German Patent Act in conjunction with Article 11 (1) of the Biopatent Directive (the farmers' exemption) which allows the use of plant propagation material by farmers for propagation or reproduction on their own farms. Section 9c (2) of the German Patent Act in conjunction with Article 11 (2) of the Biopatent Directive contains an exemption for animal breeding stock that includes making animals available for the purposes of pursuing the farmer's agricultural activity but does not include sales within the framework of or for the purposes of a commercial reproduction activity. The provisions prohibit the exchange of patented seed and breeding stock.

3.2.3 Conventional breeding methods ("essentially biological processes")

"Essentially biologically processes" are excluded from patentability under Sections 2a (1) and 2a (3) 2 of the German Patent Act in conjunction with Article 53 (b) EPC, R 26 (5) of the EPC Implementing Regulations and Article 4 (1) (b) of the Biopatent Directive. An exclusion from patentability of this kind is permitted by Article 27 (3) (b) of the TRIPS Agreement. In the relevant legislation, "essentially biological processes" (Article 53 (b) EPC; Section 2a of the German Patent Act; Article 4 (1) (b) of the Biopatent Directive; emphasis added) are defined as consisting "entirely of natural phenomena such as crossing or selection" (R 26 (5) of the EPC Implementing Regulations of 7 December 2006; Section 2a (3) 3 of the German Patent Act; Article 2 (2) of the Biopatent Directive; emphasis added). This stipulation clearly relates to the protection of traditional agricultural animal and plant breeding methods.

Given that the definition "entirely of natural phenomena such as crossing or selection" serves to explain the term "essentially biological process", it cannot be ruled out that the first formulation will prove to be the authoritative wording. Due to the phrase "consists entirely of natural phenomena", it is possible that only processes consisting *entirely* of 'natural' steps are excluded from patentability.

Legal uncertainty also results from differences in wording. The German version of the EPC has the phrase "*vollständig* auf *natürlichen Phänomenen* [...] *beruht*", which translates literally as "*based* entirely on natural phenomena", whereas the actual wording in the English version of the EPC is "*consists* entirely of natural phenomena". When it comes to interpreting these provisions, it can make all the difference whether the exclusion from patentability relates just to processes that consist entirely of crossing selection or additionally to processes that are based on them.

In any case, the stipulation creates an incentive to invent new technical steps for processes in order to patent the entire process and then the products (instead of inventing new products). This possibility is currently the subject of proceedings before the EPO Enlarged Board of Appeal consolidating cases G 2/07 (broccoli patent) and G 1/08 (wrinkled tomato patent). The oral proceedings are to be held in July 2010.

The exclusion from patentability under Article 53 (b) EPC can be sidestepped by using what is called a bottleneck patent – by patenting some part of the process that is unquestionably patentable by virtue of being technical and so gaining control and a monopoly over the process as a whole (Dolder 2009: 5). In another type of bottleneck patent, a patent is obtained not for the process itself, but for a means or device for its execution that is sufficient to gain control of the whole process (Dolder 2009: 6). Bottleneck patents are not specific to biopatenting. They can be countered with mandatory licensing.

Critics doubt whether processes that are classified as technical today are not essentially selection methods that come under the exclusion from patentability. This notably relates to genetic fingerprinting, marker-based breeding and quantitative trait locus (QTL) methods (Then/Tippe 2009: 17f.).

A paper from the German Society for Animal Production (DGfZ) (Deutsche Gesellschaft Für Züchtungskunde e. V. 2009) emphasises that biological processes only make use of existing variation. They are therefore working processes rather than production processes. [11]

The possibility of patents being granted for conventional breeding methods may have implications that are hard to foresee. Because a process patent can confer derived protection on direct products and potentially on subsequent generations, such patents may prove to be very broad in scope.

The mere possibility of patents being granted for conventional breeding methods creates great uncertainty in farming. The resulting legal uncertainty alone can negatively affect the use of animal and plant genetic resources in agriculture.

3.3 Implications for the innovation process [12]

3.3.1 Patent blockings, patent thickets and the anti-commons

With the rise of intellectual property rights in the sector, plant and animal genetic resources are increasingly being taken from the public domain into private ownership. Traditionally under plant variety protection law, improved varieties qualify for protection while traditional varieties remain in the public domain. With biopatents, on the other hand, it is possible to secure temporary private ownership of existing genetic resources provided that the resources are isolated in a technical process. Yet breeding research depends on being able to use existing genetic resources, which are limited in number and increasingly hard to obtain. Biopatents consequently open up an opportunity to make permanent what was formerly a temporary monopoly, either by buying derivative patents or by evergreening.

[11] It is yet to be seen how the various applications of the TILLING (targeting-induced local lesions in genomes) method will be classified. This is a method of molecular biology for inducing point mutations in a specific gene. It combines conventional chemical mutagenesis using ethyl methanesulphonate (EMS) with a new high-throughput screening method based on a high-resolution separation technique called high-performance liquid chromatography (HPLC). Because TILLING generates new variability, it probably qualifies as a production process. Ecotilling, on the other hand, exploits existing variability (for example in gene banks) to the full in relation to a specific gene, which means it probably qualifies as a working process.

[12] For the mutual relationship between agrobiodiversity and breeding innovation, see Beirat für Biodiversität und genetische Ressourcen beim BMELV (2006).

At macro level this can slow down the innovation process. There are also opportunities for patent blockings, where patents are used to obstruct competitors from carrying out research.
Secondly, patent owners, rather than putting patents to active use, can wait until applications their patents cover come onto the market and then harvest the licence fees. The likelihood of users overlooking granted patents or hoping that any infringements will go unpursued increases with the growth of impenetrable patent 'thickets' (Reitzig 2004; Subramanian 2008). Thirdly, the spread of intellectual property rights upstream can obstruct innovation downstream (the anti-commons problem) [13] ; partly because having many overlapping pieces of intellectual property raises transaction costs, and partly because overlapping and in some cases conflicting claims make it impossible to grant reach-through licences where licensees grant patentees rights to downstream inventions. A strain of rice enriched with beta carotin, for example (known as Golden Rice™) contains 70 pieces of intellectual property and 15 pieces of technical property spread across 31 institutions (Walsh et al. 2005: 288).
Three problems work in conjunction with regard to genetic resources: Patents are granted for DNA sequences whose functions are barely known; genes are limited in number and it is extremely hard for research to sidestep gene patents; a given gene can have many functions and many patents relate to all functions, including ones yet to be discovered by others (See 2008: 143). Gene patents can thus create true monopolies. With process patents, such monopolies can be very wide-reaching indeed. Aside from the competition law issues, patent blockings slow the innovation process. In a case currently before the European Court of Justice (Case C-428/08), however, the Advocate General argued in his opinion that the protection conferred by a patent granted for a DNA sequence (for a genetically modified soya plant) is limited to the function described in the patent and for which the patent is granted (resistance to a specific herbicide).

3.3.2 Problems arising from market concentration

While patent law is not the only driver of economic concentration in animal and plant breeding, there are nonetheless mutual links between business size, market power and patent activity.

Market concentration is high in many agricultural breeding segments and has significantly risen in recent years. The market share of the four biggest plant breeding companies grew from 8% of global sales in 1985 to 30% in 2006 (Le Buanec 2007; Louwaars et al. 2009: 25). In vegetable breeding, the five largest companies accounted for 65% of global sales in 2008 (Louwaarset al. 2009: 21). The market is dominated overall by life sciences companies such as Monsanto, Dupont, Syngenta and Bayer Crop Science (LouwaarsS et al. 2009: 25f). The high degree of concentration is paralleled in patenting activity. In plant genetic engineering, the five largest companies account for over 40% of patent applications at the EPO (2005-2006), and over 60% of patent applications (2003-2007) and over 80% of granted patents at the US PTO (2000-2004) (Louwaars et al. 2009: 35).

The level of patent protection influences the level of capital expenditure by private-sector seed companies and hence concentration levels in the seed sector (Hayes et al. 2009). In plant breeding, intellectual property rights concentrate on the just under 150 species that are cultivated today

[13] The concept of the "anti-commons" (Heller/Eisenberg 1998; Buchanan/Yoon 2000) refers to a central theorem in the theory of property rights, the "tragedy of the commons" (Hardin 1968). This denotes the overexploitation of common resources by private users due to a lack of rules excluding or limiting individual use. The case usually cited is the overgrazing of common pasture by livestock owners. The anti-commons problem, in contrast, involves the underexploitation of resources (relative to sustainable exploitation levels) by overspecification of private exclusion rights, conferred for example by patents. The anti-commons debate today mainly centres around medical inventions (Heller/Eisenberg 1998; See 2008).

(De Schutter 2009). The UN Special Rapporteur on the Right to Food now warns of patents conferring "monopoly privileges" to seed, and of smaller farmers becoming increasingly dependent on commercial seed (De Schutter 2009).

In Germany, the commercial plant breeding sector is heavily reliant on plant variety protection law because the breeders' exemption this enshrines allows breeders to use protected varieties to breed new ones without having to obtain consent from the owners of the protected varieties. This exemption also helps small and medium-sized businesses stay in the market. About 100 companies in Germany are in the business of breeding agricultural crops and about half of these maintain their own proprietary breeding programmes. The number of breeding companies in Germany is large by international standards. Many small and medium-sized breeding businesses view the widening of patent protection as a threat.

Paying licence fees for patented traits in a new variety often poses little problem for large companies in the breeding business. KWS, for example, breeds the MON810 trait into new varieties and pays a licence fee for doing so. For smaller breeding companies, especially ones serving small regional markets, fees for traits requiring the purchase of a licence can squeeze narrow margins so severely that they are forced out of the market.

How far intellectual property rights in general and patents in particular can be turned into economic power and higher revenue partly depends on market structure. Figures from the US Department of Agriculture record a 135% rise in seed prices for maize and 108% for soybean from 2001 to 2009. By contrast, the consumer price index went up by only 20 percent in the same period. Both markets were dominated by Monsanto (Neuman 2010).

In animal breeding, market power mostly stems from ownership and physical control of livestock of high breeding value. With domestic fowl, for example, breeding for the commercial sector has largely shifted from cooperatives to private breeding organisations that mainly use breeding material in their own possession. There is a large pool of biodiversity outside of this domain – for example held by poultry fanciers – but this is of little importance to commercial breeding. Market power wielded in this sector is based on physical control of commercially important breeding material and does not rely on patents. To what extent concentration in the ownership of valuable breeding material favours erosion of genetic diversity (so Institut Für Ökologische Wirtschaftsforschung et al. 2004) is something yet to be investigated. Patent law has already become significantly more important in animal breeding with the spread of new breeding techniques such as sperm sexing and somatic cloning.

3.3.3 Implications for public research

In light of the problems shown, a balancing function could be performed by publicly funded research. However, public research institutions face rising pressure to generate patents themselves (Shorett et al. 2003). Indeed, public-sector institutions accounted for over 20% of submitted patent applications and granted plant-based patents at the EPO from 1980 to 2006 (Louwaars et al. 2009: 37). Publicly funded biotechnology researchers often gear their research plans to the goal of obtaining patents, which are needed among other things to maintain access to the research field via reciprocal licensing between competing groups. In Germany as elsewhere, patent applications score more highly in the evaluation of researchers and institutions than do publications in academic journals. This is especially the case for research on microorganisms. The licensing practice of public-sector patent owners is consequently of key importance, particularly where research is carried out in public-private partnerships.

Recent years have seen lively debate among publicly funded agricultural research centres in the Consultative Group on International Agricultural Research (CGIAR) on whether to adopt 'defensive patenting' in order to maintain access to key innovative advances. This would involve such centres actively generating patents themselves and making them available licence-free to the public, mainly for developing country partners. The same question is faced by public research institutions in Germany, which generally prefer publication over patenting. The publishing of research findings does not, however, stop them from being included in others' patents as foreground knowledge.

3.4 Legal uncertainty

Current trends in biopatenting are a major source of legal uncertainty in agriculture. This can result in animal and plant genetic resources going unused because farmers and breeders are unable to foresee the legal consequences.

3.4.1 Claims to future varieties

It is often not possible in breeding to fully disclose an invention in such a way that the disclosed steps ensure a replicable outcome. Biopatents often cannot be described precisely, but only in functional terms. This makes specificity (disclosure) and replicability problematic as criteria for patentability, which are therefore replaced in plant variety and patent law by deposit mechanisms. These fail, however, in cases where claims relate to future varieties. The result is legal uncertainty. So far there is no case law on disclosure in biopatents.

3.4.2 Unclear scope of granted patents and patent applications

In many cases the scope of patents is unclear. With EP 165177 (known as the 'pig breeding' patent), it took until the opposition proceedings to decide if patent protection for the breeding method also applied to all subsequent generations of pigs bred with the patent and all pigs with the relevant genetic marker. Claims of this kind may be made for production processes but not for working processes. "Classification as a production or working process only usually takes place when it comes to a patent infringement dispute" (Walter, in Deutscher Bundestag 2009a: 15). Generally speaking, the force of a patent is not usually reviewed until infringement proceedings (Walter, in Deutscher Bundestag 2009a: 30). The resulting legal uncertainty about whether licence fees will fall due is likely to affect breeders' and farmers' breeding and production decisions, causing them to choose breeds and varieties that are less suitable but where the legal position is more certain. Even the mere attempt to obtain a patent can severely impact on others who use traditional genetic resources. Examples include the Neem patent (Reiche 2005; Semal2007) granted in 1994, contested in 1995 and withdrawn in 2000 and the Enola yellow bean patent granted in 1999, contested in 2001 and withdrawn in 2008 (Rattray 2002; Wilson/Ciat 2008).

3.5 Patenting procedures

Patenting procedures not only foster legal uncertainty, they also put traditional users of animal and plant genetic resources in agriculture at a disadvantage.

3.5.1 Characteristics of the European patenting procedure

Inventors in Germany can submit a patent application to the German Patent and Trademark Office (DPMA), which makes its decisions on the basis of the German Patent Act, or to the European Patent Office, which operates to the European Patent Convention. More than 95% of applications are probably made to the European Patent Office rather than the national patent office (Dolder, in Deutscher Bundestag 2009a: 20f.). Notices of opposition are examined by the opposition divisions and – judicially – by the technical boards of appeal and where applicable the EPO Enlarged Board of Appeal. Once granted, a European patent is converted into national patents. These can be contested before national courts. In some cases this has already led to contradictory results.

The Patent Office merely examines whether the criteria for patentability are met. The current financing model of the European Patent Office (EPO) and the European Patent Organisation (EPOrg) – with the EPOrg obtaining its funding from procedural fees collected by the EPO and (pro rata) annual fees for pending patent applications and patents in force – creates incentives to grant patent applications in case of doubt (Wissenschaftlicher Beirat beim Bundesministerium für Wirtschaft und Technologie 2007).

As mentioned earlier, the scope of a patent is only usually reviewed in opposition and infringement proceedings. This heightens the importance of such proceedings. It also creates a need for systematic monitoring of patenting activity to be sure of observing the nine-month opposition period when relevant patents are granted.

3.5.2 Reversal of the burden of proof

Under Article 34 of the TRIPS Agreement, member states must give courts the authority to reverse the burden of proof. A patent owner filing for infringement proceedings must prove that the defendant has used or marketed the patented process or product. In some cases such proof may be difficult to establish. A court may therefore reverse the burden of proof if there is substantial likelihood that an identical product was made by the patented process and if the patent owner, having made reasonable efforts, is unable to prove the infringement. If a court reverses the burden of proof, the defendant must at least make plausible that, for example, a plant or animal was not bred with the patented process. The possibility of such a reversal of the burden of proof in patent infringement proceedings increases the record-keeping burden on farmers and breeders (Tvedt/Finckenhagen 2008: 222-224). According to section 139(3) of the German Patent Law the burden of proof is principally reversed for patents on new products.

3.5.3 Transaction costs

High transaction costs are a general problem both in applying for patents and in opposing them. Patent opposition is expensive and time-consuming. Even an organisation as strong as the German Farmers' Union finds itself overburdened by the high cost of continuously monitoring patenting activity and opposing patents (Lampe, in Deutscher Bundestag 2009a: 6). Evidence suggests that as far as biopatents are concerned, most patent applications and oppositions are submitted by large companies and resourceful research institutions, while small companies and civil groups make only isolated use of such instruments (Feindt 2008). For the chemical and biotechnology industry, long approval procedures are more of a problem (Popp, BASF, in DEUTSCHER BUNDESTAG 2009a: 40). The German Patent and Trademark Office has been seen to take over 2½ years to process patent applications in 50 % of the cases (Deutscher Bundestag 2009b: 2).

4 Conclusions

The global spread of biopatenting from 1985 set off an ongoing process under which animal and plant genetic resources are increasingly being taken into private ownership. This process was essentially driven forward by developments in case law that legislators then followed (Feindt 2008). The general principles of patent law were consequently extended to the field of animal and plant genetic resources without giving proper consideration to the different production and innovation processes in that field.

Too little consideration was also given to differences between animal and plant breeding. Instead, both activities were brought under the same body of patent law. For plant breeding, an effective means of protecting intellectual property had been established from the 1960s with plant variety protection law. This ceased to meet the needs of biotechnology, however, and underwent reform largely for that reason in 1978 and 1991. Protection under the UPOV regime relates to the products of breeding; breeders must also demonstrate an improvement on previous varieties. The UPOV system does not confer protection on breeding methods themselves. In animal breeding, comparable protection for new breeds has so far failed at the problem of identifying a breed precisely enough for the purposes of protecting intellectual property.

In both plant and animal breeding, patent law allows the granting of process patents with the possibility of a derived claim to plants and animals bred with the patented process. This sidesteps the identification problems. At the same time, there is considerable uncertainty about the scope of exclusivity rights under patents for breeding methods. Specifically, fears are voiced with regard to two possibilities:

- Acquisition of exclusive rights to breeding methods and genetic resources from the domain of 'primary' production, because process patents make it possible to transfer primary biodiversity from the commons into private ownership;
- Withdrawal of traditional breeding methods from the public domain into private ownership and, once a monopoly has been established, perpetuation of the monopoly by follow-on patents and other strategies of "evergreening".

The result is heightened legal and economic risk for and greater economic pressure on small farming and breeding operations. It is a plausible assumption that biopatents lead to a reduction in available diversity in the breeding and use of animal and plant genetic resources.

There are thus three aspects to the exclusion of others from the use of genetic resources as a result of biopatenting:

- In terms of spatial reach, TRIPS and the CBD paved the way for global acceptance of the notion that intellectual property rights – normally patents and exceptionally plant variety protection rights – can be granted for biological inventions.
- In terms of temporal reach, patented inventions may enjoy de facto protection for more than the 20-year term of a patent if licensing practices and breeding strategies such as gene stacking are used to achieve evergreening. Patents also gain in time value as progress in biotechnology accelerates.
- In terms of proprietary reach, many process patents and patent applications contain very broad claims which may confer rights to a wide range of genetic resources, subsequent generations and derived products.

The control of animal and plant genetic resources that is conferred by breeding-method patents is becoming concentrated – together with the resulting products – in the hands of a small number of companies with considerable patenting expertise and capacity plus the financial staying power for complicated and long-lasting patent disputes. Small-to-medium breeding operations and most agricultural producers, on the other hand, face the prospect of additional licence fees and greater legal uncertainty. As economic concentration processes typically go hand in hand with increased standardisation in production, it is to be feared that biopatents will lead to a narrowing of the pool of animal and plant genetic resources actively used in breeding.

In the classical innovation model, the granting of intellectual property rights is assumed to speed up the innovation process. Whether patents on animal and plant genetic resources have this accelerating effect is questionable. Patent blockings and the anti-commons problem are notable in hindering access to breeding material and the use in breeding of established knowledge.

Current patent granting and review procedures cannot properly address the implications of biopatents for access to genetic resources. The scope and specificity of patents are often not clarified until opposition and review proceedings. The transaction costs of such proceedings are so high, however, that only parties with ample resources can make systematic use of them. Their duration is also a major source of legal uncertainty.

The existing organs of the patent judiciary with their field of argument closely aligned to patent law are not fit for the purpose of addressing the problems that follow on from biopatents. What is needed instead is a policy debate about biopatenting from the standpoint of the common good; as an outcome of such a debate, corrections to the interpretation of patent law, to legislation and to the applicable international agreements would probably appear desirable. This is likely to involve very long and drawn-out discussion, however.

5 Recommendations

The threatened state of agrobiodiversity has many causes that may be amplified by biopatenting. Strategies to sustain agrobiodiversity are complex and cannot be addressed here (but see for example Advisory Board On Biodiversity And Genetic Resources At The Federal Al Ministry Of Consumer Protection 2005, 2008). Key points include incorporating agrobiodiversity in other policy areas, in-situ and ex-situ conservation, open access regimes following the example of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and publicly funded research. It may be possible to exclude plant and animal genetic resources from patentability under Article 27 (2) of the TRIPS Agreement. This would require proof of a causal link between patent protection and a threat to biodiversity. Proving such a mono-causal link, however, is likely to be very difficult.

The connection between biopatents and agrobiodiversity is indirect and mediated through processes of privatisation and economic concentration. These processes may lead to a narrowing of breeding targets and of access to genetic resources and hence of the range of animal and plant genetic resources in use.

Biopatenting is enshrined in multiple provisions of national and international law. The notion of taking animal and plant genetic resources out of biopatenting therefore appears unrealistic for the medium term. The immediate focus should therefore be on the forms taken by biopatenting in practice. A close watch should be kept on the development of prevailing law so that any need for legislative action is pinpointed in good time. The German government should take a leadership role internationally in drawing attention to problematic aspects of biopatenting for animal and plant breeding. This is because Germany is one of the countries in Europe in which the breeding sector retains a diverse structure and – in plant breeding especially – is dominated by small and medium-sized businesses.

(1) In the medium term, development of the law by judicial and opposition proceedings will be the central arena of development for biopatenting. In this regard, the Board recommends:

- To address the problem of excessively broad patent claims, insufficient disclosure should be added to the legal framework as grounds for revocation, for example by supplementing Article 83 EPC.
- The problem of derived claims on animals and plants bred with a patented process and on the resulting products – in analogy to product-by-process protection – should be met with legislative clarification that breeding methods are to be classified as working processes and not production processes.
- A classification of breeding methods as working processes would also counter patent claims on subsequent generations.
- To avoid legal uncertainty, classification of a process patent as a working process or a production process should generally take place when the patent is applied for and granted.
- With regard to the problem of the lack of an inventive step, for example in gene sequencing, the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) should work in cooperation with the Federal Ministry of Justice (BMJ) to ensure that requirements for

the specific description of the function and industrial application of gene sequences are interpreted strictly and specifically.

- A particular aim should be to ensure that the protection conferred by a patent is attached as a rule to the description of protein expression by a gene and restricted to the described proteins and described functions.

(2) With regard to breeders' and farmers' exemptions, German lawmakers have largely exhausted the scope provided by the European Biopatent Directive. The exclusive marketing rights conferred on patent owners and the possibility of cumulative licence fees nonetheless give rise to uncertainty.

- BMELV should consult on this with relevant groups and formulate rules to reduce uncertainty for breeders and farmers.
- In this context, the Board advocates setting a maximum limit on fees as used in competition law (notably in monopolies regulation).
- Eventual patent blockings should be addressed by granting compulsory licences. The credible threat of a compulsory licence being granted can serve as a deterrent if very broad patent claims are allowed in the proceedings currently pending. In this way, patent owners can be discouraged from abusing patents.

(3) A crucial aspect for breeding is the potential patenting of conventional breeding methods. A case currently before the EPO Enlarged Board of Appeal involves ruling on what constitutes an 'essentially biological process'. The Board has the following recommendations in this regard:

- BMELV should assess whether it can make available legal expertise to support the interests of German breeders and farmers.
- In any event, BMELV should commission a research project on the effects of biopatenting so that it can draw more intensively on science-based evidence in the current controversies.
- The term "essentially biological process" should be more precisely defined in national and European law in such a way that conventional breeding methods are excluded from patentability. It would have to be seen whether currently ongoing EPA proceedings (the broccoli case) can be influenced in this connection.
- In any event, a stipulation that patented breeding methods are to be classified as working processes and not production processes should be inserted at a suitable place in the Biopatent Directive and the German Patent Act.

(4) With regard to the development of biopatenting, monitoring patenting activity on an ongoing basis and opposing patents involves high transaction costs that overburden even the large agricultural organisations in Germany. BMELV should therefore, in cooperation with BMJ and interested civil groups:

- Establish a public biopatent monitoring system;
- Develop a legal aid system for EPO proceedings;
- Develop an alternative funding model for the EPO.
- BMELV should appraise the EPC Implementing Regulations for starting points in this regard.

(5) Potential trends towards concentration and eventual abuse of patent rights, for example through evergreening strategies in breeding, should be countered by rigorous application of competition law nationally and internationally. The Board recommends as follows in this context:

- BMELV should enter into ongoing dialogue with the Federal Ministry of Justice (BMJ) and competent authorities to sensitise them to the problems of evergreening.
- BMELV should also invest in research on concentration processes relating to the use and control of animal and plant genetic resources.
- International experience such as the progress and outcomes of investigations by US authorities in the seed sector should be watched for implications for German and European practice.

(6) Patent blockings should be countered by exploiting the possibilities of competition law, for example to combat concerted refusals to license. The essential facilities doctrine could be extended to working methods and furnish grounds for granting compulsory licences. The Board's recommendations in this context are as follows:

- BMELV should ensure that in-house capacity is kept available to deal with these problems and that patenting and competitive activity is monitored on an ongoing and coordinated basis.
- It is to be recommended that BMELV should enter into dialogue with BMJ to develop possible counter-strategies.

(7) There are no straightforward solutions to the anti-commons problem, where interlocking intellectual property rights block access to genetic resources. Options include open-source patents and the establishment of patent pools. Open-source regimes such as ITPGRFA can also be extended.

- BMELV should ensure that it has the capacity available to monitor developments in this context. If there are signs of anti-commons problems emerging, BMELV should develop solutions in dialogue with relevant groups.
- To avoid path dependencies in the breeding process, public research capacity should be sustained despite the increasing scarcity of public funds.

(8) Finally, it should be borne in mind that biopatents can have far-reaching effects in the context of converging technologies (the cumulative use of biotechnology, information and communication technology, and nanotechnology). Application of the precautionary principle and the involvement of civil society take on special importance in this regard.

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