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Patent Protection in the Field of Animal Breeding

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ABSTRACT

There is a rapidly growing number of patent applications relevant for the animal breeding sector. Patent law is general in form and is seldom adapted to single areas of innovation. It was initially created for the purpose of granting exclusive rights to technical inventions; and it was taken for granted that higher animals, food production and pharmaceuticals were too important for mankind to be included under exclusive private rights. When patent law now is becoming increasingly in use in the animal sector, it is an unanswered question how the law will apply to this particular field of innovation. There is legal uncertainty of how the courts will apply the general law this particular field. Patent law has potential to alter the existing legal conditions for competition and investments in the field of animal breeding, and needs therefore a higher level of awareness among policy-makers, animal breeders and farmers.

KEYWORDS

Animal Genetic Resources, animal genes, breeding methods, EU Directive, innovation, patent law, patentability, scope of protection, TRIPS Agreement.

I. INTRODUCTION

This article examines the scope of patent protection in the field of animal breeding and farm animal genetic material. The expansion of the scope of patent law to the animal sector has been the subject of very little discussion, and the probable consequences for the livestock sector have not been analysed.¹ The general justification for patents--that they lead to increased innovation--is merely repeated for the livestock sector, without looking into the structure of the sector to see whether the existing incentives for research and development are sufficient, or how the introduction of patent law may alter them. (Lesser, 2002: 2-4 and 14, Langinier & Moschini, 2002: 31ff.)

Domestic animals supply 30% of total human requirements for food, and 70% of the world's rural poor depends on livestock as a component of their livelihoods (FAO, 1999). The global livestock sector consists of a variety of production systems, and farm animals are used for many different functions. Centuries of selective breeding and exchange of farm animals or germplasm among owners within and across countries have resulted in the development of

today's diversity of breeds and within-breed genetic diversity. There are more than 40 species of animals that have been domesticated (or semi-domesticated) during the past 10 to 12 thousand years that contribute directly or indirectly to agricultural production (FAO, 2000). Livestock has been undergoing constant genetic change since the first domestication; and long before patents were applicable to the sector, there were investments and improvements in animal breeding. This article focuses on how the recent introduction of patent law to farm animals in food production will apply.

Patenting of living matter is fairly new globally. In most countries, patents in the field of animal breeding are just getting started.² The watershed court case is the frequently-cited *Diamond vs. Chakrabarty* from the US Supreme Court in 1980. The question in this case was whether one particular genetically engineered bacterium could be patented; by the smallest majority possible (5 judges pro and 4 judges contra), the US Supreme Court responded with the all-encompassing statement that "anything under the sun that is made by man" is patentable.³ This American court case has had a major impact on the legal situation throughout the world, because it laid the groundwork for altering the basic principle that patent protection is not available in the field of food production.⁴

The most comprehensive global amendment of international patent law is the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement of the WTO, which requires all member countries to provide patent protection for "any inventions, whether products or processes, in all fields of technology" (TRIPS Article 27, para 1). From this comprehensive main rule, discretion is left to countries to exempt animals other than microorganisms from patentability. Even if the discretion to exempt "animals" indicates that patents are not applicable to the animal sector, the seemingly broad exemption and apparently broad discretion is narrowed down by the more precise definition of the main rule: The TRIPS agreement also requires that countries grant patents on *microorganisms* and on *non-biological processes*. Both these categories pertain to the animal sector, so that the range of possible exemptions from patentability is in fact quite narrow. Partly due to the TRIPS agreement, the comprehensive scope of patent eligibility has been expanded to be global in scope. Beyond this, further harmonisation of patent law is on its way (Tvedt 2007). This indicates that patent systems worldwide are likely to play an increasingly important role in the breeding and livestock sector.

Also other parts of international law pertain to animal genetic resources. The Convention on Biological Diversity (CBD) covers genetic material and genetic resources of all species, including animal genetic material. Its Conference of the Parties (CBD-COP) has touched upon the matter of animal genetic resources (AnGR) several times, but no CBD-COP decision thus far has addressed it in depth.⁵ Despite the lack of special attention given to this matter in the CBD, the general genetic resources-law is likely to apply to AnGR. The UN Food and Agriculture Organisation (FAO) is addressing this particular topic in its Commission on Genetic Resources for Food and Agriculture (Hiemstra et al., 2006: 10–11 and 19–21). The Commission approved the finalisation of the first *Report on the State of the World's Animal Genetic Resources*, which was one of the main topics for the agenda for the First International Technical Conference on Animal Genetic Resources held in Interlaken in September, 2007. Meanwhile, as policies or regulations of AnGR are being articulated as a topic for discussion in the CBD and in the FAO, the various national and regional patent systems are receiving and granting patents in the field of animals. This is leaving the patent system as the main

playing-field for establishing rights in the field of AnGR.

The first patent on animals of higher biological classes than microorganisms was granted in the Oncomouse case, where a mouse was genetically modified for use as a laboratory research animal.⁶ Even if the use of an animal for laboratory research and in food production is fundamentally different, patent law, due to its general character, will most likely apply the rulings of these court decisions in a parallel manner with respect to farm animals. Since the area of patenting of farm animals is new, the number of relevant court and panel decisions is as yet very limited, which increases the relevance of using practice from laboratory animals in this area even though the sectors are different. This also, however, increases the uncertainty in the legal situation as it is a fairly open question how these cases will be applied since the facts are different.

II. A MULTITUDE OF LEGAL SOURCES

Patent law is part of a complex legal picture: each patent is granted at the national level, whereas changes in the law occur at the international or regional level. Patent practice and thus patent law develop differently in each country due to discretion in the implementation of international law and due to practice in the patent offices. Therefore, one needs to go into country-specific legislation in order to write about the exact details in patent law. This article takes a European perspective, focusing on legal regulation in the European Union (EU) and cases from the European Patent Organisation (EPO). One reason for choosing Europe is that the EU Patent Directive on Biotechnological Inventions (EU Patent Directive)⁷ is in the implementation phase in the member countries. Because the consequences have not yet become evident, the effect of this directive needs to be discussed. To a large extent, the EU Patent Directive is an attempt to harmonise the legal situation in member countries with the practice that has been developing in the EPO.

In Europe, the EPO grants patents with direct effect in the member countries chosen by the patent applicant.⁸ Besides this system for European patents, the national patent office grants patents if the application is directed to the office directly. In the 31 EPO member countries, patent practice is developing in parallel at the national level and at the EPO level. Thus, in Europe, the legal situation is partly a result of the practice of the EPO Board of Appeal, the codifications in EU patent directives, and other international treaties such as the TRIPS Agreement. Patent law also develops through court cases that interpret and reinterpret the standard and general patent criteria, and thereby apply them to new fields of technology. This makes court and appeal decisions important sources of law.

III. ELIGIBILITY FOR PATENT PROTECTION IN THE ANIMAL SECTOR

What types of inventions are eligible for patent protection? This was previously left to the discretion of each country, but has been radically altered by the TRIPS Agreement, which establishes a wide scope of patentability by requiring all member countries to provide for patent protection in all fields of invention, with only some narrow exemptions: Countries are allowed to exempt patent protection of *animals other than microorganisms* and of *essentially biological processes* (TRIPS Agreement 27, para 3).

The main rule for patentability in Europe is found in EU Patent Directive Article 3:

For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature (EU Patent Directive 98/44/EC, Article 3, paras 1 and 2).

The main rule is that patents are applicable to the field of animal breeding and animal genes, and to cells and proteins, even though they were pre-existing in nature. From this broad main rule, EU Patent Directive makes two narrow exemptions: (1) “animal varieties”, which are not eligible for product patent protection; and (2) “essentially biological processes for the production of [...] animals”, which are not eligible for process patent protection (EU Patent Directive 98/44/EC, Article 4). To fully understand the scope of these exemptions, they must be discussed in the light of the scope and coverage of patent protection in the livestock and breeding sector. Because patent protection can be granted to products (see Section IV below) and to processes (see Section V), these two types of inventions are dealt with separately.

IV. PRODUCT PATENTS IN THE ANIMAL SECTOR

A. Patentability of Animals, Animal Varieties, and Animal “Biological” Material

A first question is whether countries are required to provide patent protection for animals, animal proteins, genes, and cells.

The TRIPS Agreement opens for exempting *animals* other than *microorganisms* from patent protection in national patent law. The practical implications of this exemption depend upon the interpretation of the legal concept “*other than microorganisms*”. As there is no definition or any agreed understanding of the term *microorganisms* among the parties to the TRIPS Agreement countries have significant discretion to either include or exclude animals, proteins, genes, and cells in their national patent systems. One linguistically possible interpretation of this legal concept is that it means countries have the freedom to exempt from product patent protection every category of animal-related biological invention except those that are clearly recognised as microorganisms in a biological sense. The lack of agreement of the more detailed understanding of the term *microorganisms* in the TRIPS Agreement leaves countries with considerable discretion in their interpretation and implementation in their national patent acts.

The EU Patent Directive takes a more comprehensive approach to patenting. The main rule, according to Article 3 of the EU Patent Directive, is that the patent applicant can formulate his claims to cover all categories of “product[s] consisting of or containing biological material” (EU Patent Directive 98/44/EC, Article 3). Thus, under the Directive, the question of microorganisms is not so essential, because the scope of eligibility for patent protection is more comprehensive and is not linked to the term *microorganisms*. From the broad main rule in the Directive, exemption is provided for only one narrow type of product patent claim, formulated as one particular *animal variety*. This is problematic, because *animal variety* is not

a well-defined concept in biology or in active breeding,⁹ nor is there any agreed legal definition of this term.

One historical explanation for exempting *animal varieties* from patent protection can be sought in the exemption from patent protection for *plant varieties*.¹⁰ Prior to the changes in patent law over the past 15–20 years, it was taken for granted that patents should not be granted in the food and pharmaceutical sector, because these sectors were regarded as too important for humans to be dominated by exclusive monopoly rights. Against this background, patent law exempted *plant varieties* from patentability and provided a specialised type of intellectual property rights (*sui generis*) protection for new plant varieties in the system created for establishing plant breeders' rights. In Europe, it was not considered useful to provide double intellectual property right protection under both the plant breeders' rights and the patent system for plant varieties, so *plant varieties* were exempted from patent protection.

In the animal sector, there was not a similar need for intellectual property protection, because the physical control of the animals was sufficient to secure investments in breeding. The consequence was that patents were generally not relevant for living subject matter in agriculture. Preventing double protection cannot explain the exemption for animal varieties, because there is no similar legal system to protect animal varieties. It has been suggested (Bryde, 2004) that also exempting animal varieties from patent protection is rather a coincidence, a result of copying legislation for the plant sector to the animal sector without first determining its appropriateness.

The legal term *animal variety* is also problematic from a biological point of view, because there are fundamental differences between the biology of animals and of plants (Hiemstra et al., 2006: 23–25). Plant varieties with a high degree of inbreeding can be viable – indeed, such inbreeding is often desired in plants. For animals, however, inbreeding and genetic uniformity within a given population are not desired in order to maintain the genetic variation and viability of the population.¹¹ One other crucial difference is that in plant breeding, a new plant variety may replace the variety previously grown in a large area if it finds favour with the farmers. Animal breeding is much more of a continuous work where a farmer never introduces a completely new stock or flock of animals – except in a crisis situation and for commercial farming (e.g. poultry and pig). Thus, the concept of a variety in the plant sector is not easily transferred to animal breeding and the livestock sector. (Hiemstra et al., 2006: 10, 34, 38.) The term often used for animals is *animal breed*. The trouble of introducing this as a legal concept is that there is not general agreement within biological science as to the definition of *animal bred*.

Despite these difficulties in defining *animal variety*, the term is important in patent law because it is the sole exemption from product patent protection in the EU. In the Oncomouse case, an EPO Board of Appeal (BoA) interpreted and applied the term *animal variety*.¹² The fact was that the patent application described a cancer-promoting gene which, when injected into fertilised mouse eggs, made the next generation of mice more likely to develop cancer. The core patent claims were formulated as:

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an

activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8- cell stage. [...]

17. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of Claims 3 to 10.

18. An animal as claimed in Claim 17 which is a rodent.¹³

The BoA accepted that the scope was narrowed to target rodents rather than covering all mammalian animals, because the sweeping patent claims, which referred to a “non-human mammalian animal”, were too broad for the invention in question. The BoA held that an invention could be described in the patent claims as covering more than one particular *animal variety*, and stated that the exemption for animal varieties¹⁴ did not preclude patents in the field of animals at large (T-0019/90).

This result from the BoA in the Oncomouse case has been codified in a more general manner in EU Patent Directive, Article 4, paragraph 2: “Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.” This implies that, if the patent claim does not specifically target only one particular animal variety, the patent may be granted (subject to the patent criteria). For animals, this means that inventions connected to animal species or to animal breeds may be patented. This can *de facto* result in a number of animal varieties being covered by the patent. The practical consequence of this exception is that only the patent applicant who is so unfortunate as to formulate his patent claims as to target only one particular animal variety, rather than several varieties, will be denied patent protection. This leaves the seemingly broad exemption from eligibility quite narrow in scope.

The facts of the Oncomouse case concern laboratory animals and not the livestock or animal breeding sector. However, by EU Patent Directive, the principle established in the Oncomouse case has been given a wider and less specific application, and is not confined to laboratory animals. Thus, an invention which is relevant for more than one animal variety is eligible for patent protection in Europe.

There are some important differences between technical development of an animal to be a research tool and agricultural animal breeding. For genetically modified research animals, the offspring will clearly be descended from the innovatively modified mouse, and all subsequent users of the GM-research animal will depend upon this animal. By contrast, in livestock keeping and animal breeding, the individual animals usually belong to the farmer and are not descended from the same parent individual. In more industrial branches of agriculture, such as poultry or pig-keeping, the breeding stock is more likely to be descended from recently developed pure lines, so the situation is more similar to that of laboratory animals. As structure and practice varies among branches of the breeding sector, the rules developed on the basis of the patent to a laboratory animal will apply differently and lead to different consequences among animal species and breeds.

The answer to the question of what is eligible for product patenting in the livestock sector is

therefore that almost every manner of formulating the patent claim is legal -- with the sole exception of a claim that targets only one particular *animal variety*. The concept *animal variety* is unclear in both the legal and the biological sense. Therefore, it is highly dubious whether any product patent claims are likely to be rejected on the basis of this exemption, which leaves the scope of patent protection comprehensive.

B. Scope of the Exclusive Right

The second difficult main issue for product patents in the animal sector is to determine what is covered by the exclusive right when a patent claim refers to an animal, animal genes, animal cells, or proteins.¹⁵ Even if the scope of the exclusive right is a core issue in patent law, hardly any analytical work has analysed it for the animal sector.¹⁶ Analytically, the scope of the exclusive right covers two considerations: Determining the scope of the patent claims -- what is the “invention” which is covered by the exclusive right -- and determining to which acts a patent grants an exclusive right.

The acts covered by a patent are harmonised at the global level for all fields of technology by the TRIPS Agreement, Article 28:

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 product¹⁷

These acts are formulated in a broad and general manner. What in fact is meant by to “make” an animal gene? When is one “using” an animal gene? Such questions need to be answered in order to understand how patent law will function in the animal sector. To see how patent law will apply to the animal sector, the general acts of infringement must be coupled with the individual patent claims. Because all patent applications are necessarily different since they describe the individual inventions, a general discussion of the scope of patent protection requires a look at ways in which the subject matter is typically formulated. Two types of product patent are in focus here: first, a genetically modified gene (and the GM animal to which it is introduced); and second, a naturally occurring animal gene.

1. Product Patent on a Modified Gene and on an Animal

There is no doubt that a modified animal gene is eligible for patent protection in Europe (EU Patent Directive 98/44/EC, Article 3, para 2). Obviously, the invention -- either the modified gene or the genetically modified animal in which it now occurs -- will have to meet the general patent criteria in order for a patent to be granted. As modified genes or genetically modified animals are most often *novel* and *inventive* in the patenting sense, the questions regarding the scope of the exclusive right are more difficult than those regarding whether the patent should be granted or not. The EU Directive establishes that:

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.¹⁸

The phrase “in which the product is incorporated” is a clear reference to genetically modified organisms. Thus, for genetically modified animals (GM animals) a patent on the modified gene entails that the whole GM animal in which the gene is introduced is covered by the exclusive right. The first element of the phrase “in which the genetic information is contained and performs its function” is only a reference to the fact that the gene must be present -- or “contained” -- in the organism for the animal to be covered by the exclusive right of the patent. The wording of the second element -- “and performs its function” -- indicates a delimiting criterion that narrows down the scope of the exclusive right to cases where the gene is switched on and performs as intended. If this is interpreted according to its wording, i.e. applying only to animals where the patented gene actually works, this will mean a precise scope for the patent protection targeting the actual new invention. Whether the courts will apply this criterion according to the wording remains to be seen. There has not yet been any case-law interpreting this criterion in Europe. In addition, the question of whether the gene is switched on is also a difficult question.

The scope of protection must also be seen in the light of Article 8 of the 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. (EU Patent Directive 98/44/EC, Article 8, para 1)

All offspring from the GM animal in which the modified gene appears will also be covered by the scope of the patent protection -- not only when the next generation is “identical”, but also when it occurs in “diverging form”. The criterion is that the biological material resulting from “propagation or multiplication” possesses “those same characteristics”. This criterion shows similarities to the criterion “performs its function” in Article 9. The background for the rule is explained in the preamble to the Directive:

Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself (EU Patent Directive 98/44/EC, Preamble recital 46)

Attorney- General Jacobs also confirmed this view in his preparation of the case between the Netherlands and the Commission.¹⁹

However, linking product patent protection to the function of the gene is somewhat challenging, as it is difficult to provide evidence before a court that the gene in question either has performed “its function” or possesses the “same characteristics”. The criterion “identical forms and divergent forms” shows that the exclusive right conferred by the patent will apply also where the offspring develops, as long as the patented characteristics are still present.

The scope of patent protection for GM animals becomes particularly uncertain when the patented gene and traits spread into the wilderness or into other individuals. Although such

spreading to the wilderness is not a relevant problem for most terrestrial domesticated animal species, for genetically modified farmed fish it can be a very real problem, because farm fish do escape from the confines of their nets.²⁰ The mix between one GM flock of animal that mates with individuals from a non-GM flock could in the future become a challenge, as the patented gene could make patent protection extend to the offspring of the other flock. This problem could also become greater with increasing commercial use of terrestrial GM animals in the future. If the wording of EU Patent Directive, Article 9 is to be understood literally, such a spread to the wilderness would in principle be covered by the patent. To what extent the patent protection will extend to such cases has not yet been decided by the courts.

2. Product Patent on a Naturally Occurring Animal Gene

A product patent can be granted to an already existing animal gene, according to EU Patent Directive Article 3, paragraph 2:

Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

The questions regarding product patent protection for naturally occurring genes are different from those relating to modified animal genes or genetically modified animals. With naturally occurring genes, the main problem is to delimit the scope of protection to what is already present in nature and at farms.

When the gene is described in a manner which has not previously been done and there is some indication of its use, the naturally occurring gene can be regarded as a patentable invention (EU Patent Directive 98/44/EC, Article 3, para 1). The fact that there are very few technical descriptions of animal genes means that the body of relevant *prior art* in the animal sector is limited. Thus, for the foreseeable future it will probably be fairly easy to obtain a patent on isolated and described animal genes.

The question of whether an allele of a plant gene was part of the *prior art* and thus excluded from patent protection was brought before the Enlarged Board of Appeal under the EPO in the Biogen case (T 0301/87). The European Patent Convention uses the criterion “everything made available to the public” to delimit the *prior art* and thus determine patentability (EPC Article 54 (2)). The question was whether there was “a reasonable possibility that [the gene] could be accessed by the public” when it was stored in a gene bank (Biogen case, T 0301/87, para 3.3.2). The Enlarged Board of Appeal applied the principle that the search for the gene was sufficiently comprehensive so the accessions contained in the gene bank were not regarded as a part of prior art. The gene “...had not been made available to the public by this publication itself or through this publication from the gene bank” (ibid., para 5.2). The Enlarged Board of Appeal held that if there is a need for screening the gene bank for the genetic property that the inventor is looking for, then the fact that the said gene sequence has been deposited in the gene bank is not sufficient for the gene to qualify as a part of the prior art (ibid., para 5.4). In this case, the DNA was “hidden in the multitude of clones” in the gene bank, according to the Enlarged Board of Appeal, and was therefore not regarded as a part of prior art. This principle indicates that it is not very difficult to fulfil the criteria of novelty and inventiveness because, when it comes to naturally occurring animal genes, the prior art is

narrowly defined.

A more difficult question is what is covered by the patent right to a naturally occurring animal gene. Which types of activities that involve the patented gene are covered by the exclusive right? The patent claims must be interpreted and combined with the general definition of the acts of infringement stated in TRIPS Agreement, Article 28: “acts of: *making, using, offering for sale, selling, or importing* for these purposes that product”. *That product* refers to the genetic material which is described as the invention in the patent claims. The exclusive right clearly covers the use of the gene described in the patent claims. For example, commercial work with that gene in a laboratory will probably be covered.

One fundamental difference between regular inventions and patents on naturally occurring biological material is that the vast majority of other inventions do not pre-exist in nature but are man-made from scratch. By contrast, a gene is already there in nature, albeit in a slightly different form. The fact that the gene already occurs in other individuals that exist independently from the invention gives rise to various difficulties. These challenges have led to special rules regarding the scope of protection of biotechnological patents according to the 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. (EU Patent Directive 98/44/EC, Article 8, para 1)

The formulation “shall extend to any biological material derived from that biological material” indicates that only the material that is the next generations of the patented invention is covered. The term “that biological material” is, however, less clear-cut. If the gene is isolated from another individual animal that has never even been close to the patentee, then the newly isolated gene can hardly be said to be “derived from that biological material”. If this is understood in a narrow sense, in which the scope of the patent protection to a naturally occurring gene is strictly limited to the next generations made from the isolated and purified gene, few difficulties arise.

The formulation in the Directive can also be understood in a more comprehensive and expansive manner as referring to all material derived from the similar biological material described in the patent claims when it is used in an “identical or divergent form and possessing those same characteristics”. Laboratory work on the same patented gene, but from another animal, would probably then be sufficiently close to the invention to be covered by the patent. Also this question has not found a solution in the European courts.

Outside laboratory use, the matter of product patents on naturally occurring genes raises a further difficult question: To what extent can the owner of the animal, in which this patented naturally occurring gene is present, take use of it? Can the owner use his animal for breeding, with the consequence that the gene is *used* by being transferred to the offspring, without infringing the patent? The answer to this question is probably yes: a patent is not supposed to alter on-going use and activities. But, what about genotypical selection -- what will be the case if the farmer conducts a gene test on his herd and then uses only those animals with the

patented gene for further breeding? Provided that the patented gene is coding for a desired trait, the use of such insight about whether the gene is present draws partly upon the invention in the patent. Therefore, to use knowledge about whether the patented gene is present in the animal as one breeding criterion might be deemed an infringement of the patent. If, then, all cattle-owners start scanning their herds to identify animals in which that gene is present, and then select breeding animals from those with the highest concentration of the gene, are they infringing on the patent? These questions are currently not solved by any court and will thus create a level of uncertainty for farmers (in particular since a patent is enforced by the patentholder).

The details in the patent claim will probably also give guidance in determining whether this will be considered an infringement of the patent right. On the one hand, the patentee has invested in identifying the particularly relevant gene; and to recapture this investment, it could be argued, all “uses” of the gene (and knowledge about its occurrence) in active breeding should be part of his return on the investment. On the other hand, that gene is already present in a number of animals, and their owners already have a right to the whole animal with the DNA. The property right to the individual animal includes the possibility of using that individual for breeding purposes. If such use is covered by the patent protection, the patent would entail a right to prevent others from using the biological material described in the patent claims, even if they already possessed the biological material now described in the patent claims and even though this genetic material exists independently of the invention. This interpretation is the one most in line with the wording of EU Patent Directive and the statement of the Attorney General quoted above. One consequence of applying such a broad scope to the exclusive right to a naturally occurring animal gene could be the potential legal conflicts between the patentee and all the owners of the animal with that gene present.

Another question regarding product patent protection to a naturally occurring gene is whether the description of one allele of the gene grants an exclusive right to that gene, or whether other alleles/expressions of the same gene are covered by the patent. The EU Patent Directive does not provide any explicit solutions to this question. A Swedish theorist, Westerlund, has indicated that it might be too easy to avoid infringement of gene patent: all that would be needed would be to make a minor alteration in the structure of the amino acids. She emphasises that it is too easy to “invent around” a gene patent. (Westerlund 2001: 183) This argumentation is very much based on re-combinant gene technology, and does therefore not target the current situation in the animal sector. Wesenlund does not seem to discuss regular animal breeding, which differs significantly from the gene technology applied to the genetic modification of plants. Although her argument applies to GM plants, it is less applicable to animal breeding, because genetically modified animals are not now used in commercial food production.

The Nuffield Council has proposed that product patents to naturally occurring genes should be restricted because it is difficult to “invent around” such a patent (Nuffield Council 2002: 50ff). The argument of “invent around” is closely related to one essential objective of the patent system -- to encourage others to find new and better solutions to the same technical problem as that solved by the patented invention. What they argue is that a patent to one allele should not extend to other expressions of the same gene. When a naturally occurring gene is patented, it might be hard to find other genes to achieve a solution to the same problem. This the Nuffield Council puts forward as an argument in favour of a more narrow principle for

interpretation of the patent claims describing a naturally occurring gene.

Particularly relevant here is to what extent the *inventiveness* of the patented invention can be used as a means of interpretation for determining the scope of the patent protection and thus also to determine infringements. This is an open legal question and will probably be decided through a court case on a specific instance.²¹ If such a principle of interpretation is applied, this would mean greater likelihood that patent protection would target only the new insight brought forward by the inventor. This question has not been dealt with in international law, and remains to be determined in national patent systems by the courts.

As to the scope of a patent on a naturally occurring animal gene, in light of the already existing genes in other individual animals, no decision has been made by any court. Thus, considerable uncertainty attends the scope of the exclusive right covered by such a patent. Due to the sizable differences in breeding techniques and the biology of plants and animals, merely applying the legal solutions from the plant sector is not likely to be a good solution for the animal sector. Different challenges are raised by patents on naturally occurring genes and modified ones. In practical terms, patent protection for one single gene is very likely to be sought in combination with a process patent claim that describes one way (or more) to make use of the gene. (For more about process patent protection, see Section V.)

3. Patent Protection Reaches through “That Product”

The TRIPS Agreement codifies another general principle in patent law and specifies the scope of the exclusive right to “that product”. But the question is when does a naturally occurring animal gene, a modified animal gene, or a patented animal cease to be “that product”, and is consequently not covered by the exclusive right? To what extent will animal products be covered by the patent? It is quite difficult to provide a general answer. This question could be asked in various ways -- such as whether products developed from animals (like milk, eggs or meat) are included under the patent protection if a patented invention has exactly the same genetic coding for the same traits. To determine whether infringement of the patent has occurred, the court must compare the patent claims with the product that is accused of infringement.

V. PROCESSES FOR THE PRODUCTION OF ANIMALS

Process patents raise somewhat different questions than do product patents. It is first necessary to look at the patentability of processes for the production of animals: when these are granted. Determining the scope of the protection regarding the *patented process* as such is not that difficult. The scope of process patent protection, however, also extends indirectly to product patent protection for the results of applying the patented process. This raises difficult questions when the product of the process is a living animal.

A. Patentability for Processes Relevant for Production of Animals

The TRIPS Agreement requires all member countries to provide for patent protection to “any inventions, whether products or processes, in all fields of technology”. The point of departure is that countries are obliged to grant process patents also in the field of animal breeding. TRIPS Agreement Article 27, paragraph 3, allows countries to exempt “...essentially biological processes for the production of [...] animals”, but requires countries to delimit such

an exemption and provide for patents to “other than non-biological and microbiological processes”. But what then is an “essentially biological process”? One WIPO official, de Carvalho, argues that this wording should “... be read in a restrictive manner...” since it is an exclusion. He maintains that:

...there are processes which are biological, to the extent they comprise some phase in which biological reproduction is employed, yet their most important steps consist of acts of human direct interference. These processes, in essence, are not biological. (de Carvalho, 2005: 217–218)

His understanding of the TRIPS Agreement is that these processes must therefore be patentable. However, the TRIPS Agreement does not specify the legal concept further, and since the wording here is not clear, the TRIPS Agreement allows countries discretion in their implementation and practice based on this provision. Thus, the narrow interpretation that de Carvalho puts forward cannot be the legally binding interpretation of the TRIPS Agreement, and countries have discretion to implement a broad or narrow definition of “essentially biological processes for the production of [...] animals”.

The EU Patent Directive, Article 4 uses the same terms as the TRIPS Agreement and exempts “1. (b) essentially biological *processes* for the production of plants or animals” from patent protection. The EU has taken one more step in specifying what this implies in greater detail: “A process for the production of plants or animals is essentially biological if it consists *entirely of natural phenomena* such as crossing or selection.” (EU Patent Directive 98/44/EC, Article 2, para 2) The seemingly broad term “essentially biological processes” is thus defined more narrowly than required under the TRIPS Agreement, and refers only to those processes that are *entirely* of natural phenomena. The term “entirely natural phenomena” excludes any interactions by humans. There is, however, a contradiction between these examples and the main exemption: selection and crossing presupposes a step of human action.²² This leaves the scope of patentability broad, and the exemption is very narrowly defined.

From a practical perspective, this narrow exemption would make it impossible to patent processes such as the principle of an animal eating and thus growing, or the principle of one animal meeting another in the countryside and mating. These two examples would obviously consist *entirely* of natural phenomena (and anyway, they would not have been patented, because they would probably not have been considered as inventions). Otherwise, however, it becomes harder to produce examples that would fall under the exemption. For example, the act of feeding an animal would already involve a certain level of human interaction, and thus a feeding method could be eligible for patent protection (subject to the patent criteria). Breeding techniques will also be eligible for patent protection, because breeding involves some step of human innovative action. A technique for using artificial insemination or the most basic principles for selection would clearly be processes beyond an entirely natural phenomenon and consequently outside the exemption, according to the EU Directive. In order for a patent to be granted, the patent criteria must of course be met, but the conclusion is that the exemption from eligibility in the EU is extremely narrow and will probably not have any practical effects.

The next specification of the main rule is that “Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a *microbiological* or other technical *process* or a product obtained by means of such a process”(EU Patent Directive 98/44/EC, Article 4, para

3). This must be read in conjunction with the definition of “microbiological process”, which means “any process involving or performed upon or resulting in microbiological material.” (ibid., Article 2, para 1b) A process involving or performed upon or resulting in microbiological material shall be patentable. Thus, according to the EU Patent Directive, the animal sector is allowed almost all types of process patents. The exemption from eligibility is probably without any practical significance.

B. One Example of a Process Patent Application

1. A Look at the Whole Picture

As yet, not many process patents in animal breeding have been granted. There are, however, an increasing number of filed patent applications that altogether cover a wide variety of processes (Fitzgerald, 2005, supplemented with new research):

- WO/2006/134579 “Method for preventing the inactivation, due to specific bacteriophages, of probiotic strain mixtures used in cattle-breeding”;
- WO/2006/125745 “1-(1,2-Diphenyl-Ethyl)-3-(2-Hydroxyethyl)-Thiourea compounds for combating animal pests”;
- WO/2006/108255 “A system and a method of individualization of animals and herd management”;
- WO/2006/103905 “Feed composition and method of breeding of breeding animal”;
- WO/2006/101623 “CSTF1 and C20ORF43 markers for meat quality and growth rate in animals”;
- WO/2006/073447 “Enriched PAG-55 fraction and methods for early detection of pregnancy in ungulate animals”;
- WO/2006/052994 “Systems and methods for improving efficiencies in avian species”;
- WO/2006/042885 “System for breeding, restocking and maintaining red-legged partridge and other animals with similar biological characteristics in the natural environment”;
- WO/2006/035513 “Amphiploid aquatic animal and method of breeding the same”;
- WO/2005/120219 “Facilities and methods for breeding animal or plant, animal or plant bred by the facilities and method and apparatus for generating activated gas”;
- WO/2005/101230 “Systems and methods for improving livestock production species”;
- WO/2005/095590 “Sperm suspensions for sorting into X or Y chromosome-bearing enriched populations” (not confined to one particular species);
- WO/2005/094852 “Sperm suspensions for use in insemination” (not confined to one particular species);
- WO/2005/017204 “Use single nucleotide polymorphism in the coding region of the porcine leptin receptor gene to enhance pork production”;
- WO/2005/015989 “Method for genetic improvement of terminal boars” (these patent claims will be examined in a short case study in the next subsection);
- WO/2004/088283 “Apparatus and methods for providing sex-sorted animal sperm” (not confined to one particular species);
- WO/2004/087177 “Process for the staining of sperm” (not confined to one particular species);
- WO/2004/059282 “Method and means for early detection of pregnancy in animals by

- combination testing” (not confined to one particular species);
- WO/2004/003697 “Swine genetics business system”;
- WO/2003/096799 “Multiple cloned nucleus breeding for swine production”;
- WO/2003/043524 “Compositions and methods for accurate early pregnancy diagnosis” (not confined to one particular species).

These patent applications are filed through the system for international patent search conducted by the World Intellectual Property Rights Organization (WIPO).²³ How many countries are appointed in the round of the international search varies, but in general the number is large, up to 120, and through all the four regional patent systems.

A pre-study of these patent applications shows that if all of them are granted, they will make possible a comprehensive totality of processes (methods) that will establish a strong market position based on patents in animal breeding. Read together they will establish a comprehensive body of exclusive rights to processes in the animal sector. Some of them are not linked to specific animal species and will thus cover all relevant species; others are linked to processes applied to particular species. An in-depth study of these patent applications needs to be carried out to know the effect they will have for the future of animal breeding. It is not yet possible to know whether there are more patent applications that have been filed, because the International Bureau is obliged to international publication of the international application only “after the expiration of 18 months from the priority date of that application” (PCT Article 21, (2)(a)), if the patentee does not require early publication. The scope of this article allows for only a brief introductory analysis of one example. More in-depth analyses are needed to get the complete picture.

2. Introducing One Example -- Improvement of Terminal Boars

Monsanto has applied for a patent on a method for genetic improvement of terminal boars. The patent claims of this application, which are the legally binding part of the patent, contain 69 specific claims. The system in patent law is that each patent claim forms an independent subject matter for an exclusive right. Each of them grants an independent exclusive right. The system is furthermore that one patent claim can refer to others and thus establish a complex system where one needs to read each claim individually and also in the context of the claims referred to in order to get a complete overview of the total amount of processes that the patent covers. Here we will take a closer look at a few of the most interesting claims and try to understand what they describe, starting with the basic claim in one of the patents targeting processes in swine breeding:

CLAIMS: 1. A Method for producing terminal swine parent animals having improved germplasm, the method comprising:

- a. providing at least one genetic nucleus herd and/or a target herd for which improvement is desired
- b. selecting a trait or traits, for which improvement is desired;
- c. providing semen aliquots from an elite sire selected from the genetic nucleus (GN) herd wherein the elite sire has a desired germplasm that is determinative for improving one or more selected trait (s) in the target herd;
- d. using the semen aliquots to impregnate a correlative number of breeding females in a target herd; wherein the semen from the elite sire is used to breed substantially all of the females in the target herd;

- e. producing half-sib offspring having improved germplasm when compared with the breeding females in the target herd; and
- f. providing at least one of the half-sib offspring as the terminal swine parent in a SP (swine production herd), or as a replacement animal for the GN herd, or as a replacement animal for the target herd, whereby the genetics are improved in the target herd and/or SP.

In less bio-legal-technological language, the patent concerns a method of breeding aimed at improving the genetic base of a population of pigs. Basically, you start out with one flock that you want to improve, then find the characteristic that you want improved, find semen from a male animal that has the desired traits and use it to impregnate the females of the herd, produce the next improved generation, and finally replace one or more improved animals back into the original herd. In fact, these six steps describe more or less the basic principles of breeding. Nevertheless, if the patent is granted there will be an exclusive right to prevent others from applying the same technique without paying the royalty that Monsanto demands for using the process.

One immediate observation is that this patent claim does not fall under the general exemption for processes consisting of “entirely of natural phenomena”, because this process clearly contains human contribution rather than being an entirely natural phenomenon. The patent is described as a process patent comprising a method for improving a herd, but the process/method is general in scope and is applicable to more than one breed or to one “animal variety”; thus, the exemption for *animal variety* does not apply. Therefore, this claim is not excluded from patent protection.

The question that patent offices around the globe will need to investigate is whether there is any *prior art* that can make these claims non-novel or obvious (see the next section). Before we go into the patent criteria, we will look at two of the other core claims of the same patent application in order to better understand the issue at stake for all pig breeders. The next major important patent claim is one in combination with claim 1:

7. The method of claim 1 wherein the selected elite sire is selected for as having germplasm favorable for providing offspring having at least one of the following: one or more desired qualitative or economic trait locus/loci;
 - one or more desired quantitative trait locus/loci a desired estimated breeding value (EBV);
 - a desired genotype or phenotype;
 - one or more desired health trait(s),
 - one or more desired meat quality trait(s),
 - one or more desired reproduction trait(s);
 - or one or more desired efficient growth trait(s).

If *one or more selected trait (s)*, chosen as the third step in claim 1, is among the alternatives listed in patent claim 7, the process patent is infringed. Combined with claim 1, the exclusive right is made very comprehensive in the field of pig breeding. While the list in patent claim 7 targeted phenotypic characteristics (basically the characteristics of the animal that can be easily observed), claim 8 targets identification of the desired properties at a genetic level:

8. The method of claim 1 comprising identifying female half-sib offspring having preferred *germplasm* and retaining these female half-sib offspring as breeding females in the target herd.

The combination of patent claims 1 and 8 covers identifying the mating animals by a gene test. To refer back to the section on patenting of naturally occurring genes, claim 8 is one example where a process patent could be very effective in combination with a product patent on a naturally occurring gene. Using this method, based on insight about a patented gene, would give the patent-holder wide exclusive rights. The consequences of a monopoly right to selective breeding based both on phenotypic and genotypic identification of mating animals to the breeding sector are unknown. If the patent is granted, these claims would expose pig-breeding to a high concentration of market power.

This example of a patent claim was intended merely to give an indication of the detail and comprehensiveness with which existing patent claims are formulated.²⁴ The wording of these patent claims may well leave the reader in doubt as to whether they are indeed really new and whether they meet the patent criteria.

3. The Patent Criteria -- Are These Patent Claims Going to Be Granted?

All the patent applications referred to in the previous section have been filed through the global patent application system in the World Intellectual Property Organisation (WIPO). Patent WO/2005/015989, presented in the previous section, is designated to around 120 countries and through all of the four regional patent offices. The search system of the WIPO establishes the International Bureau as a search authority in order to find items of prior art that can hinder an application from meeting the novelty and inventiveness criteria. The authority to determine whether this patent application will be granted rests with the national patent offices and with the regional patent offices.

To return to the example patent application, the breeding method: first of all, it must be regarded as an *invention* and not a *discovery*. This basic criterion is clearly fulfilled according to the current practice. The next step is to compare the patent claims with the items of prior art, the information previously known, to determine whether they fulfil the novelty criterion. In patent law, novelty is assessed by comparing the patent claims against other written sources, one by one. This consideration involves a fairly narrow reading of texts – and only if the item of prior art is not being almost identical to the patent claims, the novelty criterion is considered to be met. The relevant question is whether there are written sources that are sufficiently identical. The scope of a legal analysis does not allow for an answer to this question here, because it would require consulting a range of technical sources rather than sources of law. It depends upon the practice of the Patent Offices whether they will find such relevant sources of prior art that are sufficiently identical to rule out novelty.

The second criterion is that the described method involves a sufficient level of inventiveness. What is described in the patent claims must not be regarded as obvious to a person skilled in the art. The assessment of whether this criterion is met is also based on the relevant textual sources found in the *prior art* search. This is perhaps the criterion most critical for these patent claims, because both claim 1 and claim 7 or 8 in combination with claim 1 are methods currently in use in many breeding programs and breeding schemes. It will be both interesting

and of crucial importance to see how this criterion is dealt with in the various patent offices. Due to patent office procedures, their consideration on these issues cannot be expected to be made available. Most patent offices do not produce their considerations in a publicly available written source document. This fact makes it difficult to review the reasons for the actions taken by the patent offices. One prediction is that the various Patent Offices are likely to reach different conclusions on novelty and inventiveness, which might lead the rejection of the patent in some jurisdictions and the grant of the patents in others. This will probably also lead to cases before various boards of appeal and eventually to the courts.

The third and last criterion is that the invention must have an *industrial application*. This criterion is probably unproblematic in terms of current patent practice.

C. A Process Patent--What Is Covered by the Exclusive Right?

After a patent is granted, the next task is to determine the scope of the exclusive right that the claims would confer to the patentee. According to the TRIPS Agreement, Article 28, the scope of a process patent protection is:

(b) where the subject matter of a patent is a process, [it confers a right] 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.

The product patent covers an exclusive right to the use or application of the described method. But the scope of protection also covers *at least the product obtained directly by that process*. This means that the scope of process patent protection in the TRIPS Agreement requires countries to provide for indirect product patent protection that covers the outcome from the use of a patented method. Using a patented process might therefore give the patentee a legal position in relation to the offspring from the application of the process. If all the patent applications noted above are granted, this will have unpredictable consequences for the property rights to the next generation of animals. One problem with indirect patent protection is that it might create a situation with complex rights concerning the offspring, as the owner of the animals already has a right to his animals and the patentee has the right to prevent "using, offering for sale, selling" the product from the application of the process. The scope of protection in the TRIPS Agreement was not particularly designed for the field of animal breeding, so these consequences have probably not been foreseen by the parties negotiating the TRIPS Agreement under the WTO.

Indirect protection for products from processes is confirmed by EU Patent 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 characteristics. (EU Patent Directive 98/44/EC, Article 8, para 2)

This indicates that if the patent claims we have looked at are granted, the offspring or next

generation of animals can be covered by the exclusive right of Monsanto. The wording of the Directive implies that this protection is to extend not only to the first generation but to all subsequent generations of individuals. Thus, a linguistic interpretation indicates that all future generations of offspring from the herd improved by the use of that method will also be covered by the exclusive right.²⁵ The wording does not specify a number of generations to which the exclusive right will continue, but after the expiry of the patent (normally 20 years), the patent-holder will not have a claim to the said animals.

The indirect product by process protection will probably make it possible to have an exclusive right to entire *animal varieties* through a process patent; even if a patent claimed formulated as an *animal variety* appears to be exempted.

Indirect product protection has the potential to establish a completely new property right structure in farm animal breeding. The patentee might become entitled to exclude the original owner of the animals from the offspring if these have been produced by means of a patented process. These conflicts of rights will have to be dealt with by the courts, and the solution is not easy. On the one hand, it seems clear that a patent cannot delimit the already existing rights held by the farmer. But on the other hand, if patent law is to allow for an exemption for the cases of indirect product patent protection in the animal sector, then a process patent would not be less valuable. This difficult question seems likely to trigger a number of court cases that will probably be solved differently among countries.

VI. THE FARMERS' EXEMPTION IN ANIMAL BREEDING

Article 30 of the TRIPS Agreement allows members to:

[...] provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

This option to provide for limited exemptions in the scope of protection has not yet been thoroughly examined in the patent literature in respect to the animal sector (Hiemstra et al., 2006).²⁶ Developing countries have called for increased flexibility in the TRIPS Agreement and for wider discretion when they implement these obligations in their national patent systems. One important first step toward flexibility would be for developing countries to explore the existing possibilities and apply them in their national patent systems. The EU Patent Directive uses this flexibility for both plants and animals:

By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity. (EU Patent Directive 98/44/EC, Article 11, para 2)

This is couched in highly technical legal and animal-breeding language. The essence of the

exemption is that the farmer has a right to use the propagating material in agricultural uses but not to market it for breeding (*commercial reproduction activity*). The effect of this exemption in the scope of the patent protection is also yet to be seen. To draw the line between *commercial reproduction activity* and *purposes of pursuing his agricultural activity* is both difficult and critical in breeding, because the owner of livestock often is engaged in both types of activities (except in the most highly commercialised sectors like poultry or pig, where the breeding of hybrids and the feeding of them is more often separate). The effect of this apparently broad exemption is made optional for EU member countries: “The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.” (EU Patent Directive 98/44/EC, Article 11, para 3) Thus, the implementation of such farmers’ privilege will depend upon national implementation, and it remains to be seen whether countries will implement it in their national patent law. Differences among species and the level of commercialisation in the sector will be important factors for the consequences of this exemption.

VII. THE ORDRE PUBLIC EXEMPTION FOR ANIMALS

Finally, there is a last case-by-case exemption to patent protection applicable to the animal sector. The TRIPS Agreement specifies:

[m]embers may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, *animal* or plant *life or health* or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. (TRIPS Agreement 27, para 2)

The main rule in Europe is that all inventions are patentable if they are not explicitly exempt from being eligible for patent protection. EU Patent Directive implements this exemption for rejecting a patent application on the grounds that “their commercial exploitation would be contrary to *ordre public* or morality”, which is further specified as

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. (EU Patent Directive 98/44/EC, Article 6, paras 1 and 2, read in conjunction)

This targets *modifying the genetic identity* of animals, which basically refers to genetic modifications. Currently, GM animals are not in use in active food production for terrestrial species. Yet practice regarding this exemption is scarce, and the practice of the *ordre public* exemption is still pending.

VIII. CONCLUSIONS

From this analysis, we may conclude that the full scope of patent protection in the field of animal breeding has not yet been determined. One firm conclusion, however, is that the scope of the exemptions from patent eligibility is very narrowly defined. Several issues, particularly those related to determining the extent of patent protection in the field of animal breeding, are still left to practice and case-law development. Such case-law development will show that

patent law is founded on a narrow base of arguments, because the courts generally take into account only the sources presented by the two parties to the case.

There are several observations to be made on how the special field of animal breeding calls for adaptation of the general patent laws to this particular field of technology. Patent law assumes a general form, and the specific challenges and advantages of single technical fields for innovation are not on the agenda. Even though the EU Patent Directive aims specifically at regulating biotechnological inventions, most of its rules are not very well suited to the area of animal breeding. The conclusion in this article is that there remain many problems in applying patent law to the field of animal breeding, and these are unlikely to be taken into account in the international fora for general harmonisation of patent law. For example, the work of the Standing Committee on Law of the Patents under the WIPO suggests general rules for further harmonisation of patent standards, without taking into consideration the special needs connected to individual fields of innovation.²⁷

This might result in a call for the specialised UN Agency for Food and Agriculture (FAO) to address issues of patent law in connection with the food and agricultural sector, because this is the organisation most specialised in animal breeding and food production. The application of patents to this field of innovation is fairly recent, and there is a need for more in-depth analysis of the probable consequences of introducing patents to animal breeding. For example, are patents likely to promote or stifle breeding, research, and development in the animal sector? What distributive effects will these changes in patent law and patent practice have among farmers, livestock keepers, breeders and multinational breeding companies? More knowledge about the effects of patents in this field of technology would help to provide the courts and other decision-makers with a better foundation for deciding on questions concerning the scope of patent protection in this field of agriculture and innovation.

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¹ Rothschild & Newman, eds (2002) and Rothschild et al. (2004) are singular examples of attempts to identify patents in the animal sector. For an analysis of exchange and property rights in the field of fish breeding and fish farming, see Rosendal et al. (2006).

² In the USA, where the expansion of the application of patent law is proceeding most rapidly, there were a total of 45 animal patents granted from 1995 to 2001 (Lesser, 2002: 9).

³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) Decided June 16, 1980.

⁴ *Diamond v. Chakrabarty* was referred to by the Canadian Supreme Court in *Harvard College v. Canada (Commissioner of Patents)*, the Canadian Oncomouse Case, Neutral citation: 2002 SCC 76. File No.: 28155.

⁵ CBD COP decision III/11, IV/6 and VI/5 (welcoming the process initiated by the FAO for the preparation of the first *Report on the State of World's Animal Genetic Resources*).

⁶ The Oncomouse patents have triggered court cases in Canada and in the USA and a case before the Board of Appeal under EPO. European patent application No. 85 304 490.7, published as No. 0 169 672.

⁷ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

⁸ The EPO examines and grants patents for those countries that the applicant designates. The European Patent Convention and its Regulations form the main legal sources for the granting of such patents.

⁹ See, for example, Hiemstra et al., 2006, where the term “animal breed” is used.

¹⁰ On this, see Bryde, 2004, p. 50ff, with further references.

¹¹ For an in-depth discussion of sustainable management of animal genetic resources see Wolliams et al., 2005.

¹² EPO Board of Appeal case T-0019/90, regarding the Oncomouse patent. There is also a case before the Canadian Supreme Court regarding the patent to the same invention in Canada, *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76. File No.: 28155. The question before the Canadian Court is whether this was a patentable invention at all.

¹³ European patent application No. 85 304 490.7, published as No. 0 169 672, claim number 1, 17 and 18.

¹⁴ The term “animal variety” is used in English, while the French word is *raças animales* and German is *Tierarten*. As the three linguistic versions are equally authentic, the BoA used this as an argument for animals in general not to be exempt from patent eligibility. Their main point was that these concepts are not completely comparable, and used this divergence as an argument for a narrow interpretation of the exemption.

¹⁵ For general discussions in biotechnology, see e.g. Westerlund (2001), who discusses the concepts of *invention or discovery*, *enabling disclosure*, and *the doctrines of equivalence* for biotech patents; and Bostyn (2002), who discusses the requirement for *enabling disclosure* in depth. See also the report from the Nuffield Council (2001), which expresses various concerns.

¹⁶ For the Norwegian legal situation for plants, Matheson (2006) has dealt with this question.

¹⁷ TRIPS Agreement Article 28. All emphases in all quotes in this article are added.

¹⁸ EU Patent Directive 98/44/EC, Article 9. The reference in Article 9 to Article 5 is not relevant in this connection, as it contains exemptions for patent protection for humans.

¹⁹ Attorney-General Jacobs, paragraph 121 in his statement in the case *Netherlands – the Commission*.

²⁰ For a further discussion of this, see Rosendal et al. (2006).

²¹ Matheson (2006), at pp. 22–25 discusses this issue without concluding affirmatively. Norway has implemented a particular rule in the Patent Act § 3c specifying that “the scope of patent claims for naturally occurring biological material covers only the part of the material which is necessary for the industrial application which is described in the patent application. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”

²² This contradiction is also emphasised in a case from the Board of Appeal T 0083/05 of 22 May 2007.

²³ The WIPO offers patent applicants a service of pre-search for prior art. The legal basis for this service is the Patent Cooperation Treaty (PCT), under which the member countries undertake to accept the search for prior art as a basis for the consideration of novelty and inventiveness.

²⁴ Other core patent claims in this patent application are 33, 43, 54, 62 to 67, and 69. Patent claim 62 focuses on selection on an allelic level rather than on a genotype level.

²⁵ This interpretation would also find support in the statement from Attorney-General Jacobs in the preparatory work in the case between the Netherlands and the Commission.

²⁶ de Carvalho 2005 (pp. 304–314) writes about TRIPS Agreement Article 30 generally with further reference to Panel Report *Canada – Patent Protection of Pharmaceutical Products*, WTO document WT/DS114/R, of March 17, 2000, Panel Report adopted on 7 June 2000.

²⁷ On this point, see for example Tvedt (2005).

References

Bostyn, S.J.R., 2002: A European perspective on the ideal scope of protection and the disclosure requirement for biotechnological inventions in a harmonised patent system: The quest for the Holy Grail? *Journal of World Intellectual Property* 5, 1013-1046.

Bryde, M. (2004). *Plant and Animal Variety: The Variety Exceptions of the European Patent Organisation and the European Community Assessed in Relation to Patentable Subject Matter*. FNI Report 4/2004. Oslo: The Fridtjof Nansen Institute

de Carvalho, N. P. (2005). *The TRIPS Regime of Patent Rights*, 2nd edition. The Hague: Kluwer Law International.

FAO (2000). *World Watch List for Domestic Animal Diversity*, 3rd edition. Rome: FAO.

FAO (1999). *The Global Strategy for the Management of Farm Animal Genetic Resources*. Rome: FAO.

Fitzgerald, B. T. (2005). *Monsanto files for new invention: the pig*. www.greenpeace.org/international/news/monsanto-pig-patent-111#.

Hiemstra, S.J., Drucker, A.G., Tvedt, M.W., Louwaars, N., Oldenbroek, J.K., Awgichew, K., Abegaz Kebede, S., Bhat, P.N. & da Silva Mariante A. (2006). *Exchange, Use and Conservation of Animal Genetic Resources: Identification of policy and regulatory options*, CGN Report 2006/06. Wageningen (NL): Centre for Genetic Resources.

Langinier, C. & Moschini G. C. (2002). *The Economics of Patents*. In Rothschild, M.F. & Newman, S. (eds.) *Intellectual Property Rights in Animal Breeding and Genetics*. New York: CABI Publishing.

Lesser, W. (2002). Patents, Trade Secrets and Other Forms of Intellectual Property Rights. In Rothschild, M.F. and Newman, S. (eds.) *Intellectual Property Rights in Animal Breeding and Genetics*. New York: CABI Publishing.

Matheson, A. (2006). *Omfang og innhold av produktpatent på plantegener*. FNI Report 12/2006. Oslo: The Fridtjof Nansen Institute.

Nuffield Council on Bioethics (2001). *The Ethics of Patenting DNA*. London: The Nuffield Foundation of Bioethics.

Rosendal, K.G., Olesen, I., Bentsen, H.B., Tvedt, M.W. & Bryde, M. (2006): Access to and legal protection of aquaculture genetic resources: Norwegian perspectives, *Journal of World Intellectual Property* 9, 392–412.

Rothschild, M.F. & Newman, S. (eds) (2002). *Intellectual Property Rights in Animal Breeding and Genetics*. New York: CABI Publishing

Rothschild, M.F., Plastow, G. & Newman, S. (2004). Patenting in animal breeding and genetics, in A. Rosati (ed.) *WAAP Book of the Year 2003*. Wageningen Pers, for World Association for Animal Production (WAAP)

Tvedt, M.W. (2007). The Path to One Universal Patent. *Journal of Environmental Policy and Law*, 37/4, 297-305.

Tvedt, M.W. (2005). How will a substantive patent law treaty affect the public domain for genetic resources and biological material? *Journal of World Intellectual Property*, 8, 311-344.

Tvedt, M.W., Hiemstra, S.J., Drucker, Louwaars, N., Oldenbroek, K. (2007): *Legal Aspects of Exchange, Use and Conservation of Farm Animal Genetic Resources* FNI Report 1/2007. Oslo: Fridtjof Nansen Institute.

Westerlund, L. (2001). *Biotech Patents – Equivalency and Exclusions under European and U.S. Patent Law*. Stockholm: Faculty of Law, Stockholm University.

Wolliams J., Berg, P., Mäki-Tanila A., Meuwissen T. & Fimland E. (2005): *Sustainable Management of Animal Genetic Resources*, Copenhagen: Nordic Council of Ministers.