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Scope of Process Patents in Farm Animal Breeding

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ABSTRACT

The number of process patent applications concerning farm animal breeding is growing rapidly. Patent law is general in form and is seldom adapted to specific 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. Today, with patent law increasingly used in the animal sector, the question arises: how will the law apply to this particular field of innovation? The degree of legal uncertainty is particularly high since it is not clear how the courts of various countries will apply the general law to this particular field. Patent law has potential to alter the existing legal conditions for competition and investments in the field of animal breeding, and thus merits greater attention among policy-makers, animal breeders and farmers.

Keywords process patent; animal breeding methods; indirect product patent protection; patent law.

I. RESEARCH QUESTIONS*

This article analyses the scope of and exemptions from process patents in field of farm animal breeding, and rights conferred to the owners of such patents. Until recently, process patents were not actively applied in the farm animal breeding sector. This is changing, and currently several patent applications on inventions regarding processes in farm animal production are pending at patent offices around the world (Tvedt 2007b, Rothschild 2004). Some of these patent applications have become the subject of debate and discussion even before there have been any indications of whether they would be granted or not (Fitzgerald 2005). The patentability of inventions in biotechnology is currently on the agenda concerning implementation of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (European Community Directive on Biotechnology) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as well as in other international bodies such as the Food and Agriculture Organisation of the UN (FAO) and various Non-Governmental Organisations (NGOs) (e.g. Greenpeace and League of Pastoral Peoples). The issue of process patents on breeding methods, although not an especially hot topic in international patent law forums (Tvedt 2007a), has been brought to the agenda in the FAO, which recently noted:

Rapid developments in the field of biotechnology have increasingly drawn attention to the issue of intellectual property rights in relation to AnGR. In the event of the introduction of transgenic technologies in animals used for agricultural production, the issue of animal patenting may become more prominent (*The state of the world's animal genetic resources for food and agriculture* edited by Rischkowsky and Pilling 2007, p. 279).

Under the heading 'Emerging Legal Issues':

Animal patenting is emerging as significant issue in the livestock sector, driven in part by technological developments such as cloning and transgenetics, and the desire to profit from or promote such developments. Once again, ethical objections are raised both regarding patenting as such, and regarding some of the biotechnologies to which it might be applied. It is, however, also important to note that there are *numerous practical legal* issues that also need to be addressed – *particularly related to the scope* of patent protection (Rischkowsky and Pilling 2007, pp. 287–288, emphasis added)

There have been no court cases regarding the scope of process patents in farm animal breeding, which leaves the legal situation somewhat uncertain. Uncertainty regarding the scope of protection is not an unexpected result of applying the general system of patent

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protection to inventions in an area of technology that differs from more traditional technologies. The most obvious difference from traditional inventions is the ability of livestock to reproduce: this fact complicates the process of identifying those animals to which patent rights should apply, if, for example, patented animals should be bred with non-patented ones (Rischkowsky and Pilling 2007, p. 288). Furthermore, long production cycles make it difficult to determine how far in the production cycle the patent protection applies, and for how many generations. Additionally the significance of these issues will depend partly on the species and production system in question.

The TRIPS Agreement sets the most general international rules about the scope of patent protection. In Europe, the EC Directive on Biotechnological inventions (EC/98/44)¹ specifically addresses the scope of protection for biotechnological patents. Despite these more concrete rules for biotechnological patents there are still some uncertainties in the interpretation of the provisions. By 'scope of a patent' is meant the extent of the exclusive right granted – in other words, to which processes or products produced by those processes the patent-holder has an exclusive right to prevent others from exploiting commercially (Paterson 2001, p. 573). The protection conferred by each patent flows from an interpretation of the patent claim in each patent, coupling them with the general rules defining the acts covered by patent protection. To understand the extent of the process or method, the patent claims must be interpreted. To determine whether a third party infringes that patent, his activity must be tested against those patent claims and the general acts allowed under the exclusive right by the grant of that patent (Kolker 2000, p. 15).

This paper discusses the scope of process patents in farm animal breeding by first (Section II) approaching the most general and global rules of the TRIPS Agreement. Section III takes a closer look at European regional rules on this topic. In Section IV we offer a practical approach to how the actions covered by a process patent in farm animal breeding can be determined. Section V looks at special defences that an accused infringer could apply to avoid falling under the scope of the exclusive right. Section VI offers a look at one general patent rule, the reversal of burden of proof, specifically as regards farm animal breeding. Finally, in Section VII we draw some conclusions on process patents in the field of farm animal breeding.

II. SCOPE OF PROTECTION UNDER THE TRIPS AGREEMENT

The TRIPS Agreement specifies detailed requirements for the legislation of the Member States, including effective measures to ensure fulfilment. In consequence, World Trade Organisation (WTO) Member States are no longer allowed comprehensive national discretion in intellectual property rights, or at least not without sanctions under the trade system. The main rule under the TRIPS Agreement Article 27.1 is that countries are obliged to provide for patent protection to inventions in all fields of technology, save some important exemption. The Preamble and the title of the Agreement refer to the trade-related aspects of intellectual property, and the aim is to ensure that measures and procedures to enforce intellectual property rights do not become barriers to legitimate trade (TRIPS Agreement Preamble). It has, however been argued that the negotiations of the TRIPS Agreement were not about freeing trade, but about changing domestic regulatory and legal regimes, and that virtually all dimensions of intellectual property rights are encompassed by the provisions of the Agreement (Correa 2007, pp. 3–7).

For the purpose of analysing the scope of patent protection, TRIPS Agreement Article 28.1 (b), is of greatest interest. It establishes a minimum scope of protection to the patented process and the product thereof which all member countries must provide for in their legislation. The term ‘minimum scope of protection’ implies that Member States are obliged to ensure at least this level of protection, although they may also establish a broader scope. The minimum level of protection conferred through the TRIPS Agreement is fairly high and comprehensive (de Carvalho 2005, p. 28). Article 28.1 (b) specifies:

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. (Emphasis added)

This implies that the patentee has exclusive rights over the process as it is described and interpreted in the claims. Exclusive rights extend to products which are a direct result of the patented process. This so-called ‘indirect product protection’ covers products obtained by the patented process. The TRIPS Agreement does not, however, specify specific rules regarding the extent of protection in cases where the material is capable of self-reproduction. This section interprets the minimum provision relevant to determine the scope of protection for processes for the production of farm animals and to offspring from that process.

For patent-holders and third parties alike it is vital to know as precisely as possible the extent of the exclusive right. In fact, however, the actual extent of granted patent claims is not decided until an alleged infringement suit is determined (Westerlund 2001, p. 180). This is a challenge to legal certainty. It is of relevance to discuss the scope of the patent protection required according to the TRIPS Agreement, since this requirement applies to all members of the WTO. To be binding among legal persons, the rules of the TRIPS Agreement must be implemented in national law, and so there will probably be national differences regarding the scope of patent protection.

The natural point of departure is that the use of the process described in the patent claims is under the exclusive right of the patentee. At this level, the challenge for animal breeding patents is that only new and inventive patents are being granted, and well-known breeding methods are not included under new patent protection. This is a question of how the patent criteria are practised and applied, and thus falls outside the scope of this article (this issue has been addressed by Tvedt 2007b). There are several features in the animal sector which show that existing but not well-documented breeding methods may be regarded as novel and non-obvious, and thus potentially eligible for inclusion under patent protection (*ibid.*).

The scope of protection is extended also to cover *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 right to the offspring from the application of the process.

This extension of the right to indirect protection of the product has long been accepted in patent law (Bently and Sherman 2001, p. 493), and is often explained by reference to the fact that the exclusive right could be undermined if protection were to extend only to the process itself. This protection is particularly important where no claim has been made to the related product as such. It is also important where the process is used outside the country where the patent was granted and the product from that process then is imported to that country (*ibid.*).

Due to the principle of territoriality of patent, the patented method may be utilised in a country where the patent has not been granted. The indirect product patent protection covers import of that product to the country where the patent is valid. Such import would otherwise imply a substantial deterioration of the value of process patents.

But exactly how far does this indirect protection extend? Which products fall within the exclusiveness as a consequence of a process patent in farm animal breeding? This raises the further questions of how many future generations are covered by the exclusiveness; and how extensive the alterations of the offspring can be, through cross-breeding and selection with other animals, and still fall under the scope of the exclusive right of the process patent.

The point of departure for determining these questions is the ‘ordinary meaning’ of the terms of the treaty (Vienna Convention Article 31). The TRIPS Agreement, Article 28.1 (b), requires countries to provide for protection for the products ‘obtained directly’ by the patented process. A literal interpretation of the words ‘obtain directly’ indicates that the protection includes products achieved through the application of that described process. The term ‘directly’ suggests a qualification of the products protected, and would imply that the process patent does not extend to further generations. Of course, after the expiry of the patent (usually 20 years from granting), the patent-holder will no longer have exclusive rights to the offspring. However, between these two extremes, the wording of Article 28.1 (b) does not offer much guidance, although it has been argued that the protection for process patents is potentially very wide:

In part this is because where a range of different products flow from a single process, *all of the products fall* within the remit of the patent. It is also because the scope of protection not only concludes the products that flow from the process, but also the products that are based upon the products that flow from the process: if you like, the derivatives of the derivative. (Bently and Sherman 2001, p. 493, emphasis added)

The assumption regarding the derivatives of the derivative does not follow directly from TRIPS Agreement Article 28.1 (b), which confers rights only to the products that flow from the process. The TRIPS Agreement is a *minimum standards* agreement. The protection standard of the TRIPS Agreement is to cover any invention in all fields of technology and offer an *adequate* scope of protection (Preamble to the TRIPS Agreement). If it is to apply to process patents to farm animal breeding that could indicate that the protection extends also to the ‘derivatives of the derivative’.

The term ‘obtained directly by *that* process’ would, however, seem to imply that the patented breeding method must have been employed in order for the patent-holder to acquire exclusiveness over the offspring. To ensure that the scope of monopoly is kept within justifiable limits, there must be a qualified connection or relationship between the patented process and the product thereof (Bently and Sherman 2001, p. 493). In TRIPS Agreement Article 28.1 (b), this link is ensured by the words ‘the product obtained directly by’ *that* process. In Nordic patent theory, the product must have obtained its *substantial qualities* through the use of the patented process (NU 1963, p. 6). Furthermore, the product must not have lost its characteristics through further development. This specification gives rise to interesting questions regarding to the breeding of farm animals. What if the ‘product’ is cross-bred with a specimen that does not at all possess the characteristics described in the patent claims, or possesses only some of the relevant characteristics? The assessment seems to revolve on whether the animal has lost its *essential characteristics* due to the alteration – more precisely, the essential characteristics protected and described in the patent claims. For

each individual case of infringement there must be a separate and specific evaluation of how essential the process is for the product evaluated. This suggests that protection could extend to the offspring of one indirectly protected ‘product’ and one unrestricted animal only, if the progeny possesses the essential qualities as these are expressed in the patent claims as part of the patented process. This might be somewhat difficult for breeding method patents, since the core of the invention is not necessarily linked to one particular characteristic, but rather to how to proceed in the activity of breeding.

The term ‘directly obtained’ implies, however, that the provision does not protect against identical or similar products produced by other methods (Correa 2007, p. 298). ‘If an infringement is invoked, courts will normally determine whether the alternative process can be deemed *equivalent or not*’ (Correa 2007 footnote 108).

The use of the term ‘at least the product obtained directly’ in Article 28.1(b), indicates clearly that Member States are free to include only the first generation under the indirect process patent protection; but as the TRIPS Agreement is a minimum standard, countries may extend the protection to products not directly obtained by that claimed process (Correa 2007, p. 299). At this point there is a room for national differences under the TRIPS Agreement. The detailed application of this in practice is not solved by the TRIPS Agreement, and must be either solved in the implementation of countries or by their courts when infringement-cases are coming up.

TRIPS Agreement Article 27.3 (b) grants countries discretion to exempt ‘animals’ from eligibility of patent protection. If a country chooses to exempt animals from product patent protection, the scope of indirect process patent protection might end up granting exclusive rights to animals despite the implementation of such an exemption. The indirect product patent protection could thus become a means of circumventing such an exemption for animal product patents. Applied to the case of a process comprising a method for improving a herd, which is general in scope and applicable to more than one specific breed or one ‘animal variety’, this could imply that the exemption for animals is practically without consequence (Tvedt 2007b, p. 16). This is another issue for countries to consider in the implementation process. The next step is to analyse how these uncertainties have been dealt with in Europe, by the EC Biotech Directive and in the European Patent Organisation (EPO).

III. SCOPE OF PROCESS PATENTS UNDER EUROPEAN PATENT LAW

A. European Patent Convention

The European Patent Convention (EPC) is principally concerned with the granting of patents rather than with the scope of protection conferred (Kamstra et al. 2002, p. 47). When EPC was drafted it was decided that questions about the infringement of patents issued by the European Patent Organisation (EPO) were best dealt with by national courts (Bently and Sherman 2004, p. 519). Nonetheless, the close relationship between the validity and infringement has meant that EPO decisions have had impact on national law regarding infringement as the scope of the patent is one relevant topic when a patent is granted. The provisions and case-law of the EPO could therefore be of relevance for national courts when they establish the scope of protection of a process patent for animal production in an infringement proceeding.

Article 64(3) states that ‘any infringement of a European patent shall be dealt with by national law.’ The only guidance given as to the scope of protection is found in the provisions of Articles 64 and 69, and the Protocol on the interpretation of Article 69. According to Article 64(2), the protection conferred by a patent whose subject-matter is a process shall extend to the products obtained directly through that process. The effect is essentially that the sale and use of products made directly by utilizing a process that is the subject of a European patent constitutes infringement of that patent, as well as the use of the process itself; and the rights of a European patent must be construed accordingly (Paterson 2001, p. 16). For this provision, as for the similar regulation in Article 28.1 (b) of the TRIPS Agreement, extension of this protection is not specifically directed towards biotechnological inventions or their progeny. It is simply stated that protection extends to the products ‘directly’ obtained by the patented process, regardless of whether such products themselves are patentable (Kamstra et al. 2002, p. 48). Furthermore, while the EPC represents a harmonization of the scope of protection through the wording of the provisions, actual interpretation and use are a matter for the national courts and might be practised dissimilarly.

It has been argued that restricting the scope of protection to products which are the ‘direct’ result of the patented biotechnological process does not provide fair or adequate protection for the patent-holder (Kamstra et al. 2002, p. 48). Moreover, there might be uncertainty regarding use of a patented process for the production of self-replicating material, since the use of the patented process might not be necessary for self-replication. Whether fair or adequate protection is provided will depend on how the word ‘direct’ is interpreted. In straightforward cases where the subject-matter of an alleged infringement is the immediate end-product of the process, few difficulties arise (Paterson 2001, p. 587–588). ‘The product obtained by the means of the patented process was the product with which the process ended’ (ibid). However, if the immediate end-product of a patented process is subject to further processing, the product of such further processing may also infringe the patented process if there is no ‘loss of identity’. The relevant interpretation factor in an EPO perspective seems therefore to be the ‘loss of identity’ test,² which means whether the product obtained, subject to further processing, retained or kept its essential characteristics (Paterson 2001, p. 587). Regarding processes for the production of farm animal genetic material the question is whether replicating the invention without using the patented breeding scheme would imply that product ‘loses’ its identity. This test was seemingly construed for traditional technical inventions, and the above- mentioned case-law concerns inventions of a non-biotechnological character. In this respect, the EPO rules do not go much further than does the TRIPS Agreement.

B. The EC Biotech Directive

The Directive requires EU/EEA Member States to protect all but the exempted biotechnological inventions under national patent law. Basically, the level of protection shall be the same as for other inventions (Preamble recital 46). To achieve this, Articles 8 and 9 specify the scope of protection for biotechnological inventions. Further, Articles 10 and 11 provide new defences against infringement of the rights concerning biotechnological inventions (Bently and Sherman 2004, p. 546; for more on special defences, see section VII). The EC Biotech Directive does not specify which actions are subject to the control of the patent-holder, thus making this a matter for national discretion within the framework of the obligations of the TRIPS Agreement.

With this directive, the European Union established certain special regulations regarding biotechnological inventions. The Preamble notes that there was a need for clarification of the scope of protection regarding biological material due *inter alia* to the ability of such material to self-reproduce (Preamble recital 46). Differences in national legislation were seen as having the potential to create trade barriers and impede the functioning of the internal market (Preamble recital 5). The problem could grow if the Member States adopted new and different legislation and if national case-law interpreting such legislation developed differently (Preamble recital 6). Implementation of the EC Biotech Directive did not, however, according to the Preamble, necessitate the creation of a separate body of law in place of the rules of national patent law.

The European Parliament used the room for manoeuvre under the TRIPS Agreement to further specify the scope of protection for progeny of material obtained through a patented process. The scope of protection covering the product obtained directly through the patented process in the TRIPS Agreement Article 28.1 (b) includes in the EC Biotech Directive also 'any other biological material derived from the directly obtained material'. This implies that the patent confers a certain degree of protection on the progeny and other biological material derived from the obtained material from applying the patented process. The uncertainty about exclusive rights to future generations of the product of a patented process under the TRIPS Agreement is thus to some degree specifically addressed, in favour of increasing the scope of protection in the Directive. The Preamble (recital 12) states that the TRIPS Agreement, which has been signed by the European Community and the Member States, provides that patent protection must be guaranteed for products and processes in all areas of technology. The EC Biotech Directive could thus be seen as the means by which the European Union intended to employ the flexibility to grant a higher level of protection than required by the TRIPS Agreement, by specifying rules regarding biotechnological inventions.

1. Indirect Product Patent Protection in the EC Directive

The question is then to interpret the provisions in the Directive relevant for the scope of protection of process patents on methods for breeding farm animals. According to the principles of EC law, all Member States must apply the level of protection that the EC Biotech Directive provides. Article 8(2) of the EC Biotech Directive states:

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. (Emphasis added)

Thus, in addition to the process itself, the scope of protection extends also to material 'directly obtained' by the process. According to the first alternative in the wording, the protection is practically identical to that of the TRIPS Agreement. Article 8(2) establishes the scope of protection for the first generation of an applied breeding method. Article 8(2) states that the scope of protection includes 'any other biological material' obtained through multiplication of this material. This goes further than the TRIPS Agreement, Article 64(2) of the EPC and its national equivalents, as the protection conferred upon a claim to a process for the production of a biological material extends beyond the biological material obtained *directly* through the claimed process, and covers also the biological material 'derived from the directly obtained

biological material which possesses the same characteristics' (Kamstra et al. 2002, p. 49). The EC Biotech Directive thus offers more extensive protection for process patents.

According to Article 8(2), protection extends to *any* material 'derived' from the biological material. First of all this seems to imply that it is not only the product of the process which is protected. For processes in farm animal breeding, the product would be an animal, as would any material derived from the process. The term 'any' thus seems to indicate that also the semen and embryos of the animals produced according to the patented method are covered by the exclusive right.

It is, however, required that the material has been 'derived from the directly obtained biological material'. As noted by Kamstra et al., in a contextual interpretation, 'the term "derived" is given a broad meaning through the use of the words "through propagation or multiplication in an identical or divergent form"' (Kamstra et al. 2002, p. 49). Legal certainty seems possible in relation to what is meant by 'identical form', but the Directive provides no guidance as to what is meant by 'divergent form'. According to one standard dictionary definition, things that are 'divergent' are 'very different, or opposing, in attitudes or characteristics' (*Compact Oxford English Dictionary*, 2005). For processes in farm animal breeding, this might appear to be a rational solution as it would allow for natural genetic variation and still remain under the scope of the patent. On the other hand, 'divergent' could imply a protection that would cover almost any animals that had some connection to the applied process, and holding the core characteristics from that process, even though the animal beyond those characteristics are fairly different. That would indicate a very broad scope of protection. It is not certain whether a court will apply such broad interpretation of the term in an infringement case regarding a breeding method patent and future generations. Kamstra et al. have also noted some possible difficulties that the courts will have to address based on the regulations in Article 8 (Kamstra et al. 2002, p. 49).³ They conclude that these questions are unfortunately not answered in the implementing texts so far seen in the Member States. Consequently, the courts of the Member States will have to rely mostly on the wording of the Directive in establishing the scope of protection in infringement cases.

According to the report from the Commission to the Council and the European Parliament, COM(2005) 312 final, the wording of Article 8 might be seen as arguing for a broad scope of protection rather than a restricted one.⁴ The courts will have to determine specifically, for each infringement proceeding, how to apply the term 'divergent'. Since there is no case-law directly relevant for the assessment, it is the interpretation of Article 8(2) that will, for the most part, be decisive. Both the choice of terms and the report from the Commission (COM(2005) 312 final) indicate a far reaching scope of protection.

A related question emerges: for how many generations/multiplications the patent confers exclusive rights to the patent-holder? The wording of Article 8(2) does not specify a number of generations for which the exclusive right will continue. Clearly, after the expiry date of the patent (normally 20 years) the patent-holder will not have any exclusive rights to the process nor the products obtained. The question remains as to how many propagations or multiplications the exclusiveness covers – and here the exclusiveness seems to extend to *all* future multiplications within the period, as long as they possess the characteristics of the biological material produced by the patented process, whether in identical or divergent form.

Article 8(2) specifies that the protection offered shall extend to biological material directly obtained through *that* process. This refers only to the first generation. For subsequent progeny

and material the specification is not repeated, although it is required that the biological material be derived from the obtained material ‘through propagation or multiplication’ – which are broader terms. The words ‘propagation or multiplication’ indicates that subsequent generations are protected regardless of whether *that particular* process was applied. The practical consequences of this are difficult to foresee.

Article 8(2) imposes another qualifying term – ‘same characteristics’ – which raises the question of how substantial the differences can be between animals for them still to be covered by the scope of the patent. If the ‘products’ (the offspring of using the patented method) are introduced to a herd and then cross-bred with other individuals not possessing the same characteristics with a different breeding method, the question arises whether the process patent applies to these individuals. Considering that the patent could cover material in a *divergent form*, the answers to these questions seem to depend on how the courts will interpret the term ‘possessing those same characteristics’, and the specific differences and similarities of the said animals. The courts will have to determine what the specific characteristics are biologically, compare these with the alleged infringing products, and then determine whether this animal has ‘lost’ its identity⁵ or still possesses the specific qualities.

When a breeding process is applied to improve e.g. certain health traits, the offspring of this process possessing those improved characteristics would appear to be under the exclusive right of the patent-holder. If the offspring is cross-bred with an animal not under the indirect product protection but still possessing similar desirable health traits, the question becomes how can it be determined whether those specific characteristics originate from the patent-protected animal(s). The fact that natural genetic variation occurs adds difficulties to this assessment, from a biological and legal point of view.

2. A Closer Look at the Rationale for Extending the Scope of Protection

The rationale behind Article 8(2) needs to be discussed to better understand the rule. This rationale must be sought in the value of the patent for the patent-holder. When the invention has the capability to ‘reinvent’ itself through self-reproduction, third parties could exploit the value of the invention by freely using the offspring, if the scope of protection were too limited. The patentee would then not have an exclusive right for a full 20-year period. This rationale is specified in the Preamble of the EC Biotech Directive, recital 46:

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 (...) 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 the patented, non-self-reproducing products*. (Emphasis added)

The inventor should, according to the Preamble, be entitled to prohibit the use of the patented self-reproducing material to the same extent as for non-self-reproducing products. The objective of this extension of the right is to establish a scope of *analogous* protection for living and for non-living inventions alike. This implies that the protection conferred through the provisions of the Directive should not be more extensive than for other inventions. This, however, presupposes that the scope of protection for other inventions is of a measurable standard, and that this standard is comparable to the extent of protection for biological patents. For non-biotechnical material, protection extends to the product obtained by that process. Protection in situations analogous to the protection regarding non-self-reproducing

products would directly cover only the first ‘generation’. It is, however, hard to imagine a non-biological product that is self-reproducing. Thus, the possibilities of circumventing the patent by utilizing the product obtained seem greater for living material, since the invention itself can be employed for duplication and in further breeding.

This argument was upheld by the European Court of Justice in the opinion of Advocate General Jacobs in the Annulment case C-377/98. In section 122 the Court stated that Article 8(2) ‘adapts a well-known principle of traditional patent law to the exigencies of biotechnological inventions’. The rationale for this conferred right is given in section 121, where the Court stated: ‘in the case of patented material capable of reproducing itself, the value of the patent would clearly be eroded if it did not extend to future generations of such material.’ And in section 123 the Court emphasized that, if the material obtained through a process “could be freely propagated by a purchaser, the value of a process patent would be nullified”.

Analogous protection with non-self-reproducing products does not seem easy to achieve: either the protection is limited to the first-generation product (which opens for the possibility of reproducing the invention in future generations); or the protection is to some degree extended to derivatives of the first product (thus limiting the use of the product beyond what an analogous protection would grant to non-biological inventions). It thus appears difficult to seek justification for this rule in the regular justification of the patent law system.

The Preamble, in recital 3, emphasizes the great importance for the economic development of the European Community of making conditions favourable for development in this sector. The economic incentive expected to be created through the patent system was considered of high importance to the European Community (Preamble recital 2), necessitating regulations to ensure that such an incentive would emerge. Economic evidence is, however, hard to come by, and it is difficult to assess empirically to what degree the potential scope of protection in either direction would influence innovation and breeding. A broad scope of patent protection has the potential to redistribute economic gains, but it is not clear exactly how this will affect investments in breeding.

The patent system is based on a balance between protection of the inventor’s commercial interest, and the interest of the public to freely exploit technological advances (see e.g. Westerlund 2001, p. 77). This applies also to breeding methods for farm animals. The paramount objective is to create technical innovation without unreasonably restricting the use of the invention by others. In the case of biotechnological inventions involving animal genetic resources, the users might be industrial-level breeders, but also farmers of varying scales and production capacities. If the level of the protection applied through the provisions of the EC Biotech Directive favours the patent-holder to a greater extent, by overly restricting the use of future generations, the balance might be altered.

Much of the value of process patents on farm animal breeding methods lies in the exploitation of future improved generations. To uphold the balance between these conflicting interests may prove difficult, especially when the protected animals are part of farmers’ herds, constantly evolving through continuous breeding. How this balance is reflected in the scope of protection is not easy to concretize at the general and abstract level.

The question of adequate scope of protection could be formulated in terms of whether it is more valuable to society to allow the patent-holder a broad scope of protection so that others

who build upon this invention must seek a licence; or whether such patents should be limited in scope, so as to allow future uses of this biological material.⁶ The Preamble underscores the fundamental importance of encouraging investments through *adequate legal protection* for the purpose of industrial development (Preamble recital 1–3). The question, however, remains as to what degree this ‘adequate legal protection’ (as provided through the EC Biotech Directive) to make investments in the field of biotechnology profitable will restrict the use of animals and subsequent generations.

The commercial value of the result of the process derives from the natural characteristics of the original organism, and, it can be argued, has less to do with the invention as such. The invention might involve improving species that have been developed through cross-breeding and natural selection for hundreds of years. The patented invention could thus be seen more as merely the latest step in a continuous, long-established process. The argument of adequate reward might therefore have less relevance for process patents to breeding methods in farm animal breeding than for the development of something truly new, like a genetically modified plant.

The literal interpretation of Article 8(2) leaves uncertainty as to the scope of protection for process patents in farm animal breeding, and there is as yet no case-law on this issue. If a case is brought before the courts, where these interpretational questions is raised, the court will probably be very concrete in determining what is the adequate protection for the patented breeding method. The wording of the Directive indicates clearly that future generation will be covered by the scope of the protection; and from the Annulment case the ECJ seems to agree to that protection of future generations is necessary to make biotechnological process patents effective, also when the next generations appear in a divergent form than the first generation after the application of the patented method. A certain amount of legal uncertainty might have a chilling effect on investments in breeding, as commercial actors might consider the potential costs of a law-suit too high.

IV. A PRACTICAL VIEW ON THE ACTS COVERED

In this section the focus shifts to a discussion of which practical activities the patent-holder can refuse to permit others to perform regarding this process or products produced by that process. Having examined the scope of the protection conferred by a patent, it is important to develop our understanding of the activities that would constitute an infringement.

The TRIPS Agreement lists the various elements that form the right to exclude others from exploiting the invention (de Carvalho 2005, p. 247). Article 28.1 (b) specifies the acts that are subject to the control of the patent-holder in regarding a process patent to be: ‘act of using the process’ and the ‘using, offering for sale, selling or importing’ at least the products of the process. In other words, Article 28.1 (b) holds that a person is infringing a process patent if he uses the patented process. Furthermore, infringement can occur if a person uses, sells, offers to sell or imports any product derived from that process. The EC Biotech Directive does not, as noted, specify which acts are subject to the control of the patent-holder, thus making this a matter for combining what was said above, subject to how Article 28 of the TRIPS Agreement is implemented.

‘Act of using the process’ implies that the patent-holder can prevent third parties from

performing the method described in the claims. If the use falls within the direct definition of the patent claims, an identical use has occurred. Assessment of whether the alleged infringing process implies an identical use of the patented process is a matter of interpretation of the patent claims, and comparing these to the said activity. If the use does not fall within the direct meaning of the claims, then one must assess whether it is sufficiently similar as to constitute an infringement (Westerlund 2001 chapter 5). This is often referred to as ‘the doctrine of equivalence’. This implies that, if the alleged infringing process cannot be said to derive directly from the patent claims, such utilization might still be considered as an equivalent use of the patented process. The doctrine of equivalence thus expands the patent protection beyond what the patent-holder originally described as his invention in the patent claims. If the similarity is sufficiently qualified, despite the replacement or exclusion of one or more elements, an equivalent use can be said to have occurred, with the legal consequence being that the exclusive right applies equally. As the courts of different countries apply non-uniform doctrines of equivalence, these considerations will necessarily vary from country to country, also within Europe. (There is no international harmonisation of the doctrine of equivalence, although an attempt was made to reach consensus on this in the draft Substantive Patent Law Treaty Article 11; see Tvedt 2005, pp. 337–339.)

One related question is whether the act of crossing with other animals or using other methods represents an ‘equivalent’ use of the process. This seems to depend on how the patented process claims are formulated and how the doctrine of equivalence is applied to these acts of use. The use of a different animal in the same breeding process seems to be an equivalent use, at least if the resultant offspring possess the same characteristics as the animal obtained by the first employment of the patented process. Whether the use of the animals by means of other breeding methods should be deemed equivalent would seem to depend on how different the other method is. Additionally the question remains as to whether such other propagation or multiplication could be considered equivalent use of the product obtained. The existing sources of law do not concretize the specific details of these issues. It is therefore likely that the general principles of equivalence will be applied. The courts must assess whether the alleged infringing process includes only insignificant modifications, whether the alterations was obvious to a person skilled in the art and finally, if the alternative process provides for a certain degree of technical progress. These general principles might imply difficult assessments considering the nature of the patented subject matter – e.g. their capability to reproduce.

Given the territoriality of patent rights, as a general principle, process patents can be invoked to prevent third parties from using the patented process only in a country where the patent has been granted. Nor can the patent-holder prevent the making and sale of breeding material if the patented process was applied in a different country (Correa 2007, p. 298). The TRIPS Agreement does confer ‘indirect product protection’, extending the protection process patents to include products that are produced by application of the patented process, whether the process was executed in the country that granted the patent or elsewhere. Extension to at least the products obtained directly by the patented process imported to the country where the patent was granted thus confers a certain element of extraterritorial effect to the use of the process in a foreign jurisdiction.

The patent-holder cannot, as a point of departure, prevent the making and sale of the same product resulting from the patented process if it had been obtained through a different process. Article 28.1 (b) does not cover cases where the product is *obtainable* by the patented process but where evidence of the use of the patented process is not supplied. However, the courts

may, at their discretion, require the alleged infringer to provide evidence to show that there is no infringement having taken place (section VI).

V. SPECIAL DEFENCES IN CASE OF INFRINGEMENT OF BIOTECHNOLOGICAL PROCESS PATENTS

Once the claimant has proved that the defendant has performed an activity that falls within the scope of the patent monopoly, the obligation shifts to the defendant, who must show that this activity is exempted from liability by one of the available defences to patent infringement (Bently and Sherman 2001, p. 505). These defences could limit the scope of protection conferred to the patent-holder in certain specific situations of ‘infringing use’ of the patent. 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 interest of third parties.

During the preliminary stages of preparing the EC Biotech Directive, one of the concerns raised was that patent protection of biological inventions would have a negative impact on farming practices (Bently and Sherman 2004, p. 547). Here the legitimate interest of third parties was taken into account regarding normal exploitation and the interests of the holder of such patents. As part of the regime dealing with biotechnological inventions, new defences were therefore formulated concerning the infringement of patent or exceptions to the exclusive right for biotechnological inventions (Bently and Sherman 2004, p. 509). Acts that fall within the exemptions are not to constitute infringement, regardless of whether or not such acts would be considered infringements under Articles 8 or 9 of the EC Biotech Directive (Kamstra et al. 2002, p. 54).

A. *Necessarily Result*

Article 8(2) of the Directive requires Member States to extend the scope of protection to dealings with materials derived from the patented process (section III B 1 above). Kamstra et al., however, argue that the doctrine of exhaustion could limit the effect of this extended scope of indirect product patent protection. They emphasize that Articles 10 and 11 of the EC Directive specify limited circumstances in which the extension of scope of protection provided in Articles 8 and 9 will *not* apply (Kamstra et al. 2002, p. 53).⁷ According to Article 10:

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation *necessarily results* from the application for which the biological material was marketed, provided that the material obtained *is not subsequently used* for other propagation or multiplication. (Emphasis added)

For the patent rights to be exhausted under Article 10, it is therefore necessary to establish that the multiplication or propagation that potentially infringes the patent is an incidence of the ‘true purpose’ of the sale (Bently and Sherman 2001, p. 510). With animal breeding, it might be asked to what extent a patented breeding process sold or licensed in one Member

State could restrict the further utilization of the animals derived from the process. The extent of use of the product derived could be regulated in the contract between the patent-holder and the user. In such situations, the exhaustion could thus be contractual; for other situations, Article 10 of the Directive specify limited circumstances in which the extension of scope of protection provided for in Article 8 is not to apply.

Important here is the interpretation of the words ‘necessarily results’. As noted above, for the patent to be exhausted under Article 10, it must be established that the multiplication or propagation which potentially infringes the patent relates to the ‘true purpose’ of the sale. An interpretation of the term ‘necessarily results’ would imply that the material obtained is not used for other types of propagation or multiplication. In the case of a breeding process for e.g. better meat quality, the user of the patent could apply the breeding method to his herd in order to improve the meat quality. The question is to what degree the result of the process (future generations of animals) can be utilized in the breeding scheme. According to Article 10, the ‘product’ could not be sold as a breeding animal, nor its semen sold to other farmers, since that is not the true purpose of the sale and such multiplication does not ‘necessarily result’ from the application for which the biological material was marketed (the true purpose being to apply the breeding method to the herd in order to improve the meat quality). Sales for the true purpose would be either using the bought material mating once at the farm, or selling the meat of the animal on the basis of its high meat quality, but not to use the off-spring in further breeding. Article 10 seem to imply that sales of the offspring as breeding animals or for other breeding purposes would not ‘necessarily’ result from the application of the invention, if the purpose of applying the process was to improve certain traits in the farmer’s herd. Article 10 would allow farmers to use the patented process, and sell the improved meat – but it would not be permitted to sell the animals derived from the process or their semen to other farmers, for the purpose of propagating new animals. In other words, this defence allows farmers to apply a patented process, breed the animals and sell the agricultural product – but not to sell the animals or semen to other farmers so that they in turn could propagate new animals (Bently and Sherman 2004, p. 547). This leaves the application of Article 10 very specific.

B. The General Doctrine of Exhaustion

Article 10 of the EC Biotech Directive can also be seen as one particular manner to implement the ‘doctrine of exhaustion’. The essence of the doctrine of exhaustion is that exclusive right of the patentee does not reach as far as to further use of the products placed on the marketed by the patent-holder, domestically or internationally (Bently and Sherman 2004, p. 13). Article 6 of the TRIPS Agreement emphasises Members’ freedom to regulate exhaustion of any intellectual property rights despite of the TRIPS Agreement (Correa 2007, p. 78).⁸ The principle of ‘exhaustion of rights’ may be applied at the national, regional or international level. Under the doctrine of exhaustion, a patent-holder may not invoke the patent to prevent the further use of a product that has been placed on the market in the EU/EEA with the patentee’s consent (Bently and Sherman 2004, p. 524). The doctrine of exhaustion leaves some uncertainty regarding the use of produced animals for multiplication through breeding.

Since much of the value of a patent in farm animal breeding lies in the utilization of future generations of improved animals, the further use of the produced products could imply different assessments than in the case of traditional technical inventions. The doctrine of exhaustion does not give the purchaser a right to produce new specimens of the patent

product. Nor does the doctrine, as general principle, bestow the right to practise a patented process. This indicates that it is somewhat difficult to apply a general doctrine of exhaustion to the field of animal breeding.

The practical question arises when the patent-holder sells (or places in the market) the animal which is the result of a patented process, and thus under indirect product patent protection; to what extent is then the patent right exhausted? Often the sales or licensing agreement of the patented process or the said animal thereof will regulate the issue, no questions arise. The doctrine of exhaustion clearly does not give the buyer the right to apply the patented process itself; the right to use to animal in a breeding scheme other than the process could, however, be exhausted in this situation. One difficult question, however, is whether the specific rule in Article 10 limits the application of the doctrine of exhaustion. It is not entirely clear what the law-maker has meant about the relationship between the general doctrine and this specific rule. It is therefore an open question whether there still is room for a doctrine of exhaustion where the special criteria in Article 10 are not fulfilled which goes further in opening the right to use off-spring in breeding.⁹

C. Farmers' Privilege

To what extent the product derived from the process (offspring) may be used for further breeding within the farmers herd is subject to the regulations of Article 11, the 'Farmers' Privilege'. This 'farmers' privilege' provides a limited exception to the exclusive rights conferred by a patent by allowing the individual farmer a certain use of the protected subject-matter that would not normally be possible without infringing the protected process. Article 11 (2) states that by:

[w]ay 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. (Emphasis added)

In essence, the exemption grants the farmer the right to use the propagating material for agricultural purposes but not to market it for breeding (*commercial reproduction activity*). As noted by Bently and Sherman:

In the debates surrounding the Biotechnological Directive, one of the fears raised was that patent production over biological inventions would have a negative impact on traditional farm practices. (...) In particular, it was feared that farmers would not be allowed to use the seeds that they harvested from their crops to re-sow crops, nor would they be permitted to breed patented animals. (Bently and Sherman 2001, p. 510)

The problem would appear to be that, in relation to a patent, the breeding processes carried out on farms might represent an infringement.

Article 11 makes an exemption from the protection conferred in Article 8, which implies that the exclusive right does not extend to plant-propagating material or breeding stock sold to a farmer by the patent-holder or with his consent, provided that the farmer uses the biological material or livestock for his own agricultural purposes.¹⁰ This is intended, *inter alia*, to prevent an increase in costs in agriculture because of inventions related to farm animals. The

'farmers' privilege' of Article 11 makes an exemption from the exclusive right when the farmer uses the patented biological material for breeding livestock for his own agricultural use on the farm, but is limited regarding sales within the framework of or for the purpose of commercial reproduction activity. The basis for this exemption seems to lie in the need for to provide consistency and certainty for farmers, who should not face claims from patent-holders because (perhaps unknown to the former) these have product or process claims (Kamstra et al. 2002, p. 54). The extent and the condition of the derogation provided in Article 11 (2) shall, however, be determined by national laws, regulations and practices. This in turn means that the consistency and certainty for farmers will depend on how the exemption is implemented and practised at the national level.

The extent of this exemption seems to rely on a definition of the expression 'pursuing his agricultural activity'. To draw the line between commercial breeding activity and the purposes of pursuing agricultural activity could be difficult if the owner of the livestock engages in both types of activities. For example, is a one-off sale of the progeny of an applied breeding method a 'sale within the framework of or for the purpose of a commercial reproduction activity' (Kamstra et al. 2002, p. 55)? Or does the term imply a more qualified activity than one-off sales – say, a breeding business? There are also differences among animal species that could make this assessment difficult. With some animals, breeding of hybrids and raising and keeping livestock are separate activities, while for others the two intertwine (Tvedt 2007b, p. 20). The level of commercialization could also differ, from sector to sector, from farmer to farmer and from country to country. Further analytical work is needed to understand and suggest ways of implementing *farmers' privilege* in the farm animal sector. It is also interesting to note that developing countries have not been very active in developing exemptions in the scope of the patent protection.

VI. REVERSAL OF THE BURDEN OF PROOF

Generally the burden of proof is bestowed by law upon those who make an allegation. Concerning patents for processes, however, it has been argued that it could be difficult for patent-holders to establish evidence of infringement, and consequently easy for infringers to conceal or disguise their wrongdoing (de Carvalho 2005, p. 383). Since the TRIPS Agreement is a standard agreement for the protection of intellectual property, and one that includes patents in all fields of technology, here we must ask to what degree these difficulties also apply to process patents for the production of farm animal genetic material. Article 34 of the TRIPS Agreement obliges the Member States to establish in their national laws that courts shall have the power to reverse the burden of proof (*ibid*). However, the courts are not obliged to do so: reversal of the burden of proof is in principle a matter of their discretion, dependent on the circumstances of each case. Reversing the burden of proof imposes on the alleged infringer the obligation to provide negative proof. The alleged infringer must provide evidence that he did *not* use the patented process – which may be sometimes an impossible task (de Carvalho 2005, p. 384). To further define the question raised above: does the special character of process patents regarding farm animal genetic resources warrant a different use of these discretionary powers than for other inventions?

In other fields of technology, the rationale for the rule of the burden of proof is perhaps easier to justify. A main difference between biotechnological inventions regarding processes for producing farm animal genetic resources and other technical inventions is that the product, or result, is often not 'produced' or manufactured in the traditional sense of the word. At present,

farmers have the right to make use of their animals for further breeding. This may occur without the use of technical equipment and human intervention, as animals can, and do, mate naturally. For other technical inventions this is unthinkable. Today the use of artificial insemination has become widespread in commercial farming, but this does not mean it has become impossible to produce the ‘matter’ without recourse to patented processes. Thus the question is whether it is at all possible for a breeder or farmer to produce evidence of not having applied the patented method in question. This seems to involve assessments of a biological character, where it must be determined if an animal has been produced by the patented breeding method or if the animal could have been the result of natural occurrences or other breeding methods. The reversal of the burden of proof could seem more justifiable for technical inventions, as the technical details of the invention could make it possible to provide evidence of the use of alternative production methods.

The discretion conferred upon the national judicial authorities is not absolute. If at least one of the circumstances described in subparagraphs (a) and (b) occurs, judges shall apply presumption of infringement, and have no discretionary authority to reverse the burden of proof (de Carvalho 2005, p. 385). On the other hand, it is up to the law to define which of the circumstances is to be seen as triggering the presumption. Some WTO Members have in fact preferred to establish the presumption in both cases, thereby going further than they were obliged to do. Any identical product produced without the consent of the patent-owner shall therefore, in the absence of proof to the contrary, be deemed to have been obtained by the patented process. However, this presupposes at least one of the following:

- (a) (...) the product obtained by the patented process is *new*;
- (b) (...) there is a *substantial likelihood* that the identical product was made by the process and the owner of the patent has been *unable through reasonable efforts* to determine the process actually used.¹¹ (Emphasis added)

It must be fairly evident that the product could have been made by the same process, and the patent-holder must have attempted to prove this. The implications of Article 34 are not easy to foresee for process patents in biotechnology regarding animal genetic resources. The fact that the products themselves are capable of self-reproduction might complicate efforts to determine if the process in question was used. This might suggest an interpretation that accords some leeway as to the efforts required of the owner of the patent, ‘through reasonable efforts’. However, if the burden of proof is reversed, it is not obvious that it would be possible to produce evidence that the product was made by another process. A method for selecting and breeding for certain desired traits, by identifying these traits in the animals and combining them with the appropriate genes in other animals, might be repeated by a different process, or indeed by natural mating. The effect of the reversal of burden of proof would then seem to rely on how the term ‘reasonable efforts’ is applied by the courts. Correa emphasizes that the requirement of ‘reasonable efforts’ on the part of the patent-holder, if appropriately applied, may help to limit possible abuses of patent holders in demanding the reversal of burden of proof and avoid ‘strategic litigation aimed at blocking legitimate competition’ (Correa 2007, p. 346). As to process patents regarding farm animal production, it has been claimed that genetic companies in livestock breeding use patent policy to dominate gene markets (Gura 2007, p. 6). The appropriate application of ‘reasonable efforts’ could at least ensure that patent-holders are not granted rights to offspring that have been produced by means of other processes or methods.

According to Spranger, the farmers' rights exemption is also problematic in relation to the TRIPS Agreement (Spranger 2002, p. 246), as Article 34 imposes a reversal of the burden of proof, to the detriment of the farmer. As argued by Spranger, it is up to the farmer to prove that he did not violate the rights of the patent-holder – and, taking into account the possibility of self-sowing (or here: self-breeding), the difficulty in proving innocence is obvious. If Spranger's interpretation of TRIPS Agreement Article 34 is accurate, the 'burden' of providing evidence that the 'making of the animal or other animal reproductive material' was done for the 'purpose of pursuing his agricultural activity', lies with the alleged infringing farmer.

VII. CONCLUSIONS

Patent protection of process for farm animal production opens for several interpretational questions regarding the scope of protection and the use of ensuing generations of the applied process. The TRIPS Agreement imposes a basis for harmonization of patent law by providing minimum standards for protection of inventions in all fields of technology. Being technology-neutral, the rules of the TRIPS Agreement could apply differently when used in areas that diverge from traditional technologies. For the protection of biotechnological inventions in the EU/EEA, these differences have been taken into consideration and exclusive rights to patents in this area further specified through the provisions of the 1998 EC Directive on the Legal Protection of Biotechnological Inventions – the 'EC Biotech Directive', thereby establishing more detailed rules without solving every interpretational problem.

The wide range of stakeholders and their differing affiliations to genetic resources may imply particular challenges when it comes to imposing intellectual property rights on the resources. The ability to make use of and adjust to patent law could vary for different stakeholders. Although patent-holders and third parties may have somewhat contradictory interests, predictability is especially important when the product obtained by the patented process is a living entity capable of self-reproduction. From the patent-holder's perspective, predictability can be important because of the biological characteristics of the products obtained, as these characteristics imply that the animals may keep on evolving. Since animals may be subject to constant improvement and crossing, it is vital to know the scope of protection for determining how far the exclusive right extends regarding such evolved animals. For commercial breeders and farmers, predictability in legislation could determine the range of their breeding activities, as patents might end up restricting the use of offspring for further propagation or sale for breeding purposes.

From a literal interpretation perspective and the discussion above, it could be asked whether applying general patent protection through the provisions of the TRIPS Agreement, specified in the EC Biotech Directive, goes beyond the level of protection in other fields of technology. According to the Preamble of the EC Biotech Directive (recital 46), which especially addresses such issues, the protection is to be 'analogous'. However, based on the interpretation above it seems that the scope of protection regarding the progeny resulting from an applied process is quite wide-ranging. The interpretation could thus imply an extension of the scope of protection by granting the patent-holder rights to almost anything derived from the propagation or multiplication. Whether this would be the result of a court case regarding infringement proceedings is yet to be seen. However it would not seem to correspond fully with the general incentives underlying patent law.

A central concern in upholding the legitimacy of the patent system is the balance between inventors and third parties for the purpose of promoting technological development for the benefit of society (Westerlund 2001, p. 77). If applying general patent protection to biotechnological processes in farm animal breeding *de facto* extends the protection further than for other technical processes, and this extension was an unintended consequence, it could then be held that the relevant provisions could, to counteract this, be interpreted more narrowly when applied to biotechnological inventions for the production of animals. This could be argued in light of the rationale of the patent system, as the converse could reward the inventor to a greater extent than justified by the system. In establishing the scope of protection for biotechnological processes, legislators should have ensured, and the courts should ensure in the future, that the scope of the patent rights granted is proportionate to the invention, but such scope should also be 'analogous' with the scope of patent rights provided in other areas of technology. Such assessment might prove difficult also because of considerable variations within species and the way in which they are utilized.

In farm animal breeding, the animals that are subject to improvement through a patented process will normally be owned by breeders or farmers who apply the patented breeding method on their stock. The difficult question is to what extent the patent-holder gains rights to the animals that are obtained through the process. Based on the interpretation of the TRIPS Agreement and the EC Biotech Directive provided here, one could ask if patented processes in farm animal breeding interferes with the farmers' and breeders' property. The animals of a breeder's herd are part of his property, and in the debates surrounding the Directive, one of the fears raised was that patent protection over biological inventions would have a negative impact on traditional farm practices (Bently and Sherman 2001, p. 510). The Canadian Biotechnology Advisory Committee has held that granting exclusive rights that extend not only to the particular organism embodying the invention but also to all subsequent progeny of that organism could represent an increase in the scope of rights granted to patent-holders; furthermore, that this represents a greater transfer of economic interests from the agricultural community to the biotechnology industry than exists in other fields of science (Canadian Biotechnology Advisory Committee 2002, p. 12). If, due to the intellectual property rights, the 'acts of use' the farmers or breeders are entitled to perform are restricted to a greater extent than the property rights would indicate, it could thus be argued the EC Biotech Directive implies a shift in the balance between intellectual property and traditional property. Such a shift might be inconsistent with the basic principles that justify the patent system. Whether this will be the factual consequence remains to be seen since not many process patents have been granted and none have been subject to a court-case.

It could be argued that the provisions of the TRIPS Agreement and the EC Biotech Directive should be given an interpretation that both secures the patent-holder's right to be rewarded for the invention, and upholds the property rights of farmers and their possibility to utilize the resources belonging to them. On the other hand, adequate patent protection is perhaps not possible without including (at least to a certain extent) the use of future generations produced from the patented process. Moreover, given the strong financial incentives (EC Biotech Directive Preamble recital 1–2) and the desire to conquer this frontier technology (EC Biotech Directive Preamble recital 3), a certain reduction in farmers' property rights may prove to be a politically acceptable consequence according to the current view of the EU. Members of the WTO have broader discretion when it comes to determining the scope of patent protection, exhaustion of the right and exemptions from the patent right. The need for adapting patent law to farm animal breeding is only now being recognized.

The legal situation regarding these questions has not been fully determined by implementation of the EC Biotech Directive or through court interpretation of its provisions. It remains to be seen whether the large number of patent applications currently pending in this area of technology will be granted, as well as how the courts of different jurisdictions will interpret the patents and determine the scope of protection. This is an issue that may well affect large numbers of participants in the global market of farm animal food production.

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¹ EC Directive on the Legal Protection of Biotechnological Inventions 98/44/EC of 6 July 1998; 98/44/EC of 6 July 1998. Hereinafter referred to as the Biotech Directive or the Directive.

² The test derived from the relevant German authorities in interpretation of German patent law. As the relevant Dutch, Swiss, Danish and Austrian authorities have also adopted the 'loss of identity test', it can be taken to represent the test adopted by European law, see Paterson 2001: 588.

³ The questions are raised in regard to Article 8(1), but the authors state that the concerns raised in relation to the scope of the term 'divergent form' in Article 8(1) apply equally to Article 8.2.

⁴ Report from the Commission to the Council and the European Parliament, COM (2005) 312: 3–4. The report was requested in accordance with Article 16b of the Directive which requires the Commission to produce reports regarding the implications of implementation of the Directive.

⁵ Cf. the 'loss of identity test'.

⁶ Report from the Commission to the Council and the European Parliament, COM (2005) 312: 4.

⁷ Article 9 applies to protection conferred on a patent on a product and will therefore not be discussed here.

⁸ TRIPS Article 6: 'For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.'

⁹ It would not be in conflict with the TRIPS Agreement Article 6 to let Article 10 of the Directive be supplemented with the general doctrine.

¹⁰ <http://europa.eu/scadplus/leg/en/lvb/l26026.htm>

¹¹ TRIPS Agreement Article 34.