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Scope of Process Patents in Farm Animal Production

Exclusive Rights to Patents on Farm Animal Breeding Methods and Relevant Exemptions on the Patentability of Such Inventions

Magnus Finckenhagen

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Magnus Finckenhagen
MFI@wr.no

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Magnus Finckenhagen

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Abstract

This report analyses the scope of protection for patents regarding processes for the production of farm animals. There is a rapidly growing number of process patent applications in the farm 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; 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 increasingly used in the animal sector, the question of how the law will apply to this particular field of innovation is unanswered. Some inventions are still left out of the patentable subject matter by exemptions from patentability. The scope of these exemptions is therefore also of importance for determining to what extent protection on inventions in the protection of farm animals is obtainable. The relevant exemptions from patentability will thus also be analysed in the report. A natural point of departure for this kind of analysis is the TRIPS agreement. It establishes the general level of protection for patents in all its Member States. In Europe the scope of protection for biotechnological inventions has been subject to further legislation through the Biotech Directive (EC/98/44). Together with the TRIPS agreement it establishes the legal basis for the analysis in this report. In light of the relevant provisions of this legislation, a current pending PCT-patent application will be analysed to determine the possible scope of protection it would confer on the patent holder if granted.

Key Words

Patentability, process patents, farm animal production

Orders to:

Fridtjof Nansen Institute
Postboks 326
N-1326 Lysaker, Norway.

Tel: (47) 6711 1900
Fax: (47) 6711 1910
Email: post@fni.no
Internet: www.fni.no

Contents

Foreword

This report is based on my master thesis in law at the University of Oslo. The work was part of a project financed by the Nordic Gene Bank for husbandry. I would like to express my gratitude to everyone that has been a part of this process, especially Director cand. agric. Erling Fimland, Research Fellow Nina Alvilde Hovden Sæther, my teaching supervisor and mentor, Senior Research Fellow Morten Walløe Tvedt and all the researchers and staff at the Fridtjof Nansen Institute for allowing me to be a part of an eminent research environment.

Writing this thesis has been a great challenge for me. Hopefully it can help shed light on some of the many difficult questions that arise when one applies patent legislation to inventions regarding living matter.

Lysaker, December 2007

Magnus Finckenhagen

1 Introduction

1.1 Introduction to the subject matter of the report

This report analyses the scope of process patents in field of farm animal production, and rights conferred to the owners of such patents. Additionally the relevant exemptions from patentability for these processes will be analysed. A patent is a legal right conferred on an inventor in respect of a specific invention entitling him to prevent others different forms of utilization regarding the invention for the duration of the patent protection.[1] It can be characterized as a legal document that confers a twenty-year monopoly on the patentee, giving exclusive right to control the way the patented invention is exploited.[2]

The process patents to be analysed in the following can be characterized broadly as biotechnological inventions. A biotechnological invention is one involving a product of or containing biological material or a process by means of which biological material is produced, processed or used, or a product obtained by means of such a process.[3] Biological material is defined by the European Court of Justice as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.[4]

Currently, several patent applications on inventions regarding processes in farm animal production are pending at different patent offices around the world.[5] Some of these patent applications have been subject to debate and discussions even before there have been any indications of whether they would be granted or not.[6] The patentability of inventions in the technical field of biotechnology is currently on the agenda in both legal[7] and in other forums of discussion.[8] In addressing the situation concerning genetic resources for farm animals (AnGR), the Food and Agriculture Organization of the UN (FAO) 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.[9]

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[1] TRIPS Article 28, see also Bently and Sherman 2001, p. 309, Kolker 2000, p. 14, Stenvik 2006, p. 13.
[2] Bently and Sherman 2001, p. 329.
[3] Opinion of Advocate General Jacobs delivered on 14 June 2001, Case c-377/98. Kingdom of the Netherlands v European Parliament and Council of the European Union, section 3.
[4] Ibid.
[5] See Appendix.
[6] See Fitzgerald 2005, on the possible effects of patent application WO/2005/015989 and WO/2005/017204.
[7] E.g. implementation of the EC Directive on Biotechnology.
[8] E.g. FAO, Greenpeace, League of Pastoral Peoples, Nuffield Council on Bioethics et al.
[9] Rischkowsky and Pilling 2007, pp 279–289.

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,[10] (Emphases added).

Uncertainty regarding the scope of protection could be the result of applying the general system of patent protection to inventions in an area of technology that differs to some extent from the more traditional technologies. The most obvious difference is the ability of livestock to reproduce, a fact which complicates the process of identifying those animals to which patent rights should apply (if, for example, patented animals were to be bred with non-patented ones).[11] Furthermore long production cycles complicate decisions regarding when, for how long in the production cycle, and for how many generations the patent protection applies. Additionally the significance of these issues will depend partly on species and production system.[12] This could thus imply differences in the uncertainty regarding the scope of protection from species to species.

In the area of plant production it seems that policy-making, relevant legislation and subsequent case law have evolved further than in the case of animal production.[13] This development could help to clarify some of the uncertainties by drawing parallels to plant production. However, while there are differences among various species of animals, the differences compared to plants are even more extensive.

The FAO produced a Global Plan of Action for the sustainable use and preservation of animal genetic resources, and here the issue of the impact of intellectual property rights is also raised.[14] The legal effect of patents in farm animal production seems to have attracted considerable interest – from policy-makers on the international, regional and national levels, environmentalists, farmers and breeders of varying scales, to pastoralists and indigenous people. Since many of these *interests* can be considered to be third parties in regard to the patentee, the scope of protection for these inventions is of importance for legal predictability.

One goal of the patent system is to stimulate innovation for the public good and to reward people for useful new inventions.[15] The patent system aims to achieve this by granting to inventors exclusive (and time-limited) rights to exploit their inventions, while also promoting competition and

[10] Ibid
[11] Rischkowsky and Pilling 2007, p. 288.
[12] Ibid.
[13] See Hiemstra et al. 2006, p 18.
[14] FAO 2007 'Global Plan of Action' p. 19.
[15] Kolker 2000, p. 16.

innovation by ensuring that such inventions are fully disclosed to the public.[16] The system is intended to balance the *interests* of the public with those of the inventors.[17] This goal and balance could be seen as what legitimizes the patent system, and part of an analysis of the scope of protection is to look at the balance in this field of technology.

Recently, legal changes have been made in the field of patenting biological material. Of particular interest for this report is implementation of the EC Directive on Biotechnological inventions (EC/98/44).[18] Even though this directive specifically addresses the scope of protection for biotechnological patents, and to some degree regulates the extent of protection to the progeny of biotechnology, there are still uncertainties to the interpretation of the provisions, at least in part.

This report will investigate the *legal* framework of patent law on biotechnological inventions, more in particularly the scope of protection for process patents. As these patents concern inventions involving living material, several *moral* and *ethical* concerns and objections have been noted and discussed.[19] A general discussion of the moral and ethical issues of patentability on biotechnological inventions would fall outside the main object of this report, as this is a pure legal analysis. However, such concerns will be pointed out where relevant in the following.

The legal point of departure is that patents shall be made available for any inventions, whether products or processes, in all fields of technology.[20] This obligation pertains to all Member States of the WTO, through Article 27 of the TRIPS Agreement. For biotechnological inventions, in the EU/EEA this is specified in Article 3 of the Biotech Directive. This states that inventions that fulfil the general requirements of patent law, and are susceptible of industrial application, shall be patentable regardless of whether they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

As mentioned, this report focuses on the scope of patents regarding a process in farm animal production. By 'scope of a patent' is meant the extent of the exclusive right granted – in other words, which products or processes the patent-holder has an exclusive right to prevent others from exploiting commercially.[21] There is a relationship between the extent of this protection and an infringing use of the invention, since the protection conferred is to be determined by interpretation of the claims, and the

[16] Nuffield Council 2002, p. 12.
[17] Ibid.
[18] 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.
[19] Nuffield Council 2002, p. ix. The Nuffield Council on Bioethics released a report on the ethics of patenting DNA and concluded that, *inter alia,* ethical considerations should imply that granting of such patents should become the exception rather than the norm.
[20] TRIPS Article 27 requires this for all Member States of the WTO.
[21] Paterson 2001, p. 573

rights of the patent proprietor flow from the protection thus conferred.[22] There is, however, also a distinction[23] between the scope of protection offered and the rights conferred by the individual patent.[24] The protection conferred by a patent is determined by the terms of the claims,[25] and in particular by the categories of such claims and their technical features. In contrast, the rights conferred on the patent-holder are the legal rights which the law of designated state may confer upon the holder, for example, as regards the remedies available in respect of any infringement.[26] From a European perspective this would mean that determination of the extent (scope) of protection conferred by a patent under EPC Article 69(1) refers to what is protected, in terms of category plus technical features; whereas the rights conferred by a patent are a matter solely for the designated Contracting States, and are related to how such subject-matter is protected.[27]

For process patents this would imply that the scope of protection covers the processes described in the claims, and includes the subject-matter that is the result of the interpretation. Whether a third-party activity falls within the scope of a patent is also determined by the scope of the claim or claims.[28] The activity of the alleged infringer is compared with the process described in the claims. A patent consists of one or more claims, where a 'claim' is a single sentence which defines the monopoly sought.[29] In patent terminology, patent claims are normally divided into two[30] types: patents that grant an exclusive right to a physical entity (a product patent), and patents that provides an exclusive right to a physical activity (a process patent).[31] The reason for choosing process patents is that they, in addition to conferring exclusive right to the described process, extend the exclusiveness to material derived from the patented process to some extension. When this material is living and is capable of self-reproduction, several questions arise as to the scope of protection for such products and their offspring, and subsequently in regard to the breeders' and farmers' use of these animals. This implies some special considerations regarding the scope of indirect product protection. It extends to some degree to the future generations of the animals derived from the

[22] Paterson 2001, p. 577

[23] In Norwegian patent law this is referred to as the distinction between the *beskyttelsesomfang* of the patent and the *innhold* of the right conferred. See Ot.prp. Nr. 86 (2002-2003) p. 15.

[24] Paterson 2001, p. 577.

[25] See EPC Article 69(1), Norwegian Patents Act section 39.

[26] Paterson 2001, p. 577.

[27] Ibid.

[28] Kolker 2000, p. 15.

[29] Ibid.

[30] In some terminology a third form of patent is applied, 'use claims'. These are normally considered as subordinate to process claims and are often used when the product or process is non-novel and the novelty of the invention consist in using it in a new way or in a new field. See Stenvik 2006, p. 66.

[31] As described in the EPO case G 02/88 Mobil/Friction reducing additive [1990] EPOR 73 on page 79: 'There are basically two different types of claims, namely a claim to a physical entity (for example, product, apparatus) and a claim to a physical activity (for example, method, process, use).'

process – without, however, defining precisely what extent the protection limits the use of this offspring. Several process patents of this kind are currently pending in patent offices. [32] The implications of these patents have to my knowledge not been thoroughly analysed,[33] partly because this is a fairly new field of technology and lacks the case law that could establish a judicial precedent.

Also addressed in this report are the most relevant exemptions from patentability of biotechnological process patents. The scope of the exemptions from patentability and especially the exemptions on essentially biological inventions has been subject to court proceedings and assessed in patent theory. However, despite these proceedings and the care of the TRIPS negotiators in identifying the biotechnological inventions that may be excluded from patentability, 'a grey area has inadvertently been created: between essentially biological processes (the patentability of which may be excluded), on the one hand, and non-biological processes (the patentability which is mandatory), on the other.'[34] The language of the exemption in the TRIPS Agreement was inspired by the text of the similar exemption in the EPC.[35] The exemption in the EPC is derived directly from Article 2 of the Strasbourg Convention. At the time the Strasbourg Convention was signed in 1963, the potential importance of biotechnology could not have been predicted.[36] The growth of this area of technology has made determination of the scope of this exemption 'increasingly critical'.[37]

1.2 General purpose and background of patent law and its application to process patents for production of farm animal genetic resources

Emplacing limitations on the use of resources – whether through traditional private property rights or through intellectual property rights – has long been a debated issue. Despite this debate, most of the world's developed legal systems have had a system of patent law for some time.[38] The earliest known English patent, for example, was granted by Henry VI to Flemish-born John of Utynam in 1449.[39] Since patents are a form of property rights, the rationale for their justification is to be found within the justification of property rights in general.[40]

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[32] …the number of patents filed in the biotechnology sector at the United States Patent and Trademark Office and the European Patent Office on average increased by 13-15% p.a., compared to overall annualgrowth rates of only 5%.' (Report from the Commission to the European Parliament and Council / COM(2002) 2 final). See appendix.

[33] With a few exceptions: cf. Tvedt 2007a (forthcoming), Rothschild and Newman 2002.

[34] de Carvalho 2005, p. 217.

[35] Ibid.

[36] Paterson 2001, p. 438.

[37] Ibid.

[38] C-377/98 section 19.

[39] Ibid.

[40] Nuffield Council 2002, p. 12.

The economic rationale behind the patent system is partly based on the idea that if resources were to be put at risk to develop a new process or product, the inventor might hesitate, lest the expense prove irrecoverable. Potential competitors could simply, and without equivalent expense, pick up and use the successful results.[41] Thus the establishment of a patent monopoly, which enables the inventor to hold off the competition for a period, and ideally encourages the risk and use of resources to develop new industrial inventions.[42] On the other hand, if the monopoly is too extensive and acts to restrain the use of the patented process in an excessive manner, this could halt the progress and development of new technology. The rationale behind the patent system is therefore to provide a balance between the commercial interest of the patentee and the public utilization of progress in various fields of innovation. In other words, the patent system is meant to provide an incentive for the creation of new inventions by granting the inventor a reward, in the form of a time-limited exclusive right. This period of exclusiveness shall secure coverage for expenses and ensure the inventor an adequate profit. In return the patent-holder is obliged to publish the details of the invention as a part of the application process. This could in turn give an incentive to invent 'around' the invention, thereby leading to further progress and innovation in the field in question. Thus,

> intellectual property protection should contribute to technical innovation and the transfer of technology. Both producers and users should benefit, and economic and social welfare should be enhanced.[43]

Since general patent law is applied to the field of biotechnology, it could be assumed that the same rationale is used to legitimize exclusive rights to these inventions.[44] The extent of which the patent system creates an incentive to invest and invent is, however, difficult to measure, and the propensity of patents to promote innovation has at times been challenged.[45] While patents may serve to promote innovations, it must be recognized that once a new product has been developed or produced by a patented process, the existence of a patent inhibits competition and thereby reduces the availability of the product.[46] The balance between the two effects, and hence the outcome in terms of the economic benefits to society as a whole, is a matter of complex interactions between the length and scope of the patent and the nature of demand for the product.[47] With farm animal products, the demand is unquestionably present, and these patents are granted exclusivity for the same period of time as any other patent.

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[41] Kolker 2000, p. 16.
[42] Ibid.
[43] www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (accessed 1 February 2007)
[44] Biotech Directive's Preamble Recital 46.
[45] Rischkowsky and Pilling 2007, p. 286.
[46] Rischkowsky and Pilling 2007, p. 286.
[47] Ibid.

The question remains for the scope of protection, as to whether the nature of these inventions (capacity for self-reproduction) implies differences in the extent of the exclusive right. If the balance of the system is shifted, the patents could possibly be used as means to obtain favourable market positions. For example, Gura has stressed that hybrid pig lines are increasingly used so that breeding companies can make sure that their breeding lines are not used by others for further breeding purposes.[48] As a consequence, she claims, thanks to an aggressive policy of acquisition, cooperation and patent policy in cattle and pig genetics, companies may soon dominate gene markets with regard to livestock production.[49] Concerning the scope of protection for processes for the production of farm animals, these different interests might therefore have to be considered in order to give adequate protection. The inventor should be rewarded according to his efforts, but not exceeding this. If the scope of the patent protection is too broad, the inventor will be given an unintended benefit, which could result in a marked dominance or restriction on the use of animals, exceeding what the patent system intended. On the other hand, theoretically, if the patent system does not grant adequate scope, the inventor might seek other means to secure his exclusiveness, like concealment of the invention through trade secrets. In a wider socio-economic perspective this could inadvertently also lead to less innovation, as some of the incentive to invent might decrease or it might impede the possibility to invent around the invention.

Another aspect of the patent system is the balance between the effort invested by inventors and the extent of exclusive protection conferred on them. It could be argued that inventions involving a low level of inventiveness should accordingly be given a correspondingly narrower extent of protection.[50] For a traditional technical invention, the inventor's personal effort can normally be established, whereas with genetic resources more of the invention can be argued to exist already. First of all, the genetic resources that are utilized or further developed in a patent on a breeding process may have been subjected to thousands of years of natural selection. Second, many of the processes and also the genetic resources themselves have undergone generations of development and selection by man in the hands of farmers using of selective breeding.[51] In other words – the final product or process which materializes in a patent claim may not to the same degree be the work of the patentee, and it has been argued by the Canadian Biotechnology Advisory Committee: '[m]uch of the value of the higher life form, particularly with respect to animals, derives from the natural characteristics of the original organism and has nothing to do with the invention.'[52]

For process patents these arguments might not apply to the same extent, since the subject-matter of such inventions is some form of technical method or procedure. However, a process patent for the production of a

[48] Gura 2007, p. 6.
[49] Ibid.
[50] Stenvik 1999, pp. 743-749.
[51] Henson 1999.
[52] Canadian Biotechnology Advisory Committee 2002, p. 12.

farm animal confers rights also to the product of the process and to some extent the future generations of these products, and the value of these animals is a combination of the efforts of the patented breeding method and the natural characteristics of the animal. Furthermore, the animals used in the process are often selected on the basis of specific desired traits or qualities, and these traits might be the result of years of selection and cross-breeding. Although this is sought compensated by the requirement that the patent must be sufficiently novel and involve a certain inventive step, it stands to show that the commercial value of the patent might have been made possible through the efforts of natural selection or even selection by man. The general purpose and rationale of the patent system might require a different approach in this field of technology. The purpose of this report is to shed light on the interpretation of the relevant regulations to better understand some of these distinctive characteristics.

1.3 Relevant sources of law

Patent law is part of a complex legal picture: each patent is granted and enforced at the national level, whereas changes in the law occur at the international or regional level. The scope of protection of patents is determined by the national courts in an infringement proceeding. The point of departure for determining the scope of protection for process patents on animal breeding methods will therefore be an interpretation of the provisions of the national legislation and an interpretation of the patent claims as these are formulated by the patent applicant. There is to my knowledge no case law with direct relevance to the subject-matter of this report. The relevant provisions in the national legislation are, however, to some extent harmonized by international and regional agreements or conventions. The methodical approach of this report is therefore what obligations these international and regional regulations impose on the implementation and interpretation of national legislation regarding the scope of protection for process patents on animal breeding methods. The mixture of different patent regulations gives rise to interpretational questions, as some regulations are general and technologically neutral in nature, whilst others apply to a specific field of technology – in this case, biotechnological process patents in farm animal production. General obligations are thus imposed on a specific area, and the same scope of protection applies, without consideration of the possible specific characteristics of the subject-matter of the inventions.

The point of departure here for interpreting the scope of protection for process patents in animal breeding will be the obligations of international regulations on patent law, mainly the TRIPS Agreement. Harmonization in Europe will be analysed to determine what obligations the EPC and the EC Biotech Directive impose on Member States as regards the scope of protection for the same subject-matter. The main focus will be on the Biotech Directive, partly because it regulates patent protection for these inventions to a greater extent than the EPC, which is mainly a harmonization of the application procedure and granting of European patents. Furthermore, the Biotech Directive is currently in the implementation phase in the Member States.[53] The consequences have not yet become

[53] Tvedt 2007a, p. 3, (forthcoming).

evident, and the effect of this directive could be important to the patent applicant and to third parties involved in animal breeding.

1.3.1 International law

The international and regional regulations on patent law often oblige Member States to ensure that their national legislation complies with the provisions agreed upon. The point of departure when establishing these obligations is an interpretation that is to be

> in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.[54]

The starting point of interpretation should therefore be the 'ordinary meaning' of the terms of the treaty. However, these terms must be given a contextual interpretation in light of the purpose and objective.

1.3.2 European harmonization through the EPC

The Vienna Convention is not specifically applicable to the EPC, because it entered into force only for a limited number of countries and not for all Contracting States to the EPC.[55] Nonetheless, it has been recognized that the Vienna Convention provides a useful codification of the proper approach to the interpretation of treaties, and on the basis of this the Boards of Appeal have applied the Articles of the Vienna Convention to questions of interpretation of the EPC.[56] The point of departure when interpreting the obligations of the EPC should therefore be interpretation in good faith, in accordance with the ordinary meaning to be given to the terms of the treaty.

1.3.3 Interpretation of the EC Biotech Directive

Article 1(2) of the EC Biotech Directive specifically states that the Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements – 'in particular the TRIPS Agreement'. This implies that the TRIPS Agreement, which establishes the general scope of protection for process patents, could be a relevant source for interpreting the provisions of the EC Biotech Directive Article 8(2). On the interpretation of directives, EC law has developed a principle which obliges the national courts of the Member States to interpret their national legislation in accordance with directives, even those that have not yet been implemented.[57]

According to Article 253 of the EC Treaty, all legislative acts shall be supplied with a reasoning or explanatory rationale.[58] For directives this is done through a preamble.[59] The preamble of the Biotech Directive de-

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[54] Article 31(1) of the Vienna Convention.
[55] Paterson 2001, p. 24.
[56] Paterson 2001, p. 24.
[57] Sejersted et al. 2004, p. 50.
[58] Sejersted et al. 2004, p. 51.
[59] Ibid.

scribes, *inter alia*, the purpose, goals and objectives of the Directive, in addition to supplying guidance as to the interpretation of central provisions.[60] Some aspects of this Directive are mentioned only in the preamble, making the latter important for interpreting the provisions relevant to this report.[61]

According to Article 16 of the Biotech Directive, the Commission is required to produce reports assessing developments and implications of patenting biotechnological inventions. These reports are, according to Article 249 of the EC Treaty, not legally binding. However, according to case law of the ECJ, such reports are relevant for interpretation of Community law, and could therefore be relevant for interpretation of the Biotech Directive as well.[62]

1.4 Ongoing debate and controversy for patents regarding breeding processes for genetic resources

The grant of a patent confers a time-limited exclusive right to the patentee and the justification for such rights and the extent of these exclusive rights are to some controversial. When this system is applied to inventions for processes that yield products that are pre-existing in nature, it seems to evoke even more debate. Prior to the implementation of the Biotech Directive, which specifies the patentability and scope of protection for biotechnological inventions within the EU/EEA, but also generally in discussions on applying intellectual property rights to biological material, the debates have been many and wide-ranging. Kamstra et al. claim that the Directive on the Legal Protection of Biotechnological Inventions was one of the most contentious pieces of legislation ever passed by the European Parliament. [63] However, these discussions seem centred primarily on the concerns regarding product patents on genetic resources, whereas the implications of process patents and breeding methods for the production of genetic seem to have been given lower priority. However, the effect of a process patents could have similar implications, due to the indirect product protection. A process patent grant, in addition to exclusiveness to the process, an indirect product protection to the product obtained through the process. The controversies and discussions from the implementation process could therefore be relevant also for determining the scope of the protection for process patents, as they bring into focus the varying interests and considerations of patenting these inventions.

Another illustration of the debate comes from an environmental organization. At issue was a recent patent application[64] regarding a breeding method for swine production where the organization claimed that; 'this is a variation on a natural occurring sequence', and that the company filing the patent application 'didn't invent it'.[65] The controversy could be due to

[60] Matheson 2006, p. 8.
[61] For more on this see Sejersted et al. 2004, p. 51.
[62] Sejersted et al. 2004, p. 210.
[63] Kamstra et al. 2002, p. 1.
[64] WO 2005/015989.
[65] Fitzgerald 2005.

a misconception since the extent of these patents and the scope of the rights they confer on the patentee is unclear. Furthermore has been emphasized in patent theory that

> [t]he task of having to decide the types of subject matter that ought to be patentable invariably generates conflict and uncertainty. This is because patent law inevitably finds itself dealing with technologies that it may not yet understand. It is also because the task of having to decide whether to grant property rights in a particular type of invention raises a complex mix of legal, cultural, political and social questions.[66]

Some of the concerns mentioned above seem to be relevant for process patents regarding the production of farm animals. Biotechnology is an expanding field of technology, and the advanced forms used in breeding are fairly new.[67] It could take years to fully understand the technology involved in this field. This could create challenges to the legislation processes, and for the courts when establishing the scope of protection for these patents. It has also been held that as a specific field of technology becomes mature, application of the normal patent criteria (novelty, inventive step and industrial applicability) means that future patents will necessarily be limited in scope because the invention in question will have to be distinguished from the vast array of what is already known in the field.[68] But the converse might also be true: that when the technology is 'immature' it is difficult to establish what should be considered an adequate level of novelty and inventive step.

According to the OECD Compendium of Patent Statistics applications for biotechnology patents to the EPO grew by 5.1% a year between 1995 and 2003.[69] Also globally this field of technology seem to be seeing an increase in patent application. According to the same source, on average, Australia, Belgium, Canada, China, Denmark, Israel and the United States apply for more patents in biotechnology than in any other field.[70] This statistic does not disclose how many of these applications that concern process patents in farm animal production, or whether they were granted or not, but recent years have brought forth a few important court cases. The most debated are probably the Canadian Supreme Court case; Monsanto Canada Inc. vs. Schmeiser[71] and the Harvard Onco-mouse case[72] and the Novartis/Transgenic plant[73] from the EPO. The court

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[66] Bently and Sherman 2001, p. 362.

[67] Report from the Commission to the European Parliament Council Com(2002) 2 final: 'Recent decades have seen fundamental advances in the human understanding of the biology, molecular structure, genetic basis and ecology of all living entities.'

[68] Report from the Commission to the Council and the European Parliament, COM(2005) 312 final p 4.

[69] Organization for Economic Co-operation and Development, Compendium of Patent Statistics, 2006 p. 20. (www.oecd.org/dataoecd/5/19/37569377.pdf), (accessed 21 September 2007).

[70] Ibid.

[71] Monsanto Canada Inc. vs. Schmeiser, 2004 3CC 34.

[72] T 19/90 (1990) EPOR 501.

decisions to some degree draw up the premises for the evaluation of patentability and the scope of protection. However, when the courts determine the scope of protection, it is done on the basis of national legislation and foreign case law has only a subordinate relevance.[74] Furthermore, most of the case law thus far, seems to involve plant genetic resources. One reason could be that the body of policies and regulations has been developed mainly in the plant sector.[75] Some of the regulations and court cases, since also involving processes for the production of genetic material, can be relevant to the evaluation of animal genetic resources. For example, the scope of protection for these inventions is regulated by the same provisions of the Biotech Directive as for process patents regarding farm animals.[76] However, the legal issues seem to differ in certain ways compared to process patents regarding farm animal genetic resources. Some of these differences are pointed out in a recent study commissioned by FAO:

> While plant breeders aim at development of new varieties to replace old varieties, (…), farm animal breeding is largely based on selection of individuals within populations based on a continuum of genetic material rather than complete shifts to a new breed. The farm animal breeders are interested in individual animals and populations, while a plant variety is the main focus of plant breeders. [77]

If the invention concerns a process for the production of a new variety of a plant, the evaluation of the scope of protection would differ somewhat from a process for producing an improved specimen of an existing animal. A new variety would more clearly define the scope of the invention, whilst for the animal, the infringement proceeding could involve a comparison with an animal of the same breed and with similar characteristics.

There are also differences in the property rights to the genetic resources and also how they are utilized. Agriculturists will generally have to purchase seeds from the producer every year, thus making it less difficult for the patent-holders to enforce their rights. To utilize the protected genetic material, without owners consent farmers would then have to preserve seeds from their crops and use these instead of the licensed seeds. As for livestock farmers they will possess the genetic material for the whole length of the animals' lives – or even longer, if e.g. semen is frozen and preserved. This could make it more difficult to enforce the protection of the animals derived from the patented process, and might lead to uncertainties regarding the scope of protection of the progeny, if a farmer were to cross a patented individual with other animals in the herd. The outcome could be opposing or incompatible conflicting property rights and intellectual property rights. By contrast, in the case of an agriculturist

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[73] T 1054/96 (1999) EPOR 123.

[74] Practice from the EPO will have direct relevance for the Norwegian courts from Norway's entry to the EPC from 1 January 2008.

[75] Tvedt et al 2007a, p. 1.

[76] Article 8(2).

[77] Tvedt et al. 2007b, chapter 2.1.

this problem would be unlikely to occur since the farmer would not have any 'un-patented' genetic material to cross with the patented.

To summarize; the right to patent inventions regarding process for the production of farm animals still appears quite controversial. The debates sparked off by this controversy could shed light on some of the different interest that is considered to attain a balanced system. As the plant sector appears more evolved and has developed several bodies of policies and regulations,[78] and it seem to be more relevant case law involving patents on plants, these regulations and court decisions could make contribution to the evaluation in farm animal sector. Here it will be important to bear in mind the differences between the two fields as well.

The following chapter deals with to the methodical implications of the international character of the patent system, and gives a short presentation of the different regimes. Chapter 3 analyses the relevant exemptions from patentability for processes in farm animal production. Chapter 4 analyses the scope of protection of process patents and the rights conferred on the patentee through the provisions of the TRIPS agreement, the European Patent Convention and the EC Directive on biotechnology. Finally this is applied to the case of a current patent application in an attempt to analyse the scope of protection this specific patent will confer if granted, and the possible implications for the stakeholders.

[78] Tvedt et al. 2007a, p. 1.

2 Introduction of the regimes

2.1 Regional and international characteristics of patent protection

A patent, once granted, could lose some of its value if the exclusive right obtained in one country only; nevertheless, patents are legal identities which are territorial by nature. A patent, due to the principle of sovereignty, offers protection solely within the jurisdiction of the nation or nations that has granted a patent. The fact that a patent by nature applies only in the country where it is granted can make it necessary for inventors to protect their inventions in several countries. This has led to international initiatives of harmonization and the establishment of forums seeking to establish a common global or regional patent system. The first international regulation of industrial protection was the 1883 Paris Convention for the Protection of Industrial Property.[79] Since then other international and regional regulations have been established to harmonize the legislation and ensure a minimum level of protection globally or regionally.[80] The TRIPS Agreement regulates the patentability and scope of protection of patent rights for Members of the WTO. For the protection of biotechnological inventions, the Biotech Directive EC/98/44 provides regulations for the EU/EEA Member States. In addition, the FAO has recently negotiated a global plan of action for the conservation, sustainable use, and the fair and equitable sharing of the benefits from the use of animal genetic resources. These negotiations have not yet resulted in any treaties or other regulations, but the role of intellectual property rights in the sector is among the issues addressed.[81]

Despite various efforts, establishing a world patent system has proven to be difficult.[82] The principle of state sovereignty and differences in the need for intellectual property protection reflected in the material law has made it challenging to formulate a uniform system regarding all aspects of patenting. At present, there exists no form of 'global' patents.[83] However, the Patent Cooperation Treaty (PCT), governed by the World Intellectual Property Organization (WIPO), has established a system for international patent applications. It provides a route through which a single patent filing at a patent office can be effective in all countries of the PCT,

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[79] The Paris Convention is administered by the World Intellectual Property Organization (WIPO).

[80] In the *Journal of World Intellectual Property,* Vol. 8 No. 3 May 2005, Tvedt emphasizes that the Substantive Patent Law Treaty (SPTL) currently being negotiated in the Standing Committee of the Law of Patents will to some extent imply a further harmonization of patent law internationally. It would include a common understanding of standards governing the patent criteria, patent applications and patent claims, and their equivalent interpretation. See Tvedt 2007b, 'The Path to One Universal Patent', *Environmental Policy and Law,* Vol. 37, No. 4.

[81] For more information see www.fao.org/ag/againfo/programmes/en/genetics/angrvent2007.html (assessed 29 September 2007.)

[82] E.g. negotiations in the WIPO Standing Committee on Law of the Patents, which finally broke down in 2006 after years of deadlock: see Tvedt 2007b.

[83] Tvedt 2007b.

by enabling an inventor in the Member States to submit one application, which can eventually lead to patents being granted in all Member States chosen by the applicant on filing, (Articles 11.3, 22 and 24).[84] If a patent application is filed under the PCT, a prior art search is carried out and then the application, together with the search report, is sent to the patent office of each of the countries designated in the original application, so that they may examine the application and, if they so decide, grant a patent.[85] The PCT has no great influence on material patent law, which is the topic of this report. There are, however, currently several patent applications regarding processes for the production of animals pending in the system of the PCT/WIPO. Protection of these patents is sought globally or semi-globally, and will if granted be enforced nationally by the provisions to be analysed below. Furthermore, the international prior art search and a preliminary patentability assessment prepared through the PCT system could influence the granting procedures in the respective Member States. The PCT provides an applicant the automatic right to convert his international application into a national one.[86] By this time, the applicant will have received the international search report and is accordingly in a position to make further decisions as to the scope of his invention and the extent of international protection required.[87] In theory, the international search report could provide the basis for all further substantive examination of an application: in practice, however, further search is often made by the patent office of the countries that carry out an examination of the patent application.[88] On the other hand, the centralized procedure is of significant importance for the granting procedures in countries whose patent offices are not capable of undertaking their own examinations.[89]

The European system in the EPO has been developed partly because of the increasing number of European patent applications, and also the need for a uniform practice in processing the granting of such applications, and subsequent oppositions.[90] The European legal picture is multifaceted: the provisions of the European Union regulating the trade-related aspects of patent law in Europe are practised by the national legislators and courts and operate in addition the European Patent Convention governed by the EPO. These regulations are also subject to the international harmonization mentioned above. Furthermore, there is currently no common patent system as part of the EU.

The European patent system consists mainly of three elements: (1) the European Patent Convention, (2) EC regulations, like the Directive, and (3) national patent law of the contracting Member States. [91] From a national perspective – say, that of Norway – this implies that Norwegian

[84] Kolker 2000, p. 20, Stenvik 2006, p. 40.
[85] Kolker 2000, p. 20.
[86] Paterson 2001, p. 19.
[87] Ibid.
[88] Ibid
[89] Bently and Sherman 2004, p. 345.
[90] Paterson 2001, Preface.
[91] Dybdahl 1999, p 15.

legislators, the Norwegian Patent Office, the courts and third parties affected by patents in the area of biotechnology must take into account several partly overlapping regulations, case law and organizations. In addition some legislation and forums deals with the rights to, the preservation of and sustainable use of genetic resources. These do not, as a point of departure, have direct relevance for the courts in establishing the scope of protection. They could, however, illustrate some of the considerations implied by the contrasting interests. One example is the Convention on Biological Diversity (CBD), which entered into force in 1993. The CBD does not have an immediate impact on patent law; however, it could represent a change of attitude towards the way natural resources are exploited which may impact on the way patents are viewed.[92]

2.2 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

As intellectual property grew more important in international trade, the differences in national legislation became a source of tension in international economic relations. [93] The TRIPS Agreement sets forth principles and standards intended to ensure the availability of a minimum level of protection for intellectual property rights.[94] It is undoubtedly the most comprehensive international agreement on intellectual property protection ever established.[95] For patent rights it determines patentability and the scope of protection, and confers a set of rights to the patentee. However, it is technologically neutral: the same provisions apply for any field of technology. It stipulates that patent protection must be available for both products and processes, in all fields of technology.[96] All main elements of protection are defined: the subject-matter to be protected, the rights to be conferred, permissible exceptions[97] to those rights, and the minimum duration of protection.[98] Although the agreement establishes only minimum requirements, it contains a large number of regulations that oblige the Member States to apply a fairly extensive level of protection.[99] Failure to uphold this level of protection could result restrictions on access to foreign markets and international co-operation.[100] The TRIPS Agreement does, as mentioned, provide provisions for any inven-

[92] Bently and Sherman 2001, p. 322.
[93] 'Understanding the WTO': www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (accessed 1 February 2007).
[94] Correra 2007, p. 7.
[95] de Carvalho 2005, p. 28.
[96] TRIPS Article 27.
[97] Exemptions include inventions contrary to *ordre public* or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment; diagnostic, therapeutic and surgical methods for the treatment of humans or animals and plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.
[98] www.wto.org/english/tratop_e/TRIPS_e/intel2_e.htm (accessed 1 February 2007).
[99] Stenvik 2006, p. 36.
[100] Stenvik 2006, p. 38.

tion in all fields of technology.[101] This means that its provisions regulating the scope of protection apply for *any* patented invention, regardless of possible differences in the technologies. In their legislation, Member States must apply the minimum scope of protection for any patented process under TRIPS Article 28.1 (b), regardless of differences in technology. As discussed in chapter 1 there could be differences for patents regarding processes for the production of animals compared to other technical inventions, and these distinctions would not be accounted for in a technology-neutral agreement like the TRIPS Agreement. On the other hand, the fact that the provisions involve minimum standards does not mean that the TRIPS Agreement prohibits its members from applying a more extensive level of protection. Member States have national discretion regarding provisions extending beyond the minimum standards of the Agreement, and are permitted to specify such protection, as was done with the implementation of the EC Directive on biotechnology (see section 2.4).

2.3 European Patent Convention

The European Patent Organization was established according to the statutes of the Conventions on the Grant of European Patents (EPC). It provides a centralized system for granting European patents[102] in 37 European countries.[103] A patent granted by virtue of the Convention is called a 'European patent'; and, according to Article 2 of the Convention, a European patent has the effect of and is subject to the same conditions as a national patent granted by each state.[104] This would imply that if a process patent that confers protection on a breeding method for farm animals is granted by the EPO, it would come in effect in the European countries member to the EPC and specified in the application. This is stated in Article 64(1), which provides that a patent granted under the EPC shall confer the same right on the owner as a national patent granted in a contracting state. The legislation of the individual Member States would then have to enforce and determine the scope of protection for these patents, according to the standards set out in the TRIPS Agreement.

Legally, the EPC represents only a part of the European patent law. It regulates the central elements of the granting procedure of European patents: applications, management and granting of patents. As an additional effect of the EPC, the Member States have extensively harmonized their national patent law with the EPC material and procedural legislation.[105] The phase following the granting of a patent is generally left to national-level legislation – cf. Article 64(3), which states that infringement of a European patent shall be dealt with by national law.[106] However, as mentioned, the scope of the exclusive rights of patents is subject to the provisions of the TRIPS Agreement. Additionally, in order

[101] TRIPS Article 27.
[102] Paterson 2001, p. ix.
[103] www.epo.org/about-us.html (accessed 23 July 2007).
[104] www.epo.org/about-us.html (accessed 23 July 2007).
[105] Dybdahl 1999, p. 16.
[106] Kamstra et al. 2002, p. 47.

for there to be an effective single granting process, it was necessary for Member States to harmonize the basic rules of patent law, particularly in relation to the rules on patentability and validity.[107] Also, Article 64(2) specifies the rights conferred to the owner of a process patent. Although the primary function is to facilitate an effective granting procedure, this implies that the EPC might also influence the interpretation of the material law of the Member States, since the convention does include provisions on the scope of protection that the Member States must comply with. These general rules of patent law are, as mentioned, also harmonized internationally[108] as well as being subject to regulation and enforcement nationally. One consequence of this is that a patent granted at the EPO for two countries might be interpreted differently in each country.[109] This could mean great challenges regarding predictability for both the proprietor of the patent and the stakeholders operating in the field of technology for which the patent has been granted. The EC Biotech Directive deals with some of these challenges by further specifying the patent protection for biotechnological inventions in the EU/EEA.

2.4 The European Community

The harmonization process in the patent law of the European Union has been claimed to be not particularly evolved, considering that it commenced as early as 1959.[110] The first attempt at a common EU patent system was made through the establishment of the Community Patent Convention – which only nine Member States have signed since 1975. But while the European Community has not been involved in the reform of patent law to the same extent as in relation to trademarks and copyright, the Commission has been active in two areas:[111] concerning the duration of patents (via the Supplementary Protection Certificates scheme) and, more relevant for this report, biotechnological inventions.[112] The fast-expanding field of biotechnology has led to the implementation of a specialized directive.[113]

EC Directive 98/44/EC seek to ensure further harmonization of patent legislation regarding biotechnical inventions. It started from the premise that the subject-matter of an invention shall not be considered unpatentable solely because it is composed of living matter.[114] The Directive requires the Member States to protect biotechnological inventions under

[107] Bently and Sherman 2001, p. 316.
[108] E.g. the TRIPS Agreement.
[109] Bently and Sherman, 2001 p. 317.
[110] Stenvik 2006, p. 32.
[111] Bently and Sherman 2001, p. 317.
[112] Ibid.
[113] Cf. Preamble recital (1), which stresses the importance of regulations in this field: 'Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the *protection of biotechnological inventions* will certainly be of fundamental importance for the Community's industrial development' (emphasis added).
[114] C-377/98 subsection 7.

national patent law. It deals with the patentability[115] and scope of protection conferred on biotechnological inventions.[116] For process patents in farm animal breeding this implies that the Member States of the EU/EEA must confer rights to the process and the products from the application of the process, in accordance with the provisions of the Biotech Directive. In addition to introducing special defences,[117] the Directive also establishes a scheme for compulsory licences and cross-licences to deal with the overlap between patent and plant variety protection.[118]

The Directive requires EU/EEA Member States to protect certain biotechnological inventions under national patent law. This has given rise to questions as to the relationship between the Directive and the EPC, for example where there were conflicting regulations within the two. This was sought resolved by the EPO Administrative Council,[119] which aligned the EPC with the provisions of the Biotech Directive. The Council also provided that the Directive should be used as a supplementary means of interpreting the EPC. [120] As a result, the Recitals to the Directive can be taken into account where relevant[121] in interpreting the EPC. Furthermore, rule 23b-e has been added to the Implementing Regulations of the EPC and provides that 'Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.'[122] For the converse situation – i.e. as to the influence of the EPC on Community legislation, the Directive states in Article 1(2), that the Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements. Both the regulations of the EPC and the practice of EPO could therefore be relevant when interpreting the Directive and the implementations of EU Member States.

[115] Articles 1–7.
[116] Articles 8–11.
[117] Article 10 provides a specific regulation in regard to the exhaustion of these patents, whilst Article 11 establishes a rule of Farmers' Rights, both of which can be seen as a special defences against infringement accusations. The latter allows farmers to use animal reproductive material for the purposes of pursuing their agricultural activities. See also sections 4.5.1 and 4.5.2.
[118] Bently and Sherman 2001, p. 318.
[119] Bently and Sherman 2001, p. 319.
[120] Ibid.
[121] Ibid.
[122] Paterson 2001, p. 13.

3 Exemptions from patentability of inventions regarding processes for the production of farm animals

3.1 Introduction to the patentable subject-matter and the general requirements of patentability

In order to grasp the scope of protection we must establish an understanding of the processes that are exempted from patentability, and the link between the two. The general principle is that patents shall be available for any invention – this means products or process in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.[123] This principle (and obligation) is stated in TRIPS Agreement Article 27 as a general provision for the Member States of the WTO. The necessity for the presence of an *invention* can be considered in conjunction with the categories of excluded subject-matter.[124] First of all this would imply that a *discovery* cannot be subject to patent protection. Furthermore, most patent legislation provides a non-exhaustive list of things not regarded as inventions.[125] Finally there are some restrictions on the subject-matter which exclude certain categories from patentability. These exemptions apply to immoral inventions or inventions deemed contrary to 'ordre public', as well as inventions regarding any variety of animal or plant or any essentially biological process for the production of animals or plants. For the purpose of this report, the exemption regarding 'essentially biological processes' is the most relevant, since it in many ways demarcates the patentable subject-matter for inventions regarding process patents for animal breeding methods, thereby representing a demarcation of importance for the scope of the patent right.

3.2 Exemption from patentability for essentially biological processes

The general principle of patent law is that any invention can be subject to patent protection.[126] Nonetheless, the TRIPS agreement allows Member States to exclude certain subject-matter from patentability. In the area of

[123] TRIPS Article 27, EPC Article 52(1) and the Norwegian Patents Act sections 1–2. See also Bently and Sherman 2001, p. 362, Paterson 2001, p. 404, Stenvik 2006, p. 29. In addition to these general requirements, some theorists list a few internal requirements for patentability. These include: (1) the patent must disclose the invention in a manner that is clear and complete enough for it to be performed by persons skilled in the art (EPC Article 83), (2) the claims must be supported by the description (EPC Article 84), and (3) the patent must not be amended in such a way that it contains additional subject-matter, or extends the protection conferred by the patent (EPC art. 123(2)-(3)), cf. Bently and Sherman 2001, p. 457. As these can be regarded as requirements to the patent application and not patentability requirements for the inventions, they are less significant for this thesis and will not be further described.
[124] Paterson 2001, p 404.
[125] E.g. EPC Article 52(2)(3)
[126] TRIPS Article 27.

biotechnology, patent protection can be granted for all inventions except 'plant and animal varieties essentially biological processes for the production of plants or animals'.[127] In the following, an analysis of the latter exemption is presented.[128]

The point of departure in the TRIPS Agreement is that Article. 27.3 (b) opens for members to exclude from patentability

> *essentially biological processes* for the production of plants or animals other than non-biological and microbiological processes.' (Emphasis added)

The scope of this exemption from patentability must be established through an interpretation of the term '*essentially biological* process', and the point of departure is the 'ordinary meaning' of the terms.[129] According to the Oxford English dictionary, 'essentially' emphasizes the basic, fundamental or intrinsic nature of a person or thing, indicating that this quality is the most important one.[130] To qualify for exemption in the case of *essentially* biological processes, the biological element should therefore be the most important quality of the invention in question. A natural linguistic interpretation would thus imply that the degree of a human element in the process is decisive for the invention not to be essentially biological. In other words, whether the technical human element can be considered a necessary part of the invention or has a sufficient impact on the result of the process.

The exemption from patentability for essentially biological processes has been subject to interpretation in several cases in the EPO Boards of Appeal. Since the language of TRIPS Article 27.3(b) was inspired by the text of Article 53(b) of the EPC, it has been claimed that the jurisprudence of the EPO may be relevant for interpretation of the exemption in the TRIPS Agreement.[131] Strictly speaking, according to the principles of international law, the EPC should not influence the interpretation of the TRIPS Agreement, since the provisions of the former concern only those European countries belonging to the EPO.[132]

Whether a process is essentially biological will depend on the fundamental nature of the invention as it appears when the patent claims are interpreted. In the case T 320/87 (Hybrid plants/Lubrizol), the Technical Board of Appeal addressed the issue of whether a process (for the production of plants) is to be considered as 'essentially biological' within the meaning of Article 53(b) of the EPC. The Board stated that this would have to be:

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[127] See TRIPS Article 27.3 (b), EPC Article 53(b), EC Biotech Directive Article 4.1.
[128] For an in-depth analysis of the exemption regarding plant and animal varieties, see Bryde 2003.
[129] Cf. general rule of interpretation in the Vienna Convention on the Law of Treaties Article 31.
[130] Compact Oxford English Dictionary 2005.
[131] de Carvalho 2005, p. 217.
[132] Cf. Vienna Convention Article 34.

> judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved.[133]

The assessment seems therefore to revolve on the degree of human involvement in the process as well as its influence on the result achieved. However, the Board further emphasized that

> the necessity of human intervention alone is not yet a sufficient criterion for its not being 'essentially biological'. Human interference may only mean that the process is not a 'purely biological' process, without contributing anything beyond a trivial level.

This indicates a certain qualification of the human element in order for the invention not to be exempted. This specification was emphasized in the decision T 356/93 (Plant cells/Plant genetic system), where the Board stated that

> a process for the production of plants comprising at least one essential *technical step*, which cannot be carried out without human intervention and which has a *decisive* impact on the final result (…) does not fall under the exceptions to patentability under Article 53(b) EPC.[134] (Emphasis added).

A process should therefore not be excluded if a technical human intervention plays a *significant* role in determining or controlling the result:[135] the assessment depends upon the degree of human involvement in the process. The word 'essential' is considered to refer to the quality, not the quantity, of human involvement[136] It is not the amount of human or biological elements that are decisive, it is the *effect* of the technical element on the biological processes. A biological process can thus be a part of the invention as long as the technical elements are of the essence for the achieved result. The reason for this qualification of the human element seems to be that what is in principle essentially a biological process can, from a patent perspective, be regarded as having a certain technical character, thus qualifying in principle as an invention.[137] Therefore, the assessment of the exclusion uses the notion of technical character in a slightly different meaning.[138] Technical character here refers to a higher requirement of technicality than is required for the process to qualify as an invention. According to the interpretation of European case law, to meet the higher technical requirement it is necessary that there be at least one essential step with *decisive* impact for the end result.[139]

The question remains as to what these provisions actually exempt, in practical terms. Just which processes for the production of farm animals are *not* patentable under the provisions of the TRIPS agreement and the

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[133] T 320/87 point 6.
[134] T 356/93, point 28.
[135] See also Goldbach 1997, p. 284.
[136] Dybdahl 1999, p. 56.
[137] Westerlund 2001, p. 405.
[138] Ibid.
[139] Westerlund 2001, p. 406.

EPC? In today's modern agriculture, most breeding will involve some form of human involvement, so processes that are entirely natural would at least include animals mating without human assistance either on the farm or in the wild.

The guidelines for examination of the EPC present some examples of essential biological processes.

> A method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be *essentially biological* and therefore un-patentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation.[140] (Emphasis added).

These examples, together with the interpretation of the scope of the exemption according to the TRIPS agreement and the EPC, indicate that it is not permissible to patent processes such as an animal eating and growing, or the principle of an animal mating with another.[141] A certain human involvement in the breeding process, such as crossing or selective breeding, might also be excluded. However, beyond these examples it becomes harder to construct examples that would fall under the exemption, and thus be excluded from patent protection.[142]

In the EC Directive the exemption for essentially biological processes is further specified by the provisions in Article 2(2). Article 4 upholds the general exemption mentioned above, and in Article 2(2) it is clarified that for the purpose of the Directive.

> a process for the production of plants or animals is essentially biological if it consists *entirely* of natural phenomena such as crossing or selection.'(Emphasis added).

Article 4 uses the same term 'essential biological processes for the production of plants or animals'. However, from the specification in Article 2 (2), when compared to the wording in the TRIPS Agreement, it appears as though the discretion left in the latter to specify the exemption is used to narrow it, rendering the scope of patentability broader. For patentability this definition seems more favourable, since for exclusion it implies that the process must in its entirety consist of *natural* phenomena.[143] This provision is harmonized in the EPC by the provision in rule 23b (5). Compared to the provisions of TRIPS Agreement Article 27.3(b) and EPC Article 53(b), the provisions of the Biotech Directive and rule

[140] www.european-patent-office.org/legal/gui_lines/e/c_iv_3_4_2.htm (accessed 1 February 2007).
[141] Tvedt 2007a, p. 6 (forthcoming).
[142] Ibid.
[143] Westerlund 2001, p. 412.

23b (5) EPC exempt only processes that consist totally or completely of natural phenomena. This seem to imply a restriction on the exemption for European patents,[144] since what is an *essentially* biological process, in a literal understanding, does not necessarily consist of *entirely* natural phenomena.

The extent of the exemption from patentability for 'essentially biological processes' has been dealt with in several decisions from the Board of Appeal of the European Patent Office.[145] In the case T 0083/05 of 22 May 2007, the connection between the provision of 53(b) EPC and the provisions of the Biotech Directive was addressed.[146] It was stated that

> the wording of Article 2(2) of the Biotech Directive and rule 23b (5) in the EPC is, in the view of the board somewhat difficult to understand.[147]

The Board of Appeal interpreted the exemption in light of the legislative history of the provisions.[148] It was pointed out that the wording of EPC Article 53(b) is almost identical to the wording of Article 2(b) of the 1963 Strasbourg Convention on the Unification of Certain Points of Substantive Patent Law. The sole difference consists in that the latter provision is not a compulsory patentability exclusion: it merely provides the signatory states with the possibility of excluding the subject-matter mentioned therein from patentability in their national laws. Furthermore, Article 2(b) of the Strasbourg Convention excluded 'purely biological processes'. The Board stated that the new text meant to specify that the processes which may be 'ineligible for patents were essentially (and no longer purely) biological'.[149] The exclusion should be extended to cover processes which were fundamentally of this type even if, as a secondary feature, 'technical' devices were involved (use of a particular type of instrument in a grafting process, or of a special greenhouse in growing a plant) – it being understood that such technical devices may perfectly well be patented themselves, but not the biological process in which they are used.[150] The replacement of the narrower term 'purely' should imply that, according to the new wording, the exemption would have a broader scope than under the Strasbourg Convention.[151] The question remains as to whether the introduction of rule 23b (5) implies that the scope of the exemption due to harmonization with the Biotech Directive is further narrowed again. The Board considered:

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[144] Ibid: 'This definition brings the European practice closer to the U.S., which knows of no such exclusion.'
[145] E.g. T 0083/05 (2007), T 0356/93 (1995), T 0019/90 (1990), G 0001/98 – EBA (1999).
[146] The decision regarded a process for the production of plants, but the general statements on the interpretation could be of relevance since processes for the production of animals are exempted by the same provisions.
[147] Point 53.
[148] Points 38 to 42.
[149] Point 40.
[150] T 0083/05 p. 30-32.
[151] Point 42.

> that particularly when taking into account the adverb 'entirely', the wording of Rule 23b (5) EPC aims at a *very narrow* construction of the process exclusion contained in Article 53(b).[152] (Emphasis added)

However, in its interpretation of the provisions of 23b (5) the Board of Appeal emphasized one ambiguity in the wording:

> [o]n the one hand, only processes which consist entirely of natural phenomena are considered to be essentially biological processes for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena. This appears to be self-contradictory to some extent since the systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man.

On the background of this, the Board interpreted Rule 23b (5) EPC as meaning

> that a process which, apart for 'natural phenomena' (which appear to cover crossing and selection by way of legal fiction), contains an additional feature of technical nature would be outside the ambit of the process exclusion.[153]

In relation to the examples presented above, this should suggest that a process like crossing, inter-breeding or selective breeding would not be excluded if it contains an additional feature of a technical nature, even a small technical feature. One example might possibly be a technical feature for locating and determining the selection criteria in the genetic material of the animal.

In summary: the actual processes that fall outside the scope of patentable subject-matter appear to be relatively few. The EPO applies a very narrow construction of the process exclusion. Furthermore, it has been claimed in theory that it is a general principle in legal interpretation that an exemption from a general provision is to be construed in a narrow manner.[154] For patent protection in the EPC, document IV/2071/61-E of the historical documentation of the EPC Working Party stated: 'the concept of patentability in the European patent law must be as wide as possible'.[155] This has led to the principle of interpretation stating that, for the reason of being an exemption, exclusion from patentability for essentially biological processes should be read in a restrictive manner.[156] Thus, the point of departure in interpreting and determining the scope of exemptions from patentability is, at least according to EPO practice, that it should be read in a restrictive manner which implies a narrow construction of permitted exclusions. This principle is specified for patent exemptions in the above-mentioned decision of the Board of Appeal, T 0083/05 of 22 May 2007. The Board stated that Article 53(b) EPC repre-

[152] Point 54.
[153] Ibid.
[154] Goldbach 1997, p. 40.
[155] Referred to in Goldbach 1997, p. 40.
[156] de Carvalho 2005, p. 218.

sents an exception to the general principle of patentability as laid down in Article 52(1) EPC, and has to be interpreted narrowly.[157] The result appears to be an exemption with a limited scope of applicability, interpreted narrowly on the basis of the choice of wording, and also in nature of its being an exemption to the general rule of patentability. The exemption seems therefore not to reduce the scope of patentability for the production of biological material to any great extent.

With this in mind, we now need to look into the scope of protection for inventions that fall outside the remit of the exemption for 'essentially biological' processes.

[157] Cf. ECJ C-377/98 Para (38), which states that Article 53(b), as an exception, must be narrowly construed; see also T 0019/90 (1990).

4 Scope of protection for process patents in farm animal production

4.1 Introduction to the scope of patentees' exclusive rights to inventions on processes

A patent is a set of exclusive rights granted to the holder of the patent for a period of time. The set of rights conferred upon the patentee derives from the claims in the granted patent. The patent on a process protects the patentee's rights by entitling him to prevent others from performing the process described in the patent. Additionally the patent protection confers exclusive rights, to some degree, to the product obtained by this process. The scope protection is determined by interpretation of the patent claims,[158] where the point of departure is the wording of the claims, supplemented by the descriptions and drawings.[159] The description and claims, 'respectively, disclose the invention in a usable form, and demarcate the scope of the monopoly.'[160] The drawings provide a representation of the invention and may be used to interpret the claims.[161]

Because of the international character of the patent law, and the globalization of trade, conventions have been established aimed at harmonizing the scope of protection and establishing minimum levels of protection world wide.[162] When such agreements or conventions are established, they normally draw up general regulations for protecting patents in all fields of technology. The implications of the implementation in specific national legislation might differ, depending on the field of science to which the regulations are applied. The following will therefore address the general rules of patent law applied to one specific area of technology – farm animal breeding – and analyse the particular considerations this might create.

The most obvious difference regarding process patents in farm animal breeding is the protected material's ability to 're-invent' itself through self-reproduction. This implies that the scope of protection on the forthcoming generations is more difficult to establish. Using a patented process might give the patent-holder a legal position in relation to the offspring from the application of the process.[163] To establish the scope of protection one must determine for how many generations this applies, within the 20 year period of exclusiveness. Also, to what degree the legal position of the patent-holder applies to offspring subject to alterations outside of the described patented process. Another relevant issue regards the fact that these 'products' might not require the use of the patented process to self-replicate; and interpretational difficulties could occur regarding whether these products can be said to be 'obtained directly'[164] by the process.

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[158] Stenvik 2006 p. 362.
[159] Cf. EPC Article 69(1).
[160] Bently and Sherman 2001, p. 332.
[161] Bently and Sherman 2001, p. 339.
[162] See chapter 2.
[163] Tvedt 2007a, p. 18 (forthcoming).
[164] Cf. TRIPS Agreement Article 28.1 (b).

Appling patent law to processes for the production of animals could also have certain implications regarding traditional property. The issue has been raised of whether the scope of protection might lead to changes not only in intellectual property rights, but also in more traditional property rights of the owners of the animals. [165] It has been argued that, given the unique characteristics of biological inventions, granting the patent holder exclusive rights that extend not only to the particular organism embodying the invention, but also to all subsequent progeny of that organism, represents a significant increase in the scope of rights offered to patent holders.[166] It has also been argued that this represents a greater transfer of economic interests from the agricultural community to the biotechnology industry than exists in other fields of science.[167] The indirect product protection 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 patent-holder has the right to prevent 'using, offering for sale or selling' the product from the application of the process.[168] One part of the questions at hand is to what degree is the use of an animal, generations after the patented process has been applied, is restricted by the scope of protection conferred on the owner of the patent.

For inventions in most other fields of technology, the patentee's exclusive right as manifested in a patent claim ends at the first sale of patented goods.[169] The patented process remains the exclusive right of the patentee, but the rights to the product obtained through the process are exhausted by the first sale. For processes for the production of farm animals, the product itself has the capability to self-reproduce. If exhaustion occurs with the first sale of the product the right of the patentee could be eroded, if such exhaustion would imply that the user could now freely exploit the product for breeding purposes. This balance between patentees' rights to protect their inventions and farmers' rights to exploit their property, represented by the animals and flocks, will be addressed in the following, by analysing the degree to which a patentee may restrict the use of the product obtained by the patented process.

To a certain extent, Directive 98/44/EC seeks to compensate for some of the above mentioned differences, by more closely defining the patent protection for biotechnological inventions. The point of departure is, however, that the scope of protection granted for such inventions should be analogous to the protection of other technical inventions.[170] The question then becomes whether the character of these inventions might involve different implications that affect the scope of protection. In the annulment proceedings, the Netherlands actually argued that applying patent law to biotechnological inventions created a specific right, even a new intellectual property right, so that the Directive could not be said

[165] Canadian Biotechnology Advisory Committee 2002, p. 12.
[166] Ibid.
[167] Ibid.
[168] Tvedt 2007a, p. 18 (forthcoming).
[169] Osborne 2004, p. 646.
[170] Recital 46.

simply to 'harmonize' the national principles of patent law.[171] The argument was based on the assertion that a patent for biotechnological invention is a patent on life. Biological matter, in particular living animals or plants, could not be compared to non-living matter, which until recently was all that could be patented.[172] The fact that biological matter could reproduce without human intervention would make protecting it by patents different in kind from protecting dead matter.[173] The argument was dismissed on the basis that patents on life were in fact not new phenomena,[174] but the argumentation about the difference compared to traditional inventions could be relevant to the scope of protection for these patents. One reason for raising this issue could be found from a patent-theory perspective. One central concern in upholding the patent system, given its aim to promote technological development for benefit of society, is the balance between inventors and third parties.[175] As long as the inventor receives protection for his contribution, the incentive to innovation through the economic reward of patents will remain intact.[176] This in turn implies that protection beyond this would be unbalanced, but also that if protection were more narrow, that could lessen the incentive effect or encourage individuals or organizations not to disclose information about the inventions.[177] This issue was debated in the preliminary stages of applying patent law to biotechnological patents, and measures[178] were taken to make protection analogous to other technical fields. These measures will also be addressed in the following as they to a certain degree influence the exclusive right of the patent-holder.

The scope of protection to be established for process patents in the patent practice will eventually determine whether applying patent law to processes for the production of biological material will effect the correlation of intellectual property rights and more traditional property rights, by restricting the use of farmers' and breeders'animals. This chapter will analyse the relevant sources of law of that would form the basis of development for this patent practice.

4.2 Scope of protection under the TRIPS Agreement

The TRIPS Agreement specifies detailed requirements for the legislation of the Member States, with effective measures to ensure fulfilment.[179] As a result, TRIPS Member States are no longer allowed national discretion in intellectual property rights, or at least not without relinquishing their access to foreign markets and international co-operation.[180]

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[171] C-377/98 section 66.
[172] Ibid.
[173] Ibid.
[174] C-377/98 sections 68-70.
[175] Westerlund 2001, p. 77, Bently and Sherman 2001 p. 314.
[176] Westerlund 2001, p. 77.
[177] Bently and, Sherman 2001 p. 314.
[178] Biotech Directive Articles 10 and 11 and e.g. the pre-emptive measures addressed in the Norwegian implementation, see St. prp. Nr. 43 (2002-2003) chapter 7.
[179] Stenvik 2006, p. 36–38.
[180] Ibid.

The Preamble and the title of the Agreement refer to the trade-related aspects of intellectual property. The Agreement is to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.[181] However some analysts argued the TRIPS negotiations were not about freeing trade, but about changing domestic regulatory and legal regimes, and that virtually all dimensions of intellectual property rights are caught be the Agreements provisions.[182]

Of most interest for chapter 4 is Article 28.1 (b), which seeks to confer process-patent protection by ensuring a minimum scope of protection to the patented process and the product thereof. The term 'minimum scope of protection' implies that Member States are obliged to ensure at least this level of protection, but may also establish a broader scope of protection. The minimum level of protection conferred through the TRIPS Agreement has, however, been characterized to be fairly high and comprehensive.[183] 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 (…)
> 1. *the process and,*
> 2. *the product obtained directly by that process.*
> (Emphasis and numbering 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 processes in any field of technology. The Agreement does not, however, specify the extent of protection in cases where the material is capable of self-reproduction. The factual breadth of the claims is the subject-matter protected against, i.e. what is actually enforceable in an infringement suit.[184] The actual extent of granted claims is in fact not decided until an alleged infringement arises.[185] For patent-holders and third parties alike it is therefore vital to know as exactly as possible the extent of the exclusive right. The following will interpret the provision relevant to determine the scope of protection for processes for the production of farm animals and to the offspring from the application of the process.

Beyond the scope of protection Article 28.1 (b) specifies acts which the patent-holder entitled to perform in order to prevent others from performing as regards the process and the product derived from this. They include:

> (…) 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)

[181] TRIPS Agreement Preamble.
[182] Correa 2007, pp. 3–7.
[183] de Carvalho 2005, p. 28, Stenvik 2006, p. 36.
[184] Westerlund 2001, p. 180.
[185] Ibid.

Our first question thus concerns the extent of the patent: what can be said to fall within the protected process and the product thereof? Secondly, what forms of use may the patentee deny others from performing in regard to this process, and to what extent can the patent-holder restrict the use of the reproduced material? The latter will be addressed in section 4.4.

4.2.1 Scope of protection for the process for production of farm animals

Process claims may be drafted for various kinds of processes – for example, for processes applying chemical synthesis, genetic engineering (construction using cloned DNAs or preparation of mRNA and subsequently cDNA), isolation from a micro-organism or a combination of any of the above.[186] Once the biological material has been isolated, claims can be drafted for processes that apply the material in breeding methods and schemes to utilize the biological material in the production of a herd. This presupposes that the general requirements of patentability are fulfilled and that the process is not exempted from patentability, cf. chapter 3.

The scope of protection is, as mentioned, determined by an interpretation of the patent claims. Patent claims are the inventor's own description of what is sought protected by the invention.[187] Their function is thus to set out the scope of the legal protection conferred by the patent.[188] The exclusive right of the patent-holder vis-à-vis the described process would thus extend to the subject-matter established through an interpretation of the claim(s), where any use of the process described in the claims are covered by the exclusive right. In this interpretation the exclusiveness includes the literal understanding of the process, and also to some degree further than the literal understanding.

Patents will often include several claims, each of which confers an exclusive right upon the owner.[189] The system is therefore that each patent claim forms an independent subject-matter for an exclusive right. A claim might include several steps for the completion of the process. If a similar process does not fall within the direct interpretation of one of the claims, it might still be considered as infringing the patent. If it were so that a process would not be deemed to constitute an infringement merely by involving the replacement of only a small part of the claim, that could undermine the system of patent law.[190] The assessment must ascertain whether the similarity, despite the description, is evident enough for it to be an infringement. If the similarity is found to be present, even if one or more of the described steps have been left out or replaced, an *equivalent*

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[186] Goldbach 1997, p. 130.
[187] Stenvik 2006, p. 362.
[188] Bently and Sherman 2001, p. 336.
[189] This presupposes that the claims are independent claims. 'A statement in an independent claim describes the invention and can stand separately, while a statement in a dependent claim has to be read in conjunction with other claim descriptions, which in turn can be either independent or dependent.' (Westerlund 2001, p. 77). For a detailed review of the distinction between independent and dependant claims see Stenvik 2001, p. 316–322.
[190] Stenvik 2006, p. 363.

use of the patent has occurred.[191] The rules of claim interpretation, hereunder the doctrine of equivalence will be further addressed in section 5.1. The reason for mentioning it here is to point out that processes that does not fall within the strict literal meaning of the claims, to some extent is covered by the exclusive right of the patent-holder.

4.2.2 Scope of protection for the product obtained through the patented process – indirect product protection

The effect of TRIPS Agreement Article 28.1 (b) is, when the patented invention is a process, the scope of protection includes the product achieved as the result of that process. This exclusive right has long been accepted,[192] 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.[193] This protection is particularly important where no claim has been made to a related product as such. It is also important where the process is implemented outside the country of origin for the patent, and the product from that process is imported there.[194] The exclusive right to the patent concerns, due to the principle of territoriality, utilization of the process in the country where the patent is granted. The process can thus be utilized in other countries where the applicant for some reason has not received an exclusive right. The protection conferred on a patented process does not itself entitle a patentee to deny others the right to import from another country the product obtained by the process. An import possibility of this kind would, however, imply a substantial deterioration of the value of process patents. Conferring exclusive rights to the product obtained is an attempt to counteract this.[195]

The indirect product protection extends the protection of process patents to include products produced through the application of the patented process, whether the production has occurred in the country the patent is granted or elsewhere.[196] The interesting question is exactly how far-reaching this protection is. In other words, which products fall within the exclusiveness? For animal breeding methods, this becomes a question of for how many future generations the exclusiveness extends. Furthermore how extensive can the alterations of the offspring be, through cross-breeding and selection with other animals, and still be under the exclusive right. A relevant question in the extension of this: what acts of use of these generations are restricted without the consent of the holder of the exclusive right? The last question, regarding the use of the produced animals, will be addressed in section 4.4.

The point of departure for the determination of these question is the 'ordinary meaning' of the terms of the treaty.[197] TRIPS Article 28.1 (b)

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[191] Ibid.
[192] Bently and Sherman 2001, p 493.
[193] Stenvik 2006, p. 324.
[194] Bently and Sherman 2001, p. 493.
[195] Stenvik 2006, p. 324.
[196] Ibid.
[197] The Vienna Convention Article 31.

protects the products 'obtained directly' by the patented process. A literal interpretation of the word 'obtain directly' indicates that the protection includes products achieved through the application of the described process. The term 'directly' suggest a qualification of the products protected.

The wording of Article 28.1 (b) does not specify for how many generations to which the exclusive right will extend, but after the expiration of the patent, the patent-holder will not in any matter have exclusive rights to the patent. Furthermore, the wording does not specify, beyond the expression 'obtained directly' the extent of the exclusive right to the offspring. It has, however, 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.[198] (Emphasis added).

The assumption regarding the derivatives of the derivative does not follow directly from TRIPS Article 28.1 (b), which only confers rights to the products that flow from the process. The TRIPS Agreement is, however, a *minimum standards* agreement. The protection standard of the TRIPS Agreement shall cover any invention in all fields of technology and offer an *adequate* scope of protection.[199] If this shall apply for process patents on farm animal breeding it could suggest that the protection extends also to the 'derivatives of the derivative'. Otherwise the protection could be undermined before the 20-year period, and the protection might not be considered adequate according to the standards of the TRIPS Agreement.

The protection extends to all of the products fall within the remit of the patent. However, to ensure that the scope of monopoly is kept within justifiable limits, an important restriction is placed on the products that are protectable by process patents.[200] There must be a qualified connection or relationship between the patented process and the product thereof. In TRIPS Article 28.1 (b), this link is ensured by the words 'the product obtained directly by' *that* process. According to patent theory, the product must have obtained its substantial qualities through the use of the patented process.[201] Furthermore the product must not have lost its characteristics by further development.[202] This specification gives rise to interesting questions as to the breeding of farm animals. If the protected '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 them, has the 'product' then been 'further developed'? The assessment seems to concern whether the animal has lost its essential characteristics

[198] Bently and Sherman 2001, p. 493.
[199] See Preamble of the TRIPS Agreement.
[200] Bently and Sherman 2001, p. 493.
[201] Stenvik 2006, p. 34 and NU 1963: 6 p. 148.
[202] Stenvik 2006, p. 34 and NU 1963: 6 p. 148.

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. For the question raised above this should suggest that protection could extend to the offspring of a indirectly protected 'product' and a unrestricted animal only if the progeny possesses the essential qualities as these are expressed in the patent claims. The question remains as to whether this applies regardless of whether the patented process has been used to obtain the product. In other words, does the exclusive right extend to all future generations that can be said to possess the same characteristics, or does the exclusiveness require that the offspring was in fact produced by the patented breeding method? The term 'obtained directly by *that* process' seem to imply that the patented breeding method must have been utilized in order for the paten-holder to acquire exclusiveness over the offspring. On the other hand, the reference to 'at least the product obtained directly' in Article 28.1(b), could indicate that Member States may extend the protection conferred under process patents to products not directly obtained by the claimed process.[203] However, it has been argued that the provision 'does not mandate Members to go beyond what it provides for and doing so would dangerously blur the line differentiating process from product patents.'[204]

The extension of the protection applies regardless of whether the product is produced in the country where patent protection is granted or whether it has another origin. The term 'directly obtained' implies, however, that the provision does not protect against identical or similar products produced by other methods.[205] 'If an infringement is invoked, courts will normally determine whether the alternative process can be deemed 'equivalent or not'.[206] The relevant assessment when determining if one process breaches an existing patent must therefore involve evaluating whether the product can be assumed to have been made by means of the patented process. It can be difficult for a patent-holder to prove that the product in question has been produced by the patented process. This has led to a reversal of the burden of proof in Article 34 of the TRIPS Agreement: in case of infringement dispute, in some situations the burden of proof is to be shifted to the alleged infringer. The interpretation of TRIPS Article 34 and its implications regarding process patents for the production of farm animals will be addressed in section 4.6

An interpretation of TRIPS Article 28.1 (b) could suggest that the scope of protection for processes on farm animal breeding methods to some extent appears unclear. In particular this relates to the scope of the exclusive right to the product obtained by applying the process, and to the offspring of these 'products'. Some of these uncertainties have been addressed in the EC Biotech Directive, and the following section will interpret the relevant provisions regarding the scope of protection for process patents on farm animal production.

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[203] Correa 2007, p. 299.
[204] Ibid.
[205] Correa 2007, p. 298.
[206] Correa 2007, p. 298 (in footnote 108).

4.3 Scope of protection under European patent law

4.3.1 European Patent Convention

The European Patent Convention is principally concerned with the granting of patents rather than the scope of protection conferred.[207] When EPC was drafted it was decided that questions about the infringement of patents issued by the EPO were better dealt with by national courts.[208] Nonetheless, the close relationship between the validity and infringement has meant that decisions at the EPO have had impact on national law regarding infringement.[209] The provisions and case law of the EPO could therefore be of relevance for the 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.[210] 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 object of Article 64(2) and its national implementations is to confer a fair scope of protection to a patented process.'[211] The effect of Article 64(2) 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.[212] Consequently a European patent-holder must also be considered as having rights as regards the import of such products into designated Contracting States.[213] However, 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 simply states that protection extends to the products 'directly' obtained by the patented process, regardless of whether such products themselves are patentable.[214] Furthermore, the EPC represents a harmonization of the scope of protection through the wording of the provisions, the interpretation and use, however, is carried out by 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.[215] Moreover, there might be uncertainty regarding use of a patented process for the production of self-replicating material, since the use of the patented

[207] Kamstra et al. 2002, p. 47.
[208] Bently and Sherman 2004, p. 519.
[209] Ibid.
[210] Kamstra et al. 2002, p. 47.
[211] Kamstra et al. 2002, p. 48
[212] Paterson 2001, p 16.
[213] Ibid.
[214] Kamstra et al. 2002, p. 48.
[215] Ibid.

process might not be necessary for self-replication.[216] 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.[217] 'The product obtained by the means of the patented process was the product with which the process ended.'[218] 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'.[219] The relevant interpretation factor in a European perspective seems therefore to be the 'loss of identity' test,[220] which means whether the product obtained, subject to further processing, retained its essential characteristics.[221] 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. The question remains whether the specific character of biotechnological process patents requires different evaluation, and how courts will apply this.[222]

The scope of protection is, as mentioned, not of direct concern for the EPC. The extension of protection and claim interpretation are seen as belonging to the purview of national courts and legislators, whereas claim breadth is initially a matter for the Patent Offices, in this case the EPO.[223] The Technical Board of Appeal did, however, address the issue of scope of protection in the Biotech Directive compared to the provisions of Article 64(2) EPC. In subsection 87 the Board of Appeal states that:

> On the coming into force of the proposed EU directive, its Chapter II (Articles 8 to 11) would appear to require the national laws of EU member states to be revised, as this Chapter II *seems to give far more extensive rights* than Article 64(2) EPC, while at the same time introducing new possibilities for obtaining compulsory licences. But the Board considers that, like Article 64(2) EPC, these articles would be a matter purely for courts considering infringement and the relevant licensing authorities, and are not to be taken into account when a patent office considers compliance with the provisions of Articles 52 to 57 and 83 EPC, or national equivalents.[224] (Emphasis added)

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[216] Ibid.
[217] Paterson 2001, p. 587–588.
[218] Ibid.
[219] Ibid.
[220] 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 Gerald Patterson 2001 p. 588 and Stenvik 2006, p. 324.
[221] Paterson 2001, p. 587.
[222] See section 4.4.
[223] Kamstra et al. 2002, p. 47.
[224] T 1054/96 - 3.3.4.

The Board of Appeal appears to be of the opinion that the Biotech Directive does confer far more extensive rights to the owner of a patent on the process for the production of biological material. As the wording of EPC Article 64(2) is basically identical to Article 28.1 (b) of the TRIPS Agreement, the argument could also apply to the level of protection conferred through the TRIPS Agreement. In other words the rights conferred through the provisions of the EC Biotech Directive seem more extensive than the protection discussed in section 4.2 above. The perspective of the EPO Board of Appeal in case T 1054/96 could be relevant for the following, when the scope of protection will be addressed on the basis of an interpretation of the EC Biotech Directive.

4.3.2 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 inventions.[225] To achieve this, Articles 8 and 9 specify the scope of protection for biotechnological inventions. Furthermore Articles 10 and 11 provide new defences against infringement of the rights concerning biotechnological inventions.[226] As explained above, the scope of protection is determined by an interpretation of the patent claims (see also section 5.1 below). Within the framework of the interpretation, the rights conferred to the patent-holder are regulated in national-level legislation and are required to be equal, so that the legislation of the Member States is to be in accordance with the Directive.[227] The Biotech Directive does not specify which actions are subject to the control of the patent-holder,[228] thus making this a matter for national discretion within the framework of the obligations of the TRIPS Agreement.[229]

With this Directive, the European Union established certain special regulations regarding biotechnological inventions. However, by allowing patents on biotechnological inventions, the Biotech Directive also imposes patent law in general on an area of technology that differs from other areas. This had already been accomplished with the TRIPS Agreement's obligation to grant patents in all areas, but the Biotech Directive provides further specification. 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).[230] First of all, differences in national legislation were seen as something that might create trade barriers and impede the functioning of the internal market.[231] The problem could grow if the Member States adopted new and different legislation and if national case-law interpreting such legislation developed differently.[232] Implementation of the Biotech Directive did not,

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[225] See Preamble Recital 46.
[226] Bently and Sherman 2004, p. 546.
[227] Sejersted et al. p. 76–77.
[228] St.prp. Nr. 43 2002–2003, p. 38.
[229] See section 4.4.
[230] Preamble recital (46).
[231] Preamble recital (5).
[232] Preamble recial (6).

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 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 by the obtained material. The uncertainty about exclusive rights to future generations of the product of a patented process is thus to some degree specifically addressed.

The Preamble (in 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 Biotech Directive could thus be seen as the means by which the European Union intended to employ the flexibility in the TRIPS Agreement to specify obligations regarding biotechnological inventions. The question is then what this fulfilment implies, through an interpretation of the provisions in the Directive, regarding 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 Biotech Directive provides

Article 8(2) of the 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:
>
> 1. *extend to biological material directly obtained* through that process and to**,**
>
> 2. *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. (Numbering and emphasis added)

The Biotech Directive states that, in addition to the process itself, the scope of protection extends also to material 'directly obtained' by the process. In this part of the wording, the protection is practically identical to that of the TRIPS Agreement, and does not differ in scope from what was discussed in section 4.2. This part of Article 8(2) establishes the scope of protection for the first generation of an applied breeding method. The logical next step would then be to interpret the extent of protection conferred to subsequent generations of this animal. Article 8(2) states that the scope of protection includes 'any other biological material' obtained through multiplication of this material. This goes further than 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'.[233] Correspondingly, protection under Article 8(2) extends further than that provided under TRIPS agreement Article 28.1 (b), or at least according to what can be read directly in the wording of Article 28.1 (b). The patent-holder is granted exclusive rights to commercial exploitation of the process, to the animals 'directly' produced by this process, and moreover to their offspring.

The Biotech Directive thus offers more extensive protection for process patents. The following will analyse the details of this extension to establish the possible implications for process patents on farm animal breeding methods.

The first interpretational question refers to what subject-matter is covered by the scope of protection. 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 seem to indicate that the semen and embryos of the animals produced may is also under the exclusive right of the patent-holder.

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'.[234] 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'.[235] According to the Oxford English Dictionary, things that are 'divergent' are 'very different, or opposing, in attitudes or characteristics'.[236] For processes in farm animal breeding this could seem a rational solution as it would allow for natural genetic variation. On the other hand, the term 'divergent' could imply a protection that would cover almost any animals that had some connection to the applied process, even those with opposite or very different characteristics.

It is not certain whether a court would apply this broad meaning of the term if an infringement case regarding the use of future generations of a 'product' produced by a patented process were brought before them. In fact, the term is somewhat unclear. It limits protection to animals possessing the same characteristics; however, these may appear in a divergent form – and, according to normal English usage of the term, things that are 'divergent' are different *inter alia* in their characteristics.

The ambiguity regarding the interpretation of this term has been addressed in the patent literature. Kamstra et al.[237] have noted some possible difficulties that the courts will have to address based on the

[233] Kamstra et al. 2002, p. 49.
[234] Kamstra et al. 2002, p. 49.
[235] Ibid.
[236] Compact Oxford English Dictionary 2005.
[237] Kamstra et al. 2002, p. 49.

regulations in Article 8.[238] First of all, there is the question of whether implementation of Article 8 in the national legislation of Member States must extend protection to material that possesses characteristics of material defined by the claims of a patent which would otherwise not be covered by the claims. This question is further elaborated to whether the scope of protection should extend to 'divergent' biological material whose possession of the 'specific characteristics' would not be obvious or predictable from its derivation from the original material (possessing these 'specific characteristics') produced through the application of the invention.[239] Kamstra et al. concludes that these questions are unfortunately not answered in the implementing texts so far seen in the Member States.[240] This implies that the courts of the Member States will have to rely mostly on the wording of the Directive when establishing the scope of protection in an infringement case. 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.[241] 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 broad scope of protection.

A related question is how to determine, through interpretation of the wording of Article 8(2), when the exclusive right is exhausted. For how many generations/multiplications will the patent confer 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. However, a natural point of departure would be that, after the expiry date of the patent (normally 20 years), the patent-holder will no longer have exclusive rights to the process nor the products obtained.[242] The question remains as to how many propagations or multiplications the exclusiveness covers – and here it would seem to extend to all future multiplications within the period, as long as they possess the same characteristics as the biological material produced by the patented process. The term 'obtained directly' seems, however, to open for the question of whether the exclusiveness covers *any* subsequent material of the process regardless of whether the process was employed, or whether it is required that the patented breeding method must be used continually on the animals obtained, in order to attain exclusive rights to the offspring.

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[238] 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.
[239] Kamstra et al. 2002, p. 49.
[240] Ibid.
[241] Report from the Commission to the Council and the European Parliament, COM (2005) 312, pp. 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.
[242] Tvedt 2007a, p. 18 (forthcoming).

Article 8(2) specifies that the protection offered shall extend to biological material directly obtained through *that* process. This is, however, specified only in relation to the first generation. For subsequent progeny and material this specification is not repeated, although it is required that the biological material is derived for the obtained material 'through propagation or multiplication'. The term 'propagation or multiplication' could thus indicate that subsequent generations are protected regardless of whether *that particular* process was applied. The practical implications of this are difficult to foresee. It might, however, be that patent-holders maintain their exclusive rights to the animals regardless of how the offspring are multiplied by farmers.

In addition, the question of when the patent right is exhausted seems imply interpretational intricacy regarding the requirement of a qualified relationship between the product obtained and the ensuing progeny. How substantial must the differences be before an animal can no longer be said to possess the 'same characteristics'? And would cross-breeding with an unpatented animal mean that the resultant progeny are no longer protected? A particularly complicated assessment would apply to future generations of the 'product' derived from the process if these have been altered. If the 'products' are used in a herd, cross-bred with other individuals not possessing the same characteristics, to what degree of protection are these individuals entitled? Considering that the exclusiveness could cover obtained 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'. As a point of departure, this would be based upon how the characteristics the process is to improve are described in the patent claims. However, this seems also to imply assessments of a biological character. 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 identity[243] 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 possessing similar desirable health traits, how can it be determined whether those specific characteristics originate from the patent-protected animals? The term 'possessing those same characteristics' could also pose difficulties regarding natural genetic variations in the animals. Even if the patented process is applied, natural genetic variations could appear in future generations.

The previous interpretation of the Biotech Directive will in the following be evaluated in light of the general perspectives of the patent system and the evaluations indicated in the Preamble of the Directive. The rationale for the specification in Article 8(2) regarding the scope of protection could be found in consideration for the rights of the patent-holder, and the value of this patent to the owner. When the material has the capability to 're-invent' itself through self-reproduction, others could exploit the value

[243] Cf. the 'loss of identity test', see section 4.3.1.

of the invention by freely using the offspring. The patentee could then not have exclusive rights throughout the entire 20-year period if the protection does not extend to all future generations. This argument was upheld by the European Court of Justice in the opinion of Advocate General Jacobs in the Annulment case C-377/98.[244] 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.'[245] This principle has been incorporated in international patent legislation since at least 1958.[246] The rationale for this conferred right is given in section 121, where the Court states: '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.'[247] And in section 123 it is 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.'[248] However, the long-established principle to which the Court refers to was implemented at a time when the potential importance of biotechnology could not have been predicted.[249] It could therefore appear to have slightly different application for traditional inventions than for self-reproducing material. The principle is found in Article 5 *quarter* of the Paris Convention:

> when a product is imported into a country of the [Paris] Union [for international protection of industrial property] where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, *with regard to the imported product*, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country.[250] (Emphasis added.).

Therefore, according to a literal interpretation, the principle seems to apply to rights only to the import of the 'first' product of the process for consumption. The specification in Article 8(2) does, however, imply restrictions on the use of subsequent material of the 'first' product. The intention of the principle in the Paris Convention seems therefore to be of a slightly different nature. On the other hand, no restrictions on the future generations or on the biological material of the obtained product could enable reproduction of the product by multiplying it through breeding, or by selling the semen or embryos for that purpose. More generally, this issue relates to the balance between investment and potential reward for the patent-holder in a field, compared to subsequent innovators and users.[251] However, economic evidence is hard to come by,[252] and it is

[244] C-377/98.
[245] C-377/98 section 122.
[246] Article 5 *quarter* was inserted in the Paris Convention in 1958.
[247] C-377/98 section 121.
[248] C-377/98 section 123.
[249] Paterson 2001, p. 438.
[250] Cited in Opinion of Advocate General Jacobs delivered on 14 June 2001, C-377/98 (in footnote 137).
[251] Report from the Commission to the Council and the European Parliament, COM (2005) 312, p. 4.
[252] Ibid.

difficult to assess empirically to what degree the potential scope of protection in either direction would influence innovation and development. The ECJ seems to be of the opinion that protection of future generations is necessary to make biotechnological process patents effective. The interpretation made by the ECJ is based *inter alia* on the Preamble of the Biotech Directive, where Recital 46 states that such extension of scope is necessary to ensure the reward to which the inventor is entitled for his efforts:

> 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.)

This same Recital does also specify how the protection on future generations is to be stipulated. 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. First of all this would imply 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. Protection in situations analogous to the protection regarding non-self-reproducing products would, however, directly cover only the first 'generation'. For non-biotechnical material, protection extends to the product obtained by the process. On the other hand, one could hardly imagine a non-biological product self-reproducing. 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, if bred with another animal. Analogous protection with non-self-reproducing products thus seems not to be possible: 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 (which would limit the use of the product beyond what an analogous protection would). The broader scope of protection of Article 8(2) could be explained from these differences. On the other hand, the justification might not be equally evident for all stakeholders, as the Preamble clearly states that the patent-holder should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those situations where the patent-holder of a non-self-reproducing product could deny such application.

The Preamble further emphasizes that it is of great importance for the economic development of the European Community to make conditions favourable for development in this sector.[253] The economic incentive held to be created through the patent system was considered of high importance to the European Community,[254] necessitating regulations to ensure

[253] Preamble recital (3).
[254] Preamble recital (2)

that such an incentive would emerge. On the other hand, 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.[255] This applies also to breeding methods on farm animals and the genetic material obtained by applying such methods. The paramount objective is to create technical innovation without unreasonably restricting the use of the invention by others.[256] 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 Biotech Directive favours the patent-holder to a larger extent, by overly restricting the use of future generations, the balance is not maintained. On the other hand, 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 the farmers' herds, constantly evolving through continuous breeding.

As seen in Recital 46 of the Preamble, the basis of comparison is the extent of protection for other non-biotechnical inventions. This implies that general patent law is relevant when establishing the scope of protection for self-reproducing material. However, it is less certain how the scope of protection for other inventions can offer interpretational value for self-reproducing inventions. The very fact that the inventions are self-reproducing implies a certain distinction. The Preamble does not indicate that inventors in the field of biotechnology are to be rewarded to a different extent: simply that the inventor shall be given an adequate reward considering his efforts and his contributions to the field.

The question of an adequate scope of protection for these patents can 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 these patents to be available for patent protection.[257] 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 no case law to indicate whether the result of applying general patent law to living material *de facto* leads to a wider scope of protection for future generations of the inventive process, than in other fields of technology. The wording in the Biotech Directive Article 8(2), however, seems to imply a fairly broad scope of protection. Furthermore, the Preamble is clear in its statements that the development of this field is important and necessitates sufficient protection of biotechnological inventions.[258] As a result, Article 8(2) appears to oblige the national legislation of Member States to extend protection to material that would not otherwise be covered by the claims of the patent, since it

[255] Westerlund 2001, p. 77.
[256] St. Prp. Nr. 43 2002– 2003, p. 55.
[257] Report from the Commission to the Council and the European Parliament, COM (2005) 312, p. 4.
[258] Cf. Recitals 1 – 2.

includes material possessing the characteristics of the material derived from the obtained material in a *divergent* form. To some extent, the provisions of Article 5(3) seek to compensate for this. The Community legislators had intended at least to raise the possibility of a limited scope of protection covering only the specific industrial application identified in the patent.[259] Article 5(3) states that the industrial application must be disclosed in the patent application. However, this applies only to a sequence of a gene or a partial sequence of a gene. Article 5(3) seemingly concerns only product patents, so some uncertainty remains as to the use of subsequent biological material of an applied breeding process.

Although the wording of the Biotech Directive indicates a fairly broad scope of protection, other sources (e.g. considerations of the objective of patent law) could call for a more strict interpretation. In many ways, 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. Furthermore the invention might involve improving species that have been developed through cross-breeding and natural selection for hundreds of years. The argument of adequate reward might therefore have less relevance for these inventions, since the patented process represents only the latest step in a continuous, long-established breeding process. Then again, to develop new and improved breeding methods might require high costs of research and development, and the general idea is that the patent system might help to recoup these costs. This is stressed *inter alia* in the Preamble, Recital 1-3: [t]he protection of biotechnological inventions will certainly be of *fundamental importance* for the Community's *industrial development;*[260]

> [i]n the field of genetic engineering, research and development require a considerable amount of high risk investment and therefore *only adequate legal protection* can make them profitable;[261] [e]ffective and harmonised protection throughout the Member States is essential in order to maintain and *encourage investment* in the field of biotechnology.[262] (Emphasis added).

The question remains as to what degree this 'adequate legal protection' (as provided through the Biotech Directive) to make investments in the field of biotechnology profitable, restricts the use of animals and subsequent generations.

4.4 Acts of using that the inventor can prevent others from performing in regard to the patented process and the product obtained

After establishing what processes and products from the application of the process fall within the exclusive right of the patent-holder, we need to ask what acts of use the patent-holder can to deny others to perform regarding this subject-matter. The focus of sections 4.2 – 4.3 on the scope

[259] Ibid.
[260] Recital 1.
[261] Recital 2.
[262] Rectial 3.

of the processes or products subject to the exclusive right has now shifted to which activities the patent-holder can deny others to perform regarding this process or products.

The TRIPS Agreement lists the various elements that form the right to exclude others from exploiting the invention.[263] 'Patents accord the right to exclude, not to use. The right to use arises from economic freedom, not from the patent.'[264]

Determining patent infringement can be separated into three tasks.[265] First it is necessary to determine the types of activities that constitute an infringement. The following section will examine the types of activities that constitute an infringement of a process patent in farm animal breeding. Second, it must be ascertained whether the activity in question falls within the scope of the patented monopoly (sections 4.2 – 4.3.). In other words, the scope of the exclusive right to the process or the products obtained. Third, it needs to be determined whether the defendant is able to make use of any of the available defences to infringements. In connection with implementation of the Biotech Directive some specific defences were introduced for the infringement of biotechnological inventions. Section 4.5 examines the defences relevant to the protection of process patents in farm animal breeding.

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) provides that a person infringes a process if he or she uses the patented process. Furthermore, infringement can occur if a person uses, sells, offers to sell or imports any product derived from that process.[266] The Biotech Directive does not, as mentioned, specify which acts are subject to the control of the patent-holder,[267] thus making this a matter for national discretion within the framework of the obligations of the TRIPS Agreement.

'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. The assessment of whether the alleged infringing process implies an identical use of the patented process is a matter of an interpretation of the patent claims. If the use does not fall within the direct meaning of the claims, then one must assess whether it is sufficiently similar to constitute an infringement.[268] The doctrine of equivalence implies that, if the alleged infringing process cannot be said to derive directly from the patent claims, such utilization might still be considered

[263] de Carvalho 2005, p. 247.
[264] Ibid.
[265] This division is based on Bently and Sherman 2004, pp. 519–520.
[266] Bently and Sherman 2004, p. 528.
[267] St.prp. Nr. 43 2002–2003, p. 38.
[268] Stenvik 2001, p. 578.

as an equivalent use of the patented process. [269] The doctrine of equivalence thus expands the patent protection beyond what the patent-holder described as his invention. 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.[270]

Given the territoriality of patent rights, as a general principle, process patents can be used to prevent third parties from using the patented process only in a country where the patent has been granted.[271] The patent-holder cannot, however, as a point of departure, prevent the making and sale of the same product resulting from the patented process if it has been obtained through a different process.[272] Nor can the patent-holder prevent the making and the sale if the patented process was applied in a different country.[273] The TRIPS Agreement does, however, confer rights to products that are obtained by the patented process. This so-called 'indirect product protection' extends the protection conferred on process patents to include products that are produced by application of the patented process, regardless of whether the process was executed in the country that granted the patent or elsewhere.[274] The extension to at least the products obtained directly by the patented process thus confers a certain element of extraterritorial effect to the use of the process in a foreign jurisdiction.[275] Article 28.1 (b) does not, however, cover cases where the product is *obtainable* by the patented process but evidence of the use of the patented process is not supplied.[276] However, an obligation to provide such evidence can, at the discretion of the courts, be bestowed on the alleged infringer.[277] Additionally, as addressed in section 4.3.2, the Biotech Directive specifies indirect product protection to include 'any other biological material derived from the directly obtained biological material'. This implies that utilization of the products derived that are subject to the control of the patent-holder also covers the progeny of the obtained material, to the extent of the provisions of Biotech Directive 8(2).

The right to deny permission for the 'use' of the product obtained would, according to the wording of Article 28.1 (b), imply that the patent-holder can prevent the further use of a product that was made by the patented process. For process patents in farm animal production this implies that the use of the first generations of an applied breeding process is restricted according to the process patent-holder's rights. The exclusionary right does, as a point of departure, not extend to uses of the products marketed

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[269] Stenvik 2001, p. 578.
[270] Ibid. For a detailed review of 'equivalence' see Stenvik 2001, chapter 9 and Westerlund 2001, chapter 5.
[271] Correa 2007, p. 298.
[272] Unless the alternative process is considered equivalent to the patented process.
[273] Correa 2007, p. 298.
[274] Stenvik 2006, p. 324.
[275] Correa 2007, p. 298.
[276] Correa 2007, p. 298.
[277] See section 4.6.

by the patent-holder, domestically or internationally, where this is subject to exhaustion of rights.[278] Article 6 of the TRIPS Agreement disclaims any intent to limit the Members' freedom to regulate the issue of exhaustion of rights.[279] The principle of 'exhaustion of rights' may be applied at the national, regional or international level. Applying the principle regionally would imply that exhaustion is deemed to have occurred if commercialization took place in a country member to a regional agreement.[280] The principle of exhaustion has been applied in the European Community, on the basis of jurisprudence elaborated by the ECJ, to avoid exercise of discriminatory policies by patent-holders within the Community.[281] 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.[282] However, the doctrine of exhaustion leaves some uncertainty in regarding the use of produced animals for multiplication through breeding. The provisions of TRIPS Article 28.1 (b) apply to any technical field, and the exclusionary right does not extend to uses of the product marketed by the patent-holder where subject to exhaustion of rights. The extent to which the European doctrine of exhaustion of rights applies to material derived from the material placed in circulation by the patent-holder has not been addressed by any court.[283] Kamstra et al. state that it is reasonably clear that the doctrine of exhaustion will apply to products obtained sold with the authority of the patent-holder within the EU/EEA.[284] It is, however, not clear whether the doctrine applies to material derived from the 'patent-exhausted' material.[285] In other words, whether the utilization of the products produced by the sold or licensed product is exhausted by the first sale. The agreed terms between the patent-holder and the purchaser/user could possibly stipulate terms of use of future generations, but in the absence of such a contractual regulation, the use would have to be determined by the doctrine of exhaustion. Since much of the value of a patent in farm animal breeding can be said to originate from 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 patent-holder could be argued to have a need to uphold the exclusive right beyond the first sale or use of the protected process, since otherwise the protected invention might be reproduced simply by breeding the animals. The point of departure is that the doctrine of exhaustion does not give the purchaser a right to produce new specimens of the product exhausted.[286] Nor does the doctrine, as general

[278] Bently and Sherman 2004, p. 13.
[279] Correa 2007, p. 78 cf. 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.'
[280] Correa 2007, p. 79.
[281] Ibid.
[282] Bently and Sherman 2004, p. 524.
[283] Kamstra et al. 2002, p. 53.
[284] Ibid.
[285] Ibid.
[286] Stenvik 2006, p. 340.

principle, give the right to practice a patented process.[287] The special characteristics of patents on breeding methods could imply that these general principles also come into effect on the material derived from the patent-exhausted material.

Regarding the products obtained by the patented process, the patent-holder can also deny others the right to 'offer for sale' and 'sell' the products. 'Offering for sale' covers acts made with the intent of selling the product(s) obtained by the process.[288] 'Selling' implies the right to prevent the sale and resale of infringing products, but it does not extend to resale of products first placed on the market by the patent owner.[289] The right to deny sale or offering for sale also applies where the indirectly patent-protected product is sold to persons who intend to employ the product obtained for non-infringing activities, such as sale to someone who intends to use the product for experimental purposes.[290]

The utilisation of the product in TRIPS Article 28.1 (b) is also restricted regarding the 'importing' for the purpose of using, offering for sale, selling the animals produced by the patented process. In practice this implies that a patent-holder with exclusive rights to a process that produces animals with certain traits, could deny others from importing animals possessing the same characteristics. By implication this could restrict the individual farmers' or breeders' utilization of their animals beyond what traditional property rights implies. The breeders or farmers could not sell animals for the purpose of using the animals for breeding purposes, without the risk of the buyer infringing the exclusive right of the patent-holder or possibly themselves committing contributory infringement.

For processes on farm animal breeding methods Article 28.1 (b) implies that the patent-holder can deny the use, sale and offering for sale or importing 'at least' the animals possessing obtained directly by that process. For process patents in farm animal breeding this would at least include the first generations of improved animals. When read together with the Biotech Directive Article 8(2), the right to deny applies to any other biological material possessing the same characteristics as the breeding method improves. This presupposes that evidence can be provided to establish that the patented process was used to produce the sold animals without the patent-holders consent.

The interpretation of the extension to 'at least' the products obtained directly by the process in TRIPS Article 28.1 (b) has, according to Correa, raised several issues in the countries that have adopted this concept.[291] First of all, difficulties could arise regarding the right to deny permission for utilization of the products obtained by the process in situations where these products are excluded from patentability. One

[287] Ibid.
[288] Correa 2007, p. 297.
[289] Ibid.
[290] Bently and Sherman 2004, p. 524.
[291] Ibid.

example of this is the exemption for plant and animal varieties.[292] Correa states that when a unique process of obtaining is known, the extension would be practically the same as for protection of the product as such, thereby *de facto* overriding the prohibition against patenting the product.[293] Applied to the case of a process comprising a method for improving a herd, which is general in scope and is applicable to more than one specific breed or one 'animal variety', this could imply that the exemption for animals is practically without consequence.[294]

Another uncertainty is whether the extension of the indirect product protection applies in cases where the product obtained by the patented process has been further processed. E.g. if the animals obtained have been bred with another animal of a different herd. According to the 'loss of identity test'[295] discussed above, the concept of 'directly obtained' applies in cases where the directly obtained product has been further processed but has not lost its identity.[296] If the purpose of the patented process is to produce animals with improved genetic traits to be used in the production of other animals,[297] the use of the animal as a slaughter hog or for other purposes could imply that the product has lost its identity, and consequently fall outside the scope of protection. The patent-holder cannot refuse to allow the acts of use of these products.

A more difficult assessment is when the patent-protected offspring is used for breeding purposes. The 'act of using the process' implies carrying out the activities described in the patent claim for the defined purpose.[298] If the offspring of an applied process is used for breeding purposes outside the described methods of the patent (e.g. if the animal is bred with an animal from another herd or bred according to another breeding plan), there seems to be some uncertainty regarding what acts of use the patent-holder can deny others from performing regarding the produced animals. First of all: can the patent-holder deny the use of the progeny regardless of whether the animals were bred with animals of another herd? According to the Biotech Directive this seems to depend on whether the animals still possess the same characteristics as the directly obtained material. If another breeding plan is employed the question the courts would have to assess seems to be whether the bred animals can be said to derive directly from the obtained biological material.

A related question is whether the act of crossing with other animals or using other methods is 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 on these acts of use. The use of a different animal in the same breeding process seems to draw near an

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[292] Ibid.
[293] Bently and Sherman 2004, p. 524, (in footnote 111).
[294] Tvedt 2007a, p. 16 (forthcoming).
[295] For further information on the 'loss of identity test' see Stenvik 2006, p. 324 cf. NU 1963: 6, p.148.
[296] Correa 2007, p. 298 (in footnote 109).
[297] E.g. WO/2005/015989.
[298] Stenvik 2006, p. 321.

equivalent use, at least if the animals obtained possesses the same characteristics as the animal obtained by the first employment of the patented process. The assessment of whether the use of the animals by means of other breeding methods is 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 to these questions. However, it has to some extent been specifically addressed in the Biotech Directive Article 10. The alleged infringer is given the option of presenting some specific defences regarding the use of the product obtained by the process. The right to exploit the offspring of a patented process and future generations must therefore be seen in connection with these defences. The following sections will analyse the provisions applied on process patents on methods for breeding farm animals.

4.5 Special defences regarding infringement of biotechnological process patents as limitations to the exclusive rights

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.[299] 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 Directive, one of the concerns raised was that patent protection of biological inventions would have a negative impact on farming practices.[300] 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 to the infringement of patent or exceptions to the exclusive right for biotechnological inventions were therefore formulated.[301] 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 Biotech Directive.[302]

[299] Bently and Sherman 2001, p. 505.
[300] Bently and Sherman 2004, p. 547.
[301] Bently and Sherman 2004, p. 509.
[302] Kamstra et al. 2002, p. 54.

4.5.1 Exhaustion of biological patents

As discussed in section 4.3.2, Article 8(2) of the Directive requires Member States to extend the scope of protection to dealings with materials derived from the claimed material. Kamstra et al., however, argue that the doctrine of exhaustion of rights could dis-apply this extended scope of protection to some extent, since 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 is *not* to apply.[303] 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 what might be called the 'true purpose' of the sale.[304] 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 and 11 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 is an incident of the 'true purpose' of the sale. [305] 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 this 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,

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[303] Kamstra et al. 2002, p. 53. Article 9 applies to protection conferred on a patent on a product and will therefore not be discussed in the following.
[304] Bently and Sherman 2001, p. 510.
[305] Ibid.

(the true purpose being: to apply the breeding method on the herd to improve the meat quality). 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 derived animals of 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.[306] To what extent the product derived from the process may be used for further breeding within the farmers herd is subject to the regulations of Article 11, the 'Farmers' Privilege'.

4.5.2 'Farmers' privilege'

The so-called '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 farmers 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.'[307] The problem would appear to be that, in relation to a patent, the breeding processes carried out on farms might represent an infringement.

The protection conferred in Article 8 does not extend to plant-propagating material or breeding stock sold to a farmer by the patent-

[306] Bently and Sherman 2004, p. 547.
[307] Bently and Sherman 2001, p. 510.

holder or with his consent, provided that the farmer uses the biological material or livestock for his own agricultural purposes.[308] This is intended, *inter alia,* to prevent an increase in costs in agriculture because of inventions related to farm animals.[309] 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 farmer) these have product or process claims.[310] The extent and the condition of the derogation provided in Article 11 (2) shall, however, be determined by national laws, regulations and practices.[311] This in turn means that the consistency and certainty for farmers will depend on how the exemption is 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 his 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'?[312] Or does the term imply a more qualified activity then 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.[313] The level of commercialization could also differ, from sector to sector, farmer to farmer and from country to country.

According to Spranger, the farmers' rights exemption is also problematic in relation to the TRIPS Agreement,[314] 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 evident.[315] If Spranger's interpretation of TRIPS 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', is bestowed on the alleged infringing farmer.

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[308] http://europa.eu/scadplus/leg/en/lvb/l26026.htm
[309] Ot. prp. Nr. 86 2002-2003, p. 20.
[310] Kamstra et al. 2002, p. 54.
[311] Cf. Article 11 (3).
[312] Kamstra et al. 2002, p. 55.
[313] Tvedt 2007a, p. 20 (forthcoming).
[314] Spranger 2002, p. 246.
[315] Ibid.

4.6 Reversal of burden of proof for patents that cover processes for obtaining a product

Generally the burden of proof is bestowed by law upon those who make an allegation. When it comes to 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.[316] 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 obliges the Member States to establish in their national laws that courts shall have the power to reverse the burden of proof.[317] 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.[318] 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.[319] 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 not 'produced' in the traditional meaning of the word. Traditionally, farmers have the right to make use of their animals for further breeding. This can occur without the use of technical equipment and human intervention, as animals can 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. And thus the question is whether one can produce evidence of not having applied the 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

[316] de Carvalho 2005, p. 383.
[317] Ibid.
[318] Ibid.
[319] de Carvalho 2005, p. 384.

have no discretionary authority to reverse the burden of proof.[320] On the other hand, it is up to the law to define which of the circumstances shall be seen as triggering the presumption.[321] Some WTO Members have in fact preferred to establish the presumption in both events, thereby going further than they were obliged to do.[322] The Norwegian Patents Act does not contain any provisions on the reversal of burden of proof. It is assumed that the Civil Procedure Act *(Tvistemålsloven)* would lead to the same result as that in TRIPS Article 34,[323] but it is unclear whether this applies only to the discretionary authority or also to one or both of the obliged circumstances in alternatives (a) or (b).

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.[324] 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. (Emphasis added)

Thus, the general rule of 'reversal of burden proof' does not apply unconditionally. It must be fairly evident that the product could have been made by the same process, and an attempt to prove this must have been made by the patent-holder. 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, cf. '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, could possibly be repeated by a differing 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'.[325] As to

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[320] de Carvalho 2005, p. 385.
[321] Ibid.
[322] Ibid.
[323] Stenvik 2006, p. 452.
[324] The Norwegian Patents Act of 1910 contained a similar rule. It was later abolished for practical reasons, but the burden of proof was not considered to shift back to the patentee, and the rule is, as mentioned, considered to follow from the general procedural rules regarding burden of proof. Stenvik 2006, p. 452.
[325] Correa 2007, p. 346.

process patents regarding farm animal production, it has been claimed that genetic companies in livestock breeding use patent policy to dominate gene markets.[326] 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.

4.7 Other factors for interpretation of the scope of protection

The point of departure for determining the scope of protection for process patents on breeding methods is that this is determined by the national courts after an interpretation of the patent legislation in accordance with the obligations of international and regional regulations. These include TRIPS Agreement Article 28.1 (b), EPC Article 64(2) and Biotech Directive Article 8(2). The following sections discuss whether there are other relevant factors that could be taken into account when interpreting the claims and establishing the scope of protection.

It has been claimed in patent theory that the level of inventiveness, in addition to being a requirement of patentability, could be relevant for determining the scope of protection.[327] The argument is that inventions that involve a large inventive step should be given a broader scope of protection than inventions that represent smaller innovative element.[328] Stenvik claims that recent case law does not support this liberal interpretation of inventions with a sizable inventive character.[329] The opposite argument – that an invention with a small inventive step and in close proximity to the prior art, should be subject to restrictive interpretation when determining the scope of protection – has, however, been adduced in infringement cases.[330] Here existing case law does not provide definite clarification, and Stenvik argues that legal unity weighs against this interpretation.[331] One of the arguments against some process patents for animal breeding methods, currently at the application stage, is that they consist of general methods which are already in use.[332] They only combine these existing elements to speed up the breeding cycle for selected traits.[333] Some of the inventions have thus been argued to involve a small amount of inventiveness. Furthermore, when a field of technology is fairly new it can be difficult to establish the entirety of the prior art. Admitting the degree of inventiveness as part of the infringement assessment might therefore possibly ensure that the scope of these inventions is kept within justifiable limits.

Whether the requirement of an inventive step could be of importance not only for granting the patent, but influence the scope of protection in the interpretation of the claims in an infringement case, has also been the

[326] Gura 2007, p. 6.
[327] Stenvik 2001, pp. 743–50 in chapter 9: 'Equivalence'.
[328] Stenvik 2001, p. 744.
[329] Ibid.
[330] Rt. 1964, p. 1195, Rt. 1997, p. 1749.
[331] Stenvik 2001, p. 749.
[332] Fitzgerald 2004.
[333] Ibid.

subject of discussion in patent theory.[334] This can be formulated as a question of whether the state of the art could call for a restrictive interpretation of claims, so that the invention is limited according to what was previously known or obvious.[335] Stenvik argues that it is inevitable that some patents are granted despite the lack of inventiveness, and that revoking such patents – which is the countermeasure to this – is not satisfactory since this cannot, according to (for example) Norwegian law, be pleaded in an infringement proceeding.[336] He therefore argues that norms for the assessment of patentability should be in accordance with the norms for the assessment of infringement, so as to ensure the public's right to utilize the prior art.[337] This could be ensured by means of a general restriction of the scope of protection, by allowing the defendant to allege that the subject-matter of the infringement was part of the prior art and was thus not subject to an exclusive right.[338] In an infringement case, a restrictive interpretation could imply that actions that should be part of the prior art are not affected by the patent.[339] Ryberg, on the other hand, claims that Stenvik's considerations are not well-founded arguments.[340] Neither the wording of the Danish Patent Act § 39 (similar to the Norwegian provision) nor Article 69 of the EPC offers precise conclusions to whether this could be relevant as a means of interpreting claims when determining the scope of protection.[341] There are however, in his opinion, no arguments that could support this solution.[342] In fact, the consideration of fair protection for the patentee in the protocol of interpretation of Article 69 would not be upheld if new defences are introduced.[343] On the basis of this, Ryberg argues that ensuring the right to exploit the prior art is best maintained through the provisions on revoking of patents, and that any other information about the prior art, other than that disclosed in the patent description, is generally without consequence for the scope of protection.[344]

Whether the requirement of an inventive step can be used as a mean of interpretation of the scope of protection is as seen controversial. For biotechnological inventions there might be supplementary arguments that could support allowing the courts to consider the state of the art in connection with infringement proceedings. It has been argued that some process patents regarding farm animals are variations on natural occurring sequences, and thus do not fulfil the requirement of inventive step.[345] Westerlund argues that the lack of understanding of biotechnological

[334] Stenvik 2006, p. 383, Stenvik 1999, pp. 610–612, 743–749. Ryberg 2002, pp. 121–133, Matheson 2006, pp. 16–18.
[335] Matheson 2006, p. 16.
[336] Stenvik 2001. p. 610 cf. Norwegian Patents Act § 61.
[337] Ibid.
[338] Ibid.
[339] Stenvik 2006, p. 383.
[340] Ryberg 2002, p. 130.
[341] Ryberg 2002, p. 128.
[342] Ibid.
[343] Ibid.
[344] Ryberg 2002, p. 133.
[345] Fitzgerald 2005.

science, coupled with the unpredictability involved, entails a risk of inventions being given protection beyond their real contributions to the art.[346] In other words there might be a risk of granting an exclusive right to a process (or the use of the product of this process) which to some extent exists independently of the inventive efforts of the patentee. This is could be considered inconsistent with the basics of the patent system:[347] an applicant should not be awarded an exclusive right to an 'invention' which is based on what was already known or beyond what the invention could justify.

The fact that this field of technology is quite new could make it difficult to foresee how the technical development will proceed.[348] This could imply difficulties in establishing prior art in connection with this technology, which in turn might lead to the granting of patents despite the lack of inventiveness. One remedy could be to allow for some flexibility in interpreting the scope of protection, by allowing interpretation of the claims based on the degree of inventiveness in the infringement proceedings, and to restrict claims that, after the granting of the patent, prove to be closely connected with the prior art. This could provide the courts with the flexibility needed to adjust to this new and expanding field of technology, thus preventing patents with a too broad scope of protection,[349] and ensuring that inventors are not rewarded beyond what can be justified through the patent system.

[346] Westerlund 2001, p. 184.
[347] Matheson 2006, p. 17.
[348] Ibid.
[349] This was one of the ambitions when the Biotech Directive was implemented in Norway. See St.prp. Nr. 43 2002-2003, p. 61.

5 Analysis of a process patent application for farm animal production

5.1 General principles of claim interpretation applied on process patents on farm animal breeding

Before analysing the process patent application some general principles of claim interpretation will be addressed. These principles of interpretation define the manner by which the subject-matter of the invention is determined.

The extent of protection conferred on a patent-holder is determined by the claims of the patent, as these are interpreted.[350] The claims are the inventor's own description of the invention, and their primary function is to set out the scope of the legal protection to be conferred by the patent.[351] Since the claims define the legal scope of the invention, much will depend on the exact wording used to explain the invention.[352] EPC provisions require that, where appropriate, claims should be presented in two parts:[353] one, called the 'preamble', specifying the technical features of the invention which are necessary for the definition of the claimed subject-matter but which are already part of the prior art; and a second part that specifies the novel technical features that the applicant wishes to have protected.[354] As with all linguistic material, the claims must be interpreted in order to determine their content.[355] According to Article 69(1) of the EPC:

> The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Claims constitute the starting point for both the evaluation of patentability and the assessment of an alleged infringement. The influence on the scope of protection through the interpretation of claims therefore includes two elements: first, the interpretation and defining of the claims in the patent-granting procedure; and second the interpretation in an infringement case, in other words, when the courts define the scope of protection to be compared with the alleged infringing process. A central concern in upholding the legitimacy of the patent system, given its aim of promoting technological development for the benefit of society, is to maintain a balance between inventors and third parties: 'This balance is attained by properly defining the exclusive right so that it confers exclusivity relative to the contribution made by the inventor.' [356]

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[350] Bently and Sherman 2001, p. 499, Stenvik 2006, p. 362.
[351] Bently and Sherman 2001, p. 336.
[352] Westerlund 2001, p. 184.
[353] Bently and Sherman 2001, p. 337.
[354] EPC Rule 29(1)(b), EPO Guidelines C-III: 2. See also Bently and Sherman 2004, p. 356.
[355] Bently and Sherman 2001, p. 336.
[356] Westerlund 2001, p. 77.

Since claims define the scope of protection, then the way in which claims are interpreted is very important.[357] The point of departure is that patents regarding processes for the production of farm animal genetic material shall be given similar protection as other technical inventions.[358] They should thus be subject to the same principles of interpretation as any other invention.[359] One concern regarding such patents has been that, under the current system, they would confer a broad scope of protection on the patentee.[360] A paramount objective of patent law is argued to be to reward the inventor for his effort, proportionate to his contributions to the field of technology, as an incentive for the future production of new inventions.[361] The following presentation will analyse the general principles of interpretation and how these are applied to process patents on farm animal breeding methods. Another objective is to see whether applying the general principles of interpretation to this area of technology could lead to differences in the scope of protection, consequently resulting in broader protection than the traditional justification of the patent system could support.

All patent applications will be subject to an interpretation in the granting procedure. With infringement assessment, however, interpretation by the courts will depend on a case being filed against the allegedly infringing user of the invention. Although the point of departure is that the understanding of the claims shall be the same for both situations,[362] the evaluation is somewhat different. For the evaluation of patentability, applications are interpreted and examined to ensure that they comply with the formalities of filing as well as the four requirements of subject-matter, novelty, non-obviousness and industrial applicability.[363] The patent claims are thus compared with written sources published prior to the application date. By contrast, for assessing infringement, the question is whether the alleged infringer has made use of the process described in the claims,[364] or the product obtained through the process. The patent is thus interpreted and the result of this interpretation is compared with the actual acts that the alleged infringer has performed.

The interests of the patentee could call for some leeway in interpretation. A strictly literal interpretation could make it possible to circumvent the patent by simply making minor alterations to the invention.[365] Westerlund argues that 'to describe every possible variant of a broad claim is often burdensome for the inventor',[366] and the argument seems to be based on recognition that an applicant cannot be expected to specify and formulate his claims in a manner that would cover all possible circumventions.

[357] Bently and Sherman 2001, p. 336, (in footnote 50).
[358] Preamble recital 46 c.f. TRIPS Article 'any invention'.
[359] Matheson 2006, p. 156, Ot.prp. Nr. 86 (2002–2003) p. 15.
[360] Nuffield Council on Bioethics 2002, p. 65, St.prp. Nr. 43 (2002–2003) p. 61, Ot.prp. Nr 86 (2002–2003) chapter 6.
[361] Bently and Sherman 2001, p. 314.
[362] Stenvik 2006, p. 362.
[363] Bently and Sherman 2001, p. 346.
[364] Stenvik 2006, p. 362.
[365] Westerlund 2001, p.183.
[366] Ibid.

Indeed, even if this were possible, it might not be rational from a socio-economic perspective. For processes regarding farm animal breeding methods this could seem even more evident, in view of the ability of the protected products to self-reproduce and further evolve. The need for some flexibility in claim formulation has led to an interpretation practice that opens for exclusivity beyond what can be read directly out of the claims, hereunder the implementation in some jurisdictions of the Doctrine of Equivalence.[367] The extent of this doctrine was to a certain degree established when the Protocol on the Interpretation of Article 69 was given an addition in the revision in 2000.[368] Article 2 – Equivalents states:

> For the purpose of determining the extent of protection conferred by a European patent, *due account* shall be taken of any element which is equivalent to an element specified in the claims. (Emphasis added)

And yet, there are other interests that need to be taken in to account. It must be possible for a third party to act in accordance with existing protected inventions. If too much can be read into the patent claims and considerable exclusiveness is granted outside the literal understanding of these claims, the risk of patent infringement might increase. Furthermore, as claims demarcate the scope of the monopoly, if the claims are not clearly formulated, then the extent of protection cannot easily be discerned: 'This would lead to the undesirable situation where third parties would not be able to determine whether they were infringing the patent.'[369] In the field of animal breeding this could prove even more important. In light of the fact that the patented materials are able to 'reinvent' themselves, and the indirect product protection that could apply, farmers operating within the range of a given patent should be able to know with some certainty what actions fall within the protection of that patent. And since, throughout the protection period, the farmer will usually 'own' the animal(s) in question and thus what is produced by the patented process (in contrast to plant agriculturists, who will have to buy the patented seeds every sowing season), it is important to ensure a certain level of predictability regarding the uses to which the owner of the animal is entitled without infringing on the patent. It could be argued that the claims therefore ought to be formulated in such a way that the public should not be left in any doubt as to the subject-matter covered by a particular patent.[370] The converse could create unnecessary legal proceedings and increase the costs of patent enforcement. The existence of a regional patent organization like the EPO, which grants patents that enter into force in all member states without linguistic translation, further underlines the importance of predictability in establishing the scope of protection. The EPO has addressed the need for predictability to enable third parties to act in accordance with patent claims. In Oxy/Gel Forming

[367] See chapter 4.2.3. For an in-depth analysis see Stenvik 1999, chapter 9; regarding equivalency in biotechnological patents, see Westerlund 2001, chapter 5.
[368] Stenvik 2006, p. 365.
[369] Bently and Sherman 2001, p. 338.
[370] Ibid.

Composition,[371] the Technical Board found that a patent with 157 claims violated EPC Art. 84 and EPC r.29(5), and stated that 'patents should not be allowed to erect a legal maze or smokescreen in front of potential users of the invention to which they lay claim'.[372]

The balance between these differing interests is addressed in the EPC Protocol on the Interpretation of Article 69, which is an integral part of the convention.[373] It states that

> Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims.

This seems to be based on the concern that a purely verbal description of the invention may not entirely cover the contributions made.[374] One issue is therefore to what extent the protection extends beyond the exact wording of the claims,[375] and it is emphasized that the claims should neither be

> (…) interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated.

This addresses the interest of third parties, and the limiting of the breadth of the scope. The result should be an interpretation

> [that defines] a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

In harmonizing any law, let alone an area as complex as patent law, compromises have to be reached, and the Protocol is such a compromise.[376] It sets out two extremes of interpretation – the literalist approach and the broad guideline approach – and requires courts to seek a compromise that can balance protection of the interest of the patentee in preserving a broad monopoly with due regard for the need for others – subsequent inventors, users and other infringers – 'to know where they stand in a way that, for all its other faults, the literal approach allows them.'[377] Holyoak and Torremans, however, argue that this compromise implies moving to a looser approach with broader methods of interpretation, consequently also moving towards greater protection to the patentee; thus, they hold, more risk of infringement is placed on others who are now to be offered only reasonable degree of certainty as opposed

[371] T246/91 [1995] EPOR 526.
[372] Referred to in Bently and Sherman, 2001 p. 336.
[373] Stenvik 2006 p. 364.
[374] Westerlund 2001, p. 184.
[375] Ibid.
[376] Holyoak and Torremans 1998, p. 141.
[377] Ibid.

to the utter certainty of the literal approach.[378] For patents in the field of biotechnology, this concern could prove even more relevant. As such inventions may consist of naturally occurring living material capable of reproducing itself, it might be difficult to define the patentable subject-matter for which protection is sought, especially in the case of the product of a process for the production of an animal.

Westerlund stresses some of these concerns:

> The biotechnological decisions demonstrate certain difficulties in its application to these kinds of inventions, for instance, the problem of elucidating the relevant dissimilarities, but also for considering the significant level that put 'different' matter outside protection. More basic is also the question of how to understand 'element' of a claim regarding biotechnological inventions, such as product claims or processes that include the use of biological starting material etc.[379]

This suggests that it is difficult to clearly define the subject-matter of biotechnological inventions. A broad interpretation of the claims, to include equivalent use of the inventions, could therefore possibly aggravate the difficulty of upholding a certain level of predictability regarding the scope of protection. Another consequence of broad patents has been emphasized by the Nuffield Council on Bioethics:

> The granting of too many broad patents at too early a point in the development of an emerging area of science may restrict others from having access to the genetic information covered by the patents (…).[380]

This suggests that, in the interpretation of patent claims in an emerging area of science like biotechnological process patents in farm animal production, consideration should be given to the significant characteristics of the patented subject-matter. It would be the claim interpretation that in the final instance will determine the scope of protection; and if a great amount can be read into the claims as the invention 'evolves', the consequence might be a broad kind of protection that could act to restrict the use of others.

The considerations in the Protocol of the interpretation of Article 69 should be borne in mind when interpreting process patents in farm animal genetic resources, as for any other technical area. The question remains whether there are other distinctions for these patents that would imply different considerations when interpreting and establishing the scope of protection. In general, a term in a claim is to be interpreted according to the understanding of a person skilled in the art, provided that the descrip-

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[378] Ibid. It should be noted that in the UK, which is the authors' reference point, the tradition in claim interpretation has been the literal approach. The change that they are referring to might therefore be more evident from a UK perspective. However, the general concern that broader methods of interpretation could lead to greater protection could be of wider relevance.

[379] Westerlund 2001, p. 265.

[380] Nuffield Council on Bioethics 2002, p. 65.

tion does not contain a deviating definition. Normally, an invention shall be defined by its technical features. However, in the case of biotechnological inventions, the EPO frequently allows functional, as opposed to technical, terms in the claims. [381] 'A functional claim defines the invention by reference to the function or end it performs, rather than its structure or elements.'[382] In other words, instead of specifying what the invention is, a functional claim outlines what the invention does.[383] This practice is based on recognition of the fact that it is often impossible to define biotechnological inventions by technical terms, or it is only possible to use technical terms which unduly restrict the scope of the claims.[384] At first glance this practice seems to open for biotechnological patents that have a broader scope than in other technical areas, at least from a literal perspective. One rationale for using technical terms is to ensure that inventors are given an adequate scope of protection in accordance with their contribution to the particular field of technology, and that it should be possible for a person skilled in the art to reproduce the process thus described. If a functional term is used in a biotechnological patent claim, this could suggest that the functional term does not extend the scope of protection, although a literal interpretation might result in this, since the reason for using the term is either that a comparable technical term might be impossible to find, or the use of such a term would restrict the scope of the claim. Functional terms could be argued to be given a stricter interpretation than the literal understanding would suggest, since the reason for allowing the use of these terms is the fact that it is impossible to describe the claim using technical terms. Under the EPO, functional claims are permissible 'if from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the claim, and if these features provide instructions which are sufficiently clear for the skilled person to reduce them to practice without undue burden.'[385] This should imply that the use of functional terms is *not* admissible if employing them would lead to an unclear or broader scope of protection.

With these principles in mind, the next sections will analyse a current pending patent application regarding a process in farm animal breeding, and try to foresee what scope of protection this might confer on the patent-holder if granted. We will also enquire how this patent could restrict the use of individual animals produced by this breeding method.

5.2 A patent application regarding a process for genetic improvement of terminal boars

Currently, there are several pending patent applications regarding processes in field of farm animal genetic resources.[386] It is still uncertain whether they will be granted or not, since they have been filed through

[381] Goldbach et al. 1997, pp. 58–59.
[382] Bently and Sherman 2001, p. 339.
[383] Ibid.
[384] Goldbach et al. 1997, pp. 58–59.
[385] T 0694/92 – 3.3.4 1996.
[386] See Appendix.

the system of the PCT/WIPO, which only performs a preliminary prior art search.[387] Granting of the patent is at the discretion of the patent offices regionally or nationally after the search report is submitted together with the application. After grant, the scope of protection for these inventions and implications they might impose on the users of the patent and their herds of farm animals will then be determined on the national level by the courts in an infringement proceeding, should such occur. As seen from the interpretations made in sections 4.2 – 4.3 there is uncertainty regarding the interpretation of the provisions for the scope of process patents on farm animal breeding methods. The following sections will analyse the considerations the courts will have to take in regard to one specific patent application if it is granted. Furthermore, the section will provide an analysis of the scope of protection this patent would confer to the patentee in regards to the process, the animals produced and the progeny of such animals. In other words, we will see how this patent could establish exclusive rights that might influence the legal situations for third parties like farmers and breeders working within the range of the patent. Subsequently, we examine how third parties can execute their property rights in modern breeding without the risk of infringing the intellectual property rights of the patent-holder.

The patent chosen for study here involves a method for genetic improvement of terminal boars.[388] According the description, the term 'terminal boar' refers 'to a boar that is used to sire progeny that are harvested for pork.'[389] The reason for choosing this patent is that it contains claims that touch upon several of the interpretational questions raised above. This relates *inter alia* to indirect product protection and to the questions raised in section 4.3.2 and 4.4 of when the patent right is exhausted, both in terms of the patented breeding method and the progeny obtained. In other words: for how many generations and alterations is the offspring subject to the intellectual property rights of the patentee? Furthermore, by extension: how far does the scope of protection extend to progeny of animals that have been bred with animals independent of the patented process? These queries can be formulated as a question of the correlation between the rights of the breeders to use the animals that are subject to their property rights, and the patentee's right to enforce his intellectual property right.

Another reason for choosing the case of this patent application is that it has already caused controversy. In an article from 2 August 2005,[390] it is claimed that if this patent is granted, the holder of the patent can legally prevent breeders and farmers from breeding pigs whose characteristics are described in the patent claims, or else force them to pay royalties. This is perhaps an exaggeration to some extent. In general, a process patent would only restrict the use of animals produced by this patent – in other words, in order for farmers to be subject to licence fees, they would

[387] See section 2.1.
[388] Publication number WO/2005/015989, International Application Number PCT/US2004/024168.
[389] Para [0077].
[390] Fitzgerald 2005.

initially need to have requested the use of the patented process. The following will also analyse and the scope of the patent application based on the interpretation of the relevant provisions, *inter alia* to see whether the criticism and scepticism voiced towards this patent seem reasonable.

5.2.1 Patent claims in the patent application under study

The patent application concerning a method for genetic improvement of terminal boars contains 69 specific claims, and each patent claim forms an independent subject-matter for an exclusive right. In other words, each of the patent claims would grant an independent and exclusive right. They might, however, also refer to other claims and be combined with these. Each individual claim needs therefore to be read individually but also in the context of the claims referred to, in order to get a complete overview of the entire subject-matter to be covered by the patent. The objective of the invention is to provide a method for producing terminal parent animals in swine production: a breeding method aimed at improving the genetic base of a population of pigs. Claim 1 is an independent claim; it describes the breeding plan of the invention and implies an independent exclusive right to the process described. It includes '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.

The improvement of the genetic base of a population of pigs is accomplished by providing methods for introducing and/or fixing one or more desirable traits or alleles in a swine herd. Alternatively, the methods may be employed to eliminate a given undesirable trait or gene. The method shall enable one of ordinary skill in the art to rapidly modify swine herds by such means as introducing a desirable trait and/or allele or increasing its frequency.[391]

[391] WO/2005/015989, Para 0033 Description of illustrative embodiments.

Basically, in layman terms: the farmer starts out with one herd that he wants to improve, finds the characteristics that he wants improved, identifies animals that possess these characteristics and uses their sperm to impregnate the females of the herd, produces improved next generations and places one or more of the improved animals back into the herd.[392] More technically, the method described in Claim 1 starts out with a core group and a herd that is to be improved by the breeding method. The selection is based on one or more desired traits to improve. The characteristics that are sought to be improved include (but are not limited to) health traits, reproduction traits, meat quality traits and efficient growth traits.[393] Semen is collected from one selected elite male which is genetically superior to the average of the flock. This semen is used to artificially impregnate several females in the herd. The offspring of this process are then used as parents in production herds or as replacements in the core group to improve the genetics of this herd.[394] Seemingly, and according to some critics,[395] these six steps describe, in basic terms, the long-established fundamentals and basic principles of selective breeding. If this particular patent is granted, the claim would, however, grant an exclusive right to deny others the right to repeat this procedure without paying the required licence fee.

Claim 1 serves as a basis for a number of other claims. Claim 7 is a dependent claim (a claim in combination with Claim 1); it describes the method of Claim 1 wherein the selected elite sire is selected for the property of having germplasm favourable for providing offspring with at least one of several traits. It describes:

> [t]he 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). (Punctuation added).

Additionally, the offspring of the breeding method are covered by Claim 8, which describes:

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[392] Tvedt 2007a, (forthcoming).
[393] Claim 7 cf. description para. [0013].
[394] Explanation discussed with *cand. agric.* E. Fimland. See also Tvedt 2007a (forthcoming).
[395] E.g. Fitzgerald 2005.

> 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. (Emphasis added).

This would imply that the process confers an exclusive right to the breeding plan described in Claim 1, where the selection criterion is based on one or more of the traits listed in Claim 7. Furthermore, the patent covers using the animals of the applied breeding method as breeding animals in the target herd.

Claim 7 includes selection of one elite sire for having germplasm favourable in terms of providing one or more desired qualitative or economic trait locus/loci or more desired quantitative trait locus/loci. The term 'locus' here refers to a specific location on a chromosome, e.g. where a gene or marker is located.[396] Furthermore, it includes selection based on desired estimated breeding value or a desired genotype or phenotype. Phenotypic characteristics are basically the characteristics of the animal that can easily be detected. Genotypic characteristic refers to what can be described as the fundamental constitution of an animal in terms of its hereditary factors: in other words, the desired traits are selected on the genetic level. The traits are not specified in Claim 7. This implies that the exclusiveness to the breeding plan of Claim 1 and 7 combined covers selection based on the general trait descriptions in Claim 7. Moreover, this must be read in conjunction with several other claims. For example, in Claim 39, growth traits are said to include any trait selected from a list that includes average daily gain, average daily feed intake, feed efficiency, back fat thickness, loin muscle area, and lean percentage. In other words, if combined with Claim 1, 7 or 8 this would also grant an exclusive right to a process selecting on the basis of any one of the specified traits described in Claim 39.

Meat traits could, according to Claim 40, mean any trait selected from a list consisting of muscle pH, purge loss, muscle colour, firmness and marbling scores, intramuscular fat percentage, and tenderness. The process described in Claim 1, 7 or 8 where the selection is based on e.g. firmness and marbling scores would therefore be covered by the exclusive right of the patent.

Reproductive traits could, according to Claim 41, refer to any trait selected from a list consisting of number of piglets born per litter, piglet birth weight, piglet survival rate, pigs weaned per litter, litter weaning weight, age at puberty, farrowing rate, days to oestrus, and semen quality. The patentee could therefore deny others the right to perform the breeding plan described in Claim 1, 7 or 8, if the selection criterion is based on, for example, number of piglets born per litter.

Furthermore, health traits could, according to Claim 42, be any trait selected from a group consisting of the absence of undesirable physical abnormalities or defects, improvement of foot and leg soundness, resistance to specific diseases or disease organisms, or general resistance to pathogens.

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[396] Description Para [0060].

These qualities or traits appear quite comprehensive in the description. They seem to include a broad range of different traits, each one of which could be chosen as a selection criterion in the breeding scheme listed in Claim 1. Thus, a systematic breeding scheme as described in Claim 1 where at least one selected trait is an efficient growth trait, meat quality trait, reproduction trait, or health trait selected from one of the groups listed in Claims 39–42 and chosen as the third step, could not be repeated without risk of infringing the patent. Furthermore, Claim 8 describes the method of Claim 1 where these genotypic traits are identified in female half-sib offspring having preferred germplasm and retaining these female half-sib offspring as breeding females in the target herd. The scope of protection for the breeding plan therefore extends to the further breeding of the animals obtained, in the target herd. Thus, also the use of the progeny of the applied process is restricted for this purpose.

Based on the described claims, read as individual exclusive rights and as a whole, this patent application would appear to be broad indeed, covering a wide range of selection criterion for the selective breeding method. It would seem that the possibilities of direct infringing acts regarding this method would be numerous, since selective breeding, in the direct meaning of Claim 1, based on any of the mentioned selection criterion, would constitute infringement. Additionally, the doctrine of equivalence is applied to varying extents in different jurisdictions. This could imply that potentially infringing acts could extend to acts exceeding the literal interpretation of the described breeding method of Claim 1.

This raises two questions when coupled with the general patent law determining the scope of protection. First of all, regarding licensed users who apply the patented process: what acts are restricted regarding the progeny of the process applied? Secondly, regarding the use of other breeding methods within production of the same type of farm animal: which processes fall outside the direct or equivalent scope of the process? Might animals produced by alternative breeding methods but possessing some of the same characteristics risk being alleged to have been produced by the patented method? These questions will in the following be addressed based on the interpretation of the relevant provisions of the TRIPS Agreement and the Biotech Directive.

5.2.2 Possible implications for the licensed user of the breeding method

The claims in the chosen patent application describe a large number of different traits or qualities that can be used as selection criteria in the selective breeding scheme. They include, as mentioned, both genotypic and phenotypic traits. The patent application aims at producing genetically improved animals for the purpose of re-placing these animals into the production herd or the GN (genetic nucleus herd), but improvement is also sought independently in the target herd and the swine production herd.[397] The point of departure in TRIPS Agreement Article 28.1(b) is that the scope of protection extends to 'at least' the products 'obtained directly' by the patented process. As mentioned in sections 4.2 and 4.4,

[397] Claims 14–17.

the assessment of whether subsequent animals can be said to be 'obtained directly' by the patented process will depend *inter alia* on whether the progeny has lost its 'identity' or not. In the Biotech Directive Article 8(2) this is specified to whether the progeny still possesses the 'same characteristics' as enabled by the patented process. Regarding the patent application described above, this would imply that the scope of protection extends to all future progeny that possess any one of the traits used as selection criterion. This would include both the general definition of the traits, e.g. Claim 7, and the specified traits of Claims 39 to 41. We must then ask: what acts of use is the breeder is not allowed to perform without the consent of the patent-holder, regarding individual animals in his herd?

First of all, is the farmer allowed to cross the obtained animals with other animals, independent of the patented breeding plan? This seems to imply a question of whether this act represents a use of the patented process. If it is not deemed a use of the process, the question remains whether crossing with another animal could be considered 'use' of the product obtained by the patented process. The described method consists of a systematic selection of certain animals that possess specific traits. Crossing with other animals by means of a different process would therefore seemingly not directly infringe the process.[398] If breeding with an independent animal is not deemed as an infringing use of the patented process, might the patent-holder still enforce his rights by means of the indirect product protection? The question is whether the offspring of a crossing between one animal obtained by '*that* process' and one animal not obtained by '*that* process' is subject to indirect product protection. According to Biotech Directive Article 8(2), the scope of protection extends to any 'biological material derived from the directly obtained material through propagation or multiplication'. So far it seems as though the offspring would be covered. Article 8(2) does, however, require that the biological material possesses the same characteristics as those that the patented process enabled the animals to acquire. Regarding the above described patent application, the question of whether the patent-holder is conferred an indirect product protection to the offspring seems therefore to depend on whether the offspring can be said to possess any of the traits described in e.g. Claim 7 or Claims 39 to 41. If the offspring is deemed to possess any of these traits, the exclusiveness applies, regardless of whether these animals appear in identical or divergent form. That in turn means that this patent, if granted, would in practice cover any progeny and any other biological material that possessed the characteristics described in the claims, in identical or divergent form, if the animals can be said to derive from the directly obtained material. The acts of use of this progeny are restricted according to the provisions of TRIPS Article 28.1 (b). (See section 4.4.)

Certain specific forms of propagation and multiplication are, however, exempted from the exclusive right of the patent-holder by the provisions of Articles 10 of the Biotech Directive (see section 4.5). On the background of the exemption, the patent-holder can deny further use of the

[398] However, it might be considered an equivalent use of the process, depending on how the doctrine of equivalence is applied.

directly obtained material where the patented material is subsequently used for other propagation or multiplication than what necessarily results from applying the process. The question would then be whether crossing with an independent animal by means of a different breeding method could be considered as 'what necessarily results from the application of the process' described in section 5.2. The prerequisite of the exemption in Article 10 is that the material obtained is not used for *other* propagation or multiplication. Using the material in a different breeding method could therefore fall under patent protection, if this is considered as use for other propagation or multiplication. Furthermore, if the breeding plan is used to improve meat quality traits, the multiplication would seem to be limited to this, and would not allow the material to be used for other multiplication.

5.2.3 Possible implications for other breeders in the same field of animal production

The point of departure in an infringement proceeding is a comparison between the patented method and the suspected infringing use. The assessment of a third party would be parallel, when applying a similar breeding method and considering whether the breeding method in use could potentially infringe an existing patent. As seen above in section 5.1, this evaluation includes an interpretation of the claim that balances between a literal understanding of the claims and the approach where the claims serve more as a guideline; and where the actual protection conferred may extend to what, from an interpretation of the claims, can be considered an equivalent use.

The claims in this patent application describe a large number of different traits or qualities that can be used as selection criteria in the selective breeding scheme. A method that selects elite sire and subsequent half-sib offspring on the basis of any of the above described traits could therefore be at risk of infringing the method, provided that the breeding plan falls within the direct literal understanding of the claims. The described breeding method might, however, imply exclusiveness beyond the literal understanding of the claims. The doctrine of equivalence is applied in some jurisdictions, and it implies that protection extends to some degree to utilization of the patent also beyond the direct meaning of the claims.[399]

According to Fitzgerald, the breeding plan of the application describes very general methods of cross-breeding and selection, using artificial insemination and other breeding methods already in general use. Furthermore, that the main invention is nothing more than a particular combination of these elements designed to speed up the breeding cycle for selected traits, in order to make the animals more commercially profitable.[400] The result could therefore appear to be a general method of cross-breeding where the selection criteria cover both the qualities that can be observed (phenotypic), and also the qualities on the genetic level (geno-

[399] See Westerlund 2001, chapter 5 and Stenvik 2001, chapter 9.
[400] Fitzgerald 2005.

typic), and involves a wide variety of traits to improve. This includes selective breeding to improve health traits, meat quality traits, reproduction traits and growth traits, generally or specified to certain specific categories of these traits, as described in Claims 39 to 42. In view of the comprehensiveness of these claims, one question that seems obvious for pig breeders and farmers to ask is: what processes are *not* included in the patent? What acts can they perform without risking patent infringement? With my limited knowledge of breeding methods, (based on discussions with *cand. agric* E. Fimland), this question is not easy to answer. It implies a combination of biological and legal assessments. However, the basis of comparison can be found in the claims of patent application WO/2005/015989 as described in section 5.2.

The question of the possibility of creating and using breeding methods that fall outside the described application could also concern the animals produced by such alternative breeding methods. The point of departure is that animals produced by these methods fall outside the scope of the exclusiveness of the patent. However, when the selection criteria of the patented invention involve large numbers of desirable traits, selected at the phenotypic and the genotypic level, an alternative method might risk producing animals with the same characteristics. A breeder who had produced animals with any of these traits might additionally, due to TRIPS Article 34, be obliged to produce evidence that his animals had in fact been produced using another method. An extensive process might ensure for third parties and stakeholders in the same industry, also depending on the difficulty of producing such evidence. If the process patent is so extensive that it might restrict the use of other similar processes, it could even shift the balance within the market. Similarly, if the extensiveness of the process makes it almost impossible to prove that the offspring was produced by another method. It could then be argued that the patentholder had achieved a reward for his invention that exceeded what the rationale of the patent system could defend.

6 Concluding remarks

Patent protection of process for farm animal production opens for several interpretational questions regarding the scope of protection and the use of following 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 Agreement could apply differently used on areas that differ 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 'Biotech Directive'.

The right to exploit the genetic resources of animals produced by patented processes is an issue that engages and affects many stakeholders – ranging from international genetics and breeding companies, farmers of varying scales, pastoralists, environmental organizations and patent-holders, to international organizations dealing with intellectual property or food and agriculture, like the FAO of the UN. 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 could be important because of the biological characteristic of the products obtained, since these characteristics imply that the animals could constantly evolve. 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 the legislation could determine the range of their breeding activities, as patents could restrict 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 Biotech Directive, goes beyond the level of protection in other fields of technology. According to Preamble Recital 46 of the Biotech Directive, which especially addresses such issues, state that the protection is to be 'analogous'. However, based on the interpretation above in chapter 4 and the analysis of a pending patent application in chapter 5, it seems as 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 an infringement proceeding is yet to see. However it would not seem to fully correspond with the general incentives underlying patent law.

As noted, 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.[401] 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 contrary could reward the inventor to a greater extent than justified by the system. In establishing the scope of protection for biotechnological processes, legislators should ensure 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 great variations within species and the way in which they are utilized.[402]

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 attains rights to the animals that are obtained through the process. Based on the interpretation of the TRIPS Agreement and the Biotech Directive made in this report one could ask if patented processes in farm animal breeding restricts the use 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.[403] 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.[404] 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 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 legitimize the patent system.

Therefore, it could be argued that the provisions of the TRIPS Agreement and the 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 protec-

[401] Westerlund 2001, p. 77.
[402] Rischkowsky and Pilling 2007, Part 1 Section B.
[403] Bently and Sherman 2001, p. 510.
[404] Canadian Biotechnology Advisory Committee 2002, p. 12.

tion 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[405] and the desire to conquer this frontier technology,[406] a certain reduction in farmers' property rights may prove to be a necessary and perhaps even acceptable consequence.

The legal situation regarding these questions has not been fully determined by implementation of the 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 differing 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.

[405] See Biotech Directive Preamble recital 1–2.
[406] See Biotech Directive Preamble recital 3.

7 Appendix

7.1 Patent search on biotechnological process patents in WIPO

- (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 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 METHOD FOR BREEDING ANIMAL OR PLANT, ANIMAL OR PLANT BRED BY THE FACILITIES AND METHOD AND APPARATUS FOR GENERATING ACTIVATED GAS.
- (WO/2005/101230) SYTEMS 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' (CONFINED TO SWINE BREEDING);
- (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).[407]

[407] Source: WIPO patent search; www.wipo.int/pctdb/en/

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FRIDTJOF NANSENS INSTITUTT
FRIDTJOF NANSEN INSTITUTE

Fridtjof Nansens vei 17, P.O. Box 326, NO-1326 Lysaker, Norway
Phone: (47) 67 11 19 00 – Fax: (47) 67 11 19 10 – E-mail: post@fni.no
Website: www.fni.no