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Policy Implications from Applying Patent Law to Animal Breeding

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I. INTRODUCTION

The question at stake regards policy implications from applying patent law to the field of animal breeding. Patent law is an old legal concept, but application to the area of animal breeding is fairly new and the consequences are yet to be seen. Patenting of living subject matter is fairly new in a global context and in a large majority of countries, and patenting in the field of animal breeding is just getting started.[2] This short paper seeks to identify challenges that will appear in the near future.

Patent law, although often referred to in singular form, includes a number of legal sources:

- National level and the level of the European Patent Organisation, which receives patent applications and grants patents either for each country (the national authority) or valid for all the designated European states (EPO);
- The EU Directive on Biotechnological Patents, 98/44/EC, seeks to harmonise the legal situation in all the member countries. This is an important legal source as it brought harmonisation a long step forward in Europe;
- The Agreement on Trade-Related Intellectual Property Rights (TRIPS) under the WTO, and;
- World Intellectual Property Organisation (WIPO) is the UN organisation for harmonisation of inter alia patents.

Policy implications from applying patent law to the field of animal breeding is important from a European perspective, as this may potentially to alter the legal frames for competition in this field in Europe. This is also important from the point of view of developing countries, where there is more tension between industrialised animal breeding and self subsistence farming than in Europe.

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[2] In the US, where the expansion of application of patent law is developing most rapidly, there were according to Lesser a total of 45 animal patent from 1995 to 2001 (Lesser 2002).

II. The Life Cycle of a Patent

The life cycle of a patent can be described in four stages:

1. The scope of patentability
2. The examination and the granting of a patent:
   - The definition of the prior art and the practical working definition of prior art
   - What is required for novelty and inventive step
3. What is covered by patent protection?
4. Enforcement (not looked into here due to the limited scope of the paper).

III. Patentability for Patenting of Animals

A first question is to identify what types of inventions are eligible for patent protection. The question of patentability was previously one which was left to the discretion of each country to decide the fields of innovation where patents should be granted. This was radically altered by the TRIPS Agreement Article 27, which establishes an encompassing scope of patentability by requiring all member countries to provide for patent protection in all fields of invention, save some narrow exemptions: Countries are allowed to exempt patent protection of *animals other than micro-organisms*; and for *essentially biological processes*.[3]

The main rule for patentability in Europe is EU Patent Directive Article 3 which specifies that:

> "For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used." And that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."[4]

Thus the main rule is that patents are applicable to the field of animal breeding and animal genes, cells and proteins, despite the fact that they were pre-existing in nature.

From this broad main rule, the EU Patent Directive makes two narrow exemptions: "animal varieties" and "essentially biological processes for the production of […] animals" are not eligible for patent protection.[5] The policy question is what the practical effects from these exemptions are likely to be.

IV. Prior Art for Patents in Animal Breeding

The concept of *prior art* defines what the patent system regards as previously known and thereby not open to be included under patent protection. The main principle is that what is not novel or does not involve a sufficient level of inventiveness cannot be covered by a new patent. In principle, nothing that already is provided to the public shall be patentable; it is covered by the *prior art*. This general principle is, however, narrowed down by technical

[3] TRIPS Agreement 27, paragraph 3.
[4] EU Patent Directive Article 3 paragraph 1 and 2.
[5] EU Patent Directive Article 4.

definitions of what the patent system considers as *prior art*; and by a technical procedure for searching the existing information to determine what is *prior art*, to find out what was already known before a new patent application.

The policy question for Farm Animal Genetic Resources (FAnGR) is whether the branch of animal breeding is sufficiently formally described as to meet the requirements for the *prior art*. This question must be answered by the branch. In answering this question one must have in mind that this applies equally to all the subject matters that are eligible for patent protection (as previously explained). That is all the already known eligible subject matters must be described if that shall not be patentable.

V. Scope of Patent Protection in the Animal Sector

The question of determining the scope of patent protection is a complex one. Two main questions are of interest from a policy perspective:

1) What is covered by a product patent to an animal gene?
The relevant article in the EU Patent Directive Article 8 reads:

> "1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics."

This formulation seems to target a broader scope than only GMOs, and also cover cases where knowledge about a naturally occurring gene is used for the purpose of transferring that particular (patented) gene to the next generation of individuals. One policy issue could be that the owner of animals with the desirable genes (that are patented) might have his possibilities reduced when it comes to the use of knowledge about the gene as a means in further breeding.

The next relevant article in the EU Patent Directive Article 9 reads:

> "The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, [...] in which the product **in incorporated** and in which the genetic information is contained and performs its function."

This wording targets cases where the patented gene is transferred into an organism. The wording indicates that a patent does not cover a situation where the gene is not transferred to another organism, but already exists previously in the organism.

2) What is covered by a process patent relevant for FAnGR?

The relevant article in the EU Patent Directive Article 8 reads:

> "2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. "

This implies that the direct result applying the patented process is covered by a process patent. This raises a difficult question about which subsequent or following generations of animals are covered by the scope of such a process patent.

VI. Concluding Observation

The term “patents promote increased research and development.” is often repeated. No empirical studies of the effects from applying patents to plants or plant breeding have been presented. There is no analysis of the probable effects from applying patents to animal breeding. Patent law is developing on a case-by-case basis. This reduces the potential for an overview of the overall challenges, as the law is altered by small steps rather than major changes. The effects from applying patent law to the animal breeding sector are very uncertain and needs to be further studied.