

# Current Patent Law as it Applies to Animal Genetic Resources and Breeding Practices

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# ***My Background:***

- *Legal studies – International Law, Intellectual property rights Patents - CBD (PHD finalised in 2007)*
- *Report: A Nordic Approach to Access and Benefit Sharing (including FAnGR);*
- *Access and Property Rights to Marine GR in Norwegian Fish Farming Sector (FNI report with the focus on marine resources);*
- *How will the new WIPO draft Substantive Patent Law Treaty affect Genetic Resources? (Journal of World Intellectual Property 2005 no 3 May)*
- *Options for User Country Legislation for a Fair and Equitable Benefit Sharing (Journal of World Intellectual Property 2006 no 2 March)*
- *Beyond Access – How can user countries meet the obligation of fair and equitable benefit sharing under the CBD? (forthcoming 2006)*
- *FAO project on FAnGR: Farm Animal Genetic Resources – Exchange, Conservation and Sustainable Use – Policy and Regulatory Options (forthcoming 2006)*



# Current Patent Law as it Applies to Animal Genetic Resources and Breeding

## *What is current patent law?*

- *National level – one system for each country*
- *TRIPS – The Agreement on Trade-Related Intellectual Property*
- *The Treaties under the World Intellectual Property Organisation: including the draft Substantive Patent Law Treaty*
- *Practice for granting a patent – practice in courts when a patent is enforced or challenged*
- *Enforcement of a patent (licences/contract) between private parties*
- *Regional patent law: e.g. EU Directive on Biotechnological Patents, European Patent Organisation, African Patent Offices ...*

*“Law in Books and Law in Practice”*



# **As it applies to animal genetic resources:**

***Depending upon national legislation and practice.***

***Need to get into the details!***

***Focus on the international level, but we also need to exemplify with national legislation (EU patent directive, as US law is too severe)***



# The Life Cycle of a Patent

1. The scope of patentability
2. The examination and the grant of a patent:
  - What is an invention?
  - The definition of the prior art and the practical working definition of prior art
  - What is required for novelty and inventive step and industrial application
3. What is the scope of the patent protection?
4. Enforcement – between private parties



# 1. As it applies to animal genetic resources:

## *Patentability at the international level: What does the TRIPS agreement say?*

1. *Main rule: “patents shall be available for any inventions, whether products or processes, in all fields of technology” (27.1) (unless one of the severe exemptions apply)*
2. *may exempt “plants and animals other than micro-organisms” (27.3)*
3. *may exempt “essentially biological processes for the production of plants or animals” (27.3)*
4. *But must provide for patents to “other than non-biological and microbiological processes” (27.3)*



# Patentability

The difference of product patent and process patent.

1. A product – what is covered by the patent claims in accordance with the acts that are covered
2. A process (including the indirect product patent)



# Patentability - products

EU Pat. Dir. art. 4:

“1. The following shall not be patentable:

(a) plant and animal varieties; [...]”

Animal variety is not a defined term in breeding – uncertain whether any invention will be exempt due to this wording. Therefore, this exemption might be too uncertain to be applied.

“2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.”

General inventions to animals can be patentable if not restricted to one variety. As the term variety is uncertain, the implication might be a broad scope of patentability.

Read in conjunction: a broad scope for product patents according to the EU Pat. Dir.



# Patentability - process

EU PD art. 4:

“1. (b) essentially biological **processes** for the production of plants or animals.” (emphasised here)

The definition of “essentially biological processes” must be regraded in the light of the definition in art 2. para 2:

“A process for the production of plants or animals is essentially biological if it consists **entirely of natural phenomena** such as crossing or selection.” (emphasised here)

The question is whether there are any modern breeding techniques that consists **entirely of natural phenomena?**  
The policy question is what are the implication of patents to such techniques, this needs to be answered by others than lawyers. (jf. Indirectly protection of the products made by such a technique – the scope of patent proetction.)



# Patentability - process

EU PD art. 4:

“3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a **microbiological** or other technical **process** or a product obtained by means of such a process.” (emp. here)

EU PD art. 2:

“1. For the purposes of this Directive, [...]

(b) 'microbiological process' means any process involving or performed upon or resulting in microbiological material.”

The policy question arises: what is a microbiological process according to patent law.



# Patentability - process

The board then defined the term "micro-organism" as... including not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, ie all generally unicellular organisms with dimensions beneath the **limits of vision** which can be propagated and manipulated in a laboratory, including plasmids and viruses." (case-law review EPO)

(New R. 23b(6) EPC defines a "microbiological process" as any process involving or performed upon or resulting in microbiological material. The boards have not yet issued a decision interpreting this definition.)

Genes and cells – probably a wide application, and thus a narrow scope of exemption. Especially when combined with the patentability of invention not confined to one variety.



# Micro-organisms

Definition in patent law:

- Everything which is not visible by the eye
- That is: genes or cells as parts or components of higher organisms  
(Source: practice from The European Patent Organisation – Not international agreement on this!)
- Question: Can you agree to this legal definition from a biological view-point?



# Practical examples on the exclusion from patentability

- One specific animal "variety", (if it is possible to imagine suchlike)
- A patent to the principle of crossing a male and a female animal *per se* in the classical natural manner.
- Selection *per se* as a natural phenomenon



# Patent claim in Pig breeding:

The following method can be covered by a patent:

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

- a. providing at least one genetic nucleus herd and/or a **target herd** for which improvement is desired
- b. **selecting a trait** or traits, for which improvement is desired;
- c. **providing semen** aliquots from an elite sire selected from the genetic nucleus (GN) herd wherein the elite sire has a **desired germplasm** that is determinative for improving one or more selected trait (s) in the target herd;



## Claim 1 cont.:

- 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. ”



## Claim 2 – 6:

2. The method of claim 1 wherein the herd (s) for which improvement is desired is selected from one or more of the group consisting of : a genetic nucleus herd, a production nucleus herd, crossbred boar multiplier herd, an external genetic nucleus herd, and a crossbred gilt multiplier herd.
3. The method of claim 2 wherein the target herd is a production nucleus herd.
4. The method of claim 2 wherein the target herd is a crossbred boar multiplier herd.
5. The method of claim 2 wherein the target herd is a crossbred gilt multiplier herd.
6. The method of claim 2 wherein the target herd is an external genetic nucleus herd.



## Claim 7:

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



## Claim 8:

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

[cut claims no. 9 – 69]



# Is these claims exempted from patent protection:

Is this an animal variety?

(No, the invention applies to more than one variety)

Is this an essentially biological process?

(No, these techniques all involve some non-biological, technical elements)



## 2. Will the patent be granted?

Depends on whether the patent criteria are fulfilled.

Invention?

Novelty – compared to the prior art?

Inventiveness?

Industrial application (a play with words)?

Sufficiently described?



# Invention?

Invention – undefined

Mere discovery



# *Prior art for AnGR*

When determining novelty and inventiveness,  
the term prior art is crucial

Not regulated in the TRIPS (but will be  
regulated in the SPLT)

Depending upon the general rules for  
searching for *prior art*

Article 54(2) EPC the state of the art shall be  
held to comprise everything made  
available to the public before the date of  
filing of the European patent application.



# *The Prior Art:*

Article 8 (1) Draft Substantive Patent Law Treaty:

“The prior art with respect to a claimed invention shall consist of all information which has been made available to the public anywhere in the world in any form [as prescribed in the Regulations,] before the priority date of the claimed invention.”



## ***Rule 8 (1) Draft SPLT Regulations:***

“(1) [Form of Availability to the Public] Information made available to the public in any form, such as in written form, in electronic form, by oral communication, by display or through use, shall qualify as prior art under Article 8(1).”



## ***Rule 8 (2) (a) Draft SPLT Regulations:***

“(2) [Accessibility to the Public] (a) Information shall be deemed to be made available to the public, if there is a **reasonable possibility** that it could be accessed by the public. The reasonable possibility that information could be accessed by the public shall be considered to exist if it is possible for the public to gain access to the content of the information and to acquire possession of that content.”



# Prior art for AnGR

Biogen case **T 0301/87**:

“Accordingly, the mere existence of a DNA sequence coding for a polypeptide of the IFN-alpha type, within the multitude of clones of "Lawn's gene bank" cannot automatically mean that the chemical compound (polynucleotide) concerned does become part of the state of the art. The latter would only then be the case if the existence of the compound concerned had recognisably been made publicly available.”



# The policy issue Prior art for FAnGR

The policy question for FAnGR depends on whether the branch of animal breeding is sufficiently formally described as to meet the requirements for the *prior art*. This applies strongly for Livestock Keepers, but:

This question must be answered by the branch/keepers. In answering this question one must have in mind that this applies equally to all the 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.



# Novelty and inventiveness for AnGR

These considerations are textual comparisons between what is already made available to the public and the described invention. The policy question arising is whether all used and known techniques and genes that are used also are sufficiently described to prevent the public domain to be delimited.



# Novelty for AnGR

Art. 12.2: “A claimed invention shall be novel. It shall be considered novel if it does not form part of the prior art[, as prescribed in the Regulations].”

Rule 14: (b) “Any item of prior art relevant to the determination of lack of novelty may only be taken **into account individually** and may not be combined with other items of prior art.”



# Inventiveness for AnGR

Art. 12.3: “A claimed invention shall involve an inventive step. It shall be considered to involve an inventive step (be non-obvious) if, having regard to the differences and similarities between the claimed invention and the prior art as defined in Article 8(1), the claimed invention as a whole **would not have been obvious** to a person skilled in the art at the priority date of the claimed invention[, as prescribed in the Regulations].”



# Industrial Application



# Will this patent be granted?

Probably differences among countries.  
Un-easy predicted  
Court-cases will be challenged (if  
rejected rather than if granted)



## 3. Scope of protection:

A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: **making, using, offering for sale, selling, or importing** for these purposes that product;
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes **at least the product obtained directly** by that process.



## How broad protection will this give for the pig claims?

Any “act of using the process” for the purpose of

“using, offering for sale, selling, or importing for these purposes at least the product obtained directly from the process”



# How broad protection will this give for the pig claims?

What is covered by a process patent relevant for AnGR?

The relevant articles in the EU Pat.Dir:

Article 8:

” 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 use of the process in a commercial setting is under the patent right.

This also implies that the direct result by applying the patented process is covered by a process patent.



What happens when we combine  
this process patent with a product  
patent on one gene?

Breeding based on knowledge of one  
piece of genotypic knowledge

The gene and knowledge about the  
existence of that gene in breeding  
activities.



# What is covered by a product patent to an animal gene?

The relevant articles in the EU Pat.Dir:

## Article 8

”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 targets foremost GMOs. But might also cover when knowledge about a naturally occurring gene is used for the purpose of transferring that particular (patented) gene to the next generation of individuals. Open question – to be decided by courts. The 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.



# What is covered by a product patent to an animal gene?

The relevant articles in the EU Pat.Dir:

Article 9:

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

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



# Conclusion of the scope of right

For sure the application of the process.  
The combination with a product patent  
on a gene, a cell or \_\_\_\_\_



## 4. Enforcement

Who will take the risk of not entering into a licensing agreement and face the court case?

Law in books and law in practice?



# Observations I:

The field of patent to AnGR is relatively unexplored and in a first phase. Patent law is mostly general rules applying to different areas of law, this raises a challenge as the law-making seldom is targetted to the particular needs of AnGR. It is probable that this adaptation to AnGR is going to be by case-law. This limits the possibilities for the law-maker to bring in strategically concerns for the branch itself.



# Observations II:

The term "Patents promote increased research and development." is often repeated.

However, no empirical studies of the probable effects from patents to animals or animal breeding.

Case-law based development. The case-law of some countries made internationally interesting via international law (the first case will have large interest).

Tentative conclusion: Can draw only very uncertain conclusions on the effects from patents in animal breeding



*Thank you for the  
attention!*

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