International Technical Expert Workshop

Exploring the need for specific measures for access and benefit-sharing of animal genetic resources for food and agriculture.

First Session: The context for the development of AnGR specific ABS measures

Presentation 1.3 Relevant developments in IPR regimes pertaining on animal breeding (technology patents; impact on conventional selection)

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IPR regimes and AnGRFA: present situation and possible impacts

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Introduction and questions

In this presentation we explore the need for specific measures for access and benefit-sharing of animal genetic resources for food and agriculture in the context with Intellectual Property Rights.

We set out from the results of a workshop on Rights to AnGR that identified two scenarios. 1) the present scenario of loss of AnGR diversity, due to market failure; here IPRs such as GIs and TMs may play a role to promote niche markets. And 2) the emerging scenario of increasing patent protection, more and more affecting everyday agriculture through the entry of biotechnology and so-called 'breeding method' patents." We are speaking here of the second aspect, of IPRs conferring temporary monopoly rights and their impact on animal breeding.

If we consider this type of rights at the interface with ABS, the following questions are in the foreground: firstly the question on the impact on *access* to the relevant genetic information. Access to genetic resources - in relation to AnGR - would be by access to the animal, and/or to germplasm and embryos; or – eventually - access to an isolated piece of DNA; secondly, and related to the first question, the impact on AnGR diversity and sustainable use; and thirdly, the issue of the fair and equitable sharing of benefits resulting from the utilisation of the resources (and of associated TK.

The basic issue is if the "AnGR patents" change the conventional "Access and Benefit Sharing mechanisms" in AnGRFA which consisted in the private contracts of sale of the "genetic resource"(i.e. the animal or its germplasm) and, included in the price, the license to utilize the genetic information, i.e. the progeny. If this is the case, the ultimate question is if the "fair and equitable benefit sharing" and the maintenance of diversity are impacted in a way that generates the need for balancing, counteracting institutions/devices. Yet, even if the result indicates a need for the creation of complementary instruments, the question remains whether the ABS system is the optimum instrument to reach the intended goals. [1]

In order to answer these questions, the following elements will be analysed: firstly the rationales of the two mechanisms – patents and the ABS system – both aiming at creating incentives for furthering

[1] These goals - transposed to AnGRFA - would read as follows: to facilitate access to genetic information of animal breeds (and to TK associated with GRs such as Traditional breeding techniques, knowledge about specific qualities (?)), and to share fairly and equitably the economic benefit.

a public good. Secondly, and overview of the present legal (and procedural) situation and its application re patenting of animals is given, and the results analysed in view of the questions raised above.

Rationales and objectives of patents and linkages to ABS and CBD

Patents grant monopoly rights, limited in time, in order that the holder is able to reap economic means invested in research and R&D. The background idea is that thus incentives are created for investment in research and thus for scientific progress and the promotion of economic growth. Two facts make patents important tools in modern biotechnology/genetic engineering: new technology, private research, cost-intensive, with market potential. It is to be pointed out that patents are a tool that works in conjecture with the market; this means that the patented inventions are commercial in intent. The public good to be promoted is creativity and economic growth.

The background idea of the ABS system is to create incentives for *conservation and sustainable use* of biological diversity and to contribute to poverty eradication and the improvement of livelihoods of indigenous and local communities, by assigning some economic value (also) to naturally occurring resources or resources developed by incremental evolution through human intervention. Compensation for *past* efforts is provided by sharing the benefits resulting from the utilisation of the resources with the "providers". The public goods served are conservation and sustainable use of biodiversity, and equity.

Questions are, what components of the breeding process are/can be patented; what is the scope of such protection and, and ultimately whether such IPRs limit the accessibility of genetic information and its utilization in conventional breeding. Another question resulting from these reflections is which are the stakeholders on which Bio-patents may have an impact. The hypothesis is that the impact may be different for smallholders/farmers, small industrial breeders and big multinational companies. [2]

The legal situation

The WTO TRIPS Agreement sets global minimum standards for the protection of intellectual property. It obliges WTO member states to grant patents to novel, inventive, industrially applicable and sufficiently disclosed inventions, in all fields of technology without discrimination. Hereby, the patentability of 'animals' is however explicitly left open to domestic regulation. Member states may exclude '*animals*' from patentability under Article 27 § 3 of the TRIPs Agreement, as well as '*essentially biological processes'* for their production.

Two difficulties arise with regards to AnGRFA: 1) the term 'animals' is not defined in the Agreement and controversy thus exists over the extent of this possibility. Another important element is that production methods that are not essentially biological must be granted patents when they fulfil the normal patentability criteria. The animals that are 'directly derived' from that method will have to fall

[2] The impacts of transactions costs for applying for patents and for opposing them, see Peter H. Feindt, Adovisroy Board on Biodiversity and Genetic Resources at the BMLEV, 2010: Biopatents – A threat to the Use and Conservation of Agrobiodiversity. Position Paper of the BMELV9 p. 22/3. ("Heightened legal and economic risk for and greater economic pressure on small farming and breeding operations. It is a plausible assumption that biopatents lead to a reduction in available diversity in the breeding and use of animal and plant genetic resources" (p. 23).

under the protection of the process patent on the basis of Article 28 of the TRIPs Agreement that confers protection to – at minimum - products obtained directly by the process. This can lead to broad patent claims and further leads to the patentability of subsequent generations as long as they express the protected characteristics.

On the regional and national levels, given the lacking WTO case law and clear definitions in the TRIPs Agreement, countries widely differ in the approach on patenting animal genetic resources. The *European Union*, in its 1998 Directive on the legal protection of biotechnological inventions, confirms the approach taken under the European Patent Convention in the pre-biotechnology area to exclude plant and animal varieties from patentability. The problem is that the taxonomical rank of 'animal variety' is unclear. The European Union and the European Patent Office both also exclude essentially biological processes from patentability, but in sum do provide a large patentability of '*biological material*' in general.

Other countries such as Canada have opted to exclude '*higher life forms*' from patentability. In its Harvard College decision, the Canadian Supreme Court interpreted the Canadian Patent Act in a way that excludes plants and animals from *direct* patentability. Yet, Canada is the perfect example of the exclusion of higher life forms from patentability but patents for their production methods are available and their scope extends to the animals. Similarly, gene sequences and cells are patentable in Canada, and these patents extend in scope to the organisms in which they are (re-) incorporated.

In the *United States*, the probably most quoted case in the history of patenting (biotechnology), *Chakrabarty*; has settled the matter. Under the Chakrabarty decision (deciding over the patentability of micro-organisms), the US Supreme Court decided that what matters for patent law is not whether something is living or not, but whether it is man-made or not. In 1987, when being confronted with the first patent applications for transgenic animals (e.g. the Oncomouse), the United States Trademark and Patent Office made clear in its Notice on Animal Patentability that this includes *non-naturally occurring non-human multicellular living organisms, including animals*.

In summarizing the following can be stated: 1) most developed countries allow for the patenting of biotechnology but each have established a complex set of rules in this relation. 2) In many cases, higher life forms are excluded from patentability. Yet, this can 3) be rather simply circumvented by biotechnological applications (by gene sequence and cell patenting for instance) and by process patents. 4) In turn, it is under debate in Europe whether the exclusion of 'essentially biological processes' from patentability extends to methods such as traditional breeding methods of crossing and selection combined with marker selection[3]. 5) However, patents can never apply to traditional methods and products *per se*, given the lacking novelty. [4]

[3] The question is whether patents should be granted to processes that largely build upon traditional methods. This is at the centre of public debates and judicial appeals in Europe, based on three pending cases where breeding methods are combining crossing and selection (two of them with marker selection): the Brassica case, the Tomatoes case (both jointly pending before the Enlarged Board of Appeal) and the Monsanto pig case. At stake is the interpretation of the notion 'essentially biological', so far narrowly interpreted by the EPO.

[4] Only a failure in prior art documentation can lead to what is criticized as the patenting of 'traditional agriculture'. This however, is not a systemic but a practical issue.

What is being patented today is thus mainly biotechnology, and within this category mainly transgenic animals engineered for medical purposes. Agricultural applications rather have to be sought in marker selection processes for instance, but only rarely in transgenic animals as such. Exceptions such as the 'SuperSalmon' exist, yet even more than the technology itself, the market does not appear ready for such applications. Thus in difference to PGRFA, gene-transfer from South to North – if it occurs – takes place through conventional breeding. However, as conventional breeding more and more goes into the direction of using biotechnological tools (marker selection, etc); biotechnology and accompanying patents do start to make their entry.

Impacts

The main effect of the patent system on AnGRFA is to be found in the ownership structure; ownership of the genetic resources is reversed in relation to patent protected animals. Whereas the ownership over progeny is classically with the owner of the female animal, the ownership over the progeny of patent protected animals is with the patent holder, regardless of the gender of the animal. The consequence is a shift in property rights from farmers towards patent owners/inventors for the period of the patent protection.

In ABS terminology, this means that access to the (patented) genetic resource for its utilization in breeding becomes more complicated and more expensive (regarding purchasing price and transaction costs). Besides the negotiation with the owner of the animal, a license to use the animal for further breeding is to be obtained. Whether it is given or not is in the discretion of the patent holder. Certain legal systems, including the European patent system; have in this context decided to allow so-called farmers' privileges in their patent laws. It thus forms a limited exception to the rights, enabling the use of subsequent animal generations on the farms.

A more indirect effect is caused by the legal insecurities and the concurrent economic and legal costs and risks for the farmers and breeders. Firstly, a certain degree of doubt subsists as to the concrete extension of patent protection over subsequent generations; legal insecurity may thus rise where the patented characteristics must be traced in sixth or seventh generations of patent protected individuals for instance. Secondly, the current patent granting procedures, testing only the criteria of novelty and inventiveness, do not address the implications of a possible (too) broad scope of biopatents. This is frequently only clarified through review proceedings initiated by opposing the patent in question.

The hypothesis is that these facts have a relatively stronger impact on small producers and breeding enterprises[5]. This in turn may lead to a concentration of the control of animal genetic resources that in turn may lead to a standardisation of production; in parallel to the production of pigs and hens, where concentration and standardisation are achieved by trade secrets and hybridisation.

Conclusions

On the basis of these reflections, we submit some preliminary conclusions for discussion. One basic conclusion is that, given the above results, it might be useful to investigate the option of *sui generis* rights in parallel to the ABS question.

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[5] Compare e.g. Feindt 2010, a.a.o. p. 23.

Besides, we propose to further investigate the question of the impact of IPRs on access, diversity and promotion of livelihoods on the basis of different scenarios encompassing small breeding companies and farmers in “herd-book” countries, and initiatives for controlled breeding/certification in the “South”.