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Animal Breeders' Rights?

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Analysing the regulatory framework of innovation in the realm of animal genetic resources delivers an immediate astonishment. Whereas IP systems to protect plant varieties have been developed since the 1930s, no such system has ever been conceived or even thoroughly studied in relation to animal breeds. The question is whether this inaction is rooted in a lack of necessity, biological obstacles, or in a simple lack of (policy) analysis. The present paper presents the hypothesis that the creation of such a system could – if properly tailored thereto – respond to a number of needs. It identifies and analyses the elements which could call for the implementation of 'Animal Breeders' Rights': innovation, the conservation and use of biodiversity, and economic development of agricultural regions. Then, it looks at the likely obstacles to finally addressing the concrete shape it could take.

Contents

Introduction

Biotechnology[1] and its applications have been at the centre of many debates in the past decades. The development of genetic engineering[2] and the surrounding ethical and safety concerns have also spread the controversy to the field of intellectual property rights (IPRs). This is because in many countries today, biological material – if brought to laboratory form and discovered a function – will be patentable.

'Patenting life' gives 684,000 hits on Google. For a narrow and technical matter, this is an unprecedented 'popularity'. In comparison, the word 'patenting' in general only triples the number, giving a total of 1,620,000 hits. With 684,000 hits, 'patenting life' has the Internet popularity of a retired movie star and beats that of seven-times world champion snooker player Stephen Hendry (494,000 hits), for instance.

The popularity of the issues relating to IPRs and the way they apply to biotechnology is, however, based on a number of misunderstandings. Certain distinctions and clarifications are required before the matter can be addressed. At the outset, therefore, it must be noted that:

- **Acceptance by consumers** of biotech products has often been low; especially in Europe. Still predominant on **European agricultural markets** today, are products emanating from 'traditional' breeding. At most, these have been improved with biotechnological tools but never with genetic engineering. The situation is different regarding medicinal applications, but this means that, in relation to agriculture, most of the innovation on the market is still 'traditional' or 'low-tech'. Against this background, we ask whether IPRs like patents play a role here at all since they seem connected to biotechnology.

- The debate on IPRs and biological material must **distinguish between** those **IPRs** covering a biological substance (patents, utility models, ('*sui generis*') plant breeders' rights (PBRs)) and those which cover commercial signs used in relation to biological products and processes (trademarks, geographical indications). Whereas the latter do not appear to be an important subject for further specific scrutiny, patents

[1] **Biotechnology**: any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify. This includes, but is not limited to genetic engineering. It however focused on technical applications using biological systems. Definition from Article 2 of the Convention on Biodiversity ('CDB' - Convention on Biological Diversity, 5 June 1992, 39 *International Legal Material* 1027 (2000)).

[2] **Genetic engineering:** modifying genotype (the genetic constitution of an organism), and hence phenotype (the external, visible characteristics of an organism), by transgenesis (the introduction of a gene or genes into cells, which leads to the transmission of the input gene (transgene) to successive generations). Definition in: A. Zaid, H.G. Hughes, E. Porceddu and F. Nicholas, *Glossary of Biotechnology for Food and Agriculture*, The Food and Agriculture Organisation of the United Nations, FAO Research and Technology Paper N° 9, 2001, available online at: http://www.fao.org/DOCREP/004/Y2775E/y2775e00.htm#Contents (last visited 18 April 2011)).

and PBRs grant an ownership right; a right to exclude others from using the covered subject matter. Whether this is a plant variety or a biotechnologically engineered mouse, the right holder alone decides who has access to the protected subject matter (within the constraints nonetheless of the exceptions and limitations set by patent and/or competition law). These systems are designed to promote innovation in the fields they cover, by protecting and incentivising investment in research and development (R&D). This is done by the promise and the grant of such an ownership right. However, it should be noted that they do not grant the 'right to use' to the right holder (this is subject to other fields of law), but only the 'right to exclude others from using'.

- The debate on these types of IPRs and their application to biological material often fails to **distinguish among the different types of biological resources** at stake. Even if it does, it usually focuses on plant biotechnology and/or the ethical aspects of the patenting of innovation based upon human biological resources. In particular, **animal genetic resources** (AnGR) appear to be neglected.[3] In literature on IP law and agriculture for instance, one rarely encounters a paragraph focusing on AnGR specifically. Nonetheless, the conclusions are usually made in relation to agriculture as a whole. Similarly, in literature on the ethical aspects of biotechnology, one almost never encounters a specific analysis of AnGR. Now, AnGR may not need a specific approach. But there is no doubt that the question without deserves a specific analysis.

- This lack of specific analysis is **reflected in the laws as well**. Most exclusions or limitations in patent laws address 'plants and animals' *im gleichen Atemzug*. This is the case for instance in Europe, where 'plants and animal varieties' are excluded from protectable subject matter.[4] Under international law, countries have the choice whether or not to exclude 'plants and animals' from patentability.[5]
  There is however one exception to this amalgam in IP law. *Sui generis* systems as established in the realm of plant varieties, are not in place for animal 'varieties' or rather animal breeds.[6] This means that part of

[3] Exceptional in this regard are: M. TEMMERMAN, Intellectual Property and Biodiversity: Rights to Animal Genetic Resources, Amsterdam, Kluwer International, forthcoming November 2011; F. ROTHSCHILD and S. NEWMAN (Eds.), Intellectual Property Rights in Animal Breeding and Genetics, Oxon and New York, CABI Publishing, 2002; and W. LESSER, Animal Patents: The Legal, Economic and Social Issues, New York, Stockton Press, 1989.

[4] Article 53 (a) of the European Patent Convention (Convention on the Grant of European Patents, Munich, 3 October 1973, as last revised in 2000, 1065 United Nations Treaty Series 199, available online at: http://www.epo.org/law-practice/legal-texts/epc.html (Hereafter EPC; last visited 5 May 2011)).

[5] Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex IC to the Agreement Establishing the World Trade Organization, Marrakesh, 15 April 1994, 33 *International Legal Material* 1197 (1994), available at: http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf (Hereafter TRIPS Agreement; last visited 17 June 2010)).

[6] **Breed:** "*1.a sub-specific group of domestic livestock with definable and identifiable external characteristics that enable it to be separated by visual appraisal from other similarly defined groups*

AnGR innovation, the part that is not covered by patent law, occurs outside any IP protection. So-called low-tech innovation in relation to AnGR, although still dominating the market as mentioned above, may not be the subject of IP rights promising an ownership right to the substance as such. Technology enabling to new varieties to be created has progressed faster in relation to plant genetic resources (PGR), and so has the pressure for IP protection in this area.

Thus we see three elements of analysis; three gaps in law and literature: 'low-tech' innovation (marketed agricultural innovation), AnGR, and *sui generis* IPRs. Against this background, this paper analyses the possibility of a *sui generis* IP right for animal breeds**:** *Animal Breeders' Rights*.

The field of AnGR is marked by some specificities, which must be taken into account when discussing IP protection. It obviously functions against a specific biological background, but also in a specific conservation context, in a specific market environment, and in a specific innovation climate. Within AnGR, one must also make a distinction between those used 'for food and agriculture', those used for medicinal purposes (where biotechnology and genetic engineering do bring marketed 'products'), and others. For the purposes of this paper, we focus on the first of these: **animal genetic resources for food and agriculture** (AnGRFA).

To discover whether there is a need for a *sui generis* system of IP protection in this field, it is thus essential to know the answers to several questions:

- First, what are the elements at play in this analysis?
    - innovation?
    - biodiversity?
    - conservation?
    - the competition environment?
    - economic development of agricultural regions?
- Second, what is the practical feasibility of a *sui generis* system; and what are the elements of analysis here?
    - Would it be used at all – taking into account the actual structure of innovation in this field and the specific biological nature of animals? Is there a demand or need in practice (or only in theory)?

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within the same species. 2. a group of domestic livestock for which geographical and/or cultural separation from phenotypically similar groups has led to acceptance of its separate identity."

Definition in: A. Zaid, H.G. Hughes, E. Porceddu and F. Nicholas, *Glossary of Biotechnology for Food and Agriculture*, The Food and Agriculture Organization of the United Nations, FAO Research and Technology Paper N° 9, 2001, available online at: http://www.fao.org/DOCREP/004/Y2775E/y2775e00.htm#Contents (last visited 18 April 2011)).

- Finally, what would the shape of such a system be – taking into account the answers to the above questions?

    - Which elements from PBR systems can be used by analogy (and which elements cannot)?
    - Which elements must be added on the basis of the biotech experience?
    - Which elements inherent to the field of AnGR must be added?

The hypothesis is that the success of such a system may depend on how it is received and used in practice, yet that the need for it is intrinsic and the opportunity apparent.

In the following sections we explain the 'why', and subsequently the 'how'. We start by discussing the specific elements for or against a *sui generis* system for animal breeds. Then, we look at the practical issues and obstacles in relation to such a system. Finally, taking into account these two assessments, we address the question of what a *sui generis* system would have to look like in concrete terms.

I. Reasons for and against Animal Breeders' Rights

Before deciding to call for a *sui generis* IP system for AnGRFA, it is first necessary to analyse the elements that such a system can influence. Then, one must ask whether the analysis of how these elements operate in the field of AnGR specifically, calls for the implementation of such a system or not, given a consideration of the theoretical design possibilities of the *sui generis* rights. The latter is the subject of section III. The former is the focus of this section. The mutual influence of these elements will be the subject of the conclusion.

In general, IPRs are designed to act as incentives to *innovation*. To do so, they affect the *competition* environment in a certain field. This in turn, in the field of biological material, can influence *biodiversity* (the creation of new diversity ('rearranged' biodiversity) and the distribution of existing diversity). It can also have *ethical implications*. If tailored to influence biodiversity or used strategically, IPRs furthermore have an underestimated effect on the *conservation* of genetic resources. Finally, IPRs have an influence on the level of *economic development* of a given country – in allowing copying industries or innovative ones.

This is no different for *sui generis* IP rights. However, their (as yet to be determined) shape can take into account the practicalities of each element more specifically and set the balance between them differently from the way other IP systems do.

We next look at each of the above-mentioned elements (with the exception of the ethical implications) and analyse how they function within – and affect – the specific field of AnGRFA.

A. (The protection of) innovation and the increased importance and value of information

Biotechnology has triggered a strong decoupling of (the value of) genetic resources from the physical animals embodying them. It has also altered the value and character of AnGR, by increasing the technical character of the information about them. This calls for ownership mechanisms adequate to cope with this development. Traditional ownership governed by customary law, possibly monitored with herd-books, must be rethought in view of these changes.

Innovation in AnGRFA that are on the market today, is not leading to diversity. It is focused on enhancing productivity within breeds, to develop animals which are uniform in size and weight for use in industrial production,[7] and which would allow automated slaughtering, cutting and

[7] *"A system of livestock farming in which animals are kept indoors throughout the greater part of their lives in conditions of very restricted mobility"* (McGRAW-HILL, *Dictionary of Scientific and*

packaging.[8] AnGRFA markets therefore offer almost genetically uniform products. A high percentage of poultry on the European market for instance, stems from two chicken breeds only, and a similar situation is to be found on the swine market. Exceptions exist, of course, such as the French Poulet de Bresse, yet these cover only niche markets, are three times as expensive as 'normal' chickens, are (geographically) limited in production, and are (thus) reaching only a small group of European consumers. Consumers hence hardly have any choice regarding the breed their chicken and pork stems from, and are furthermore poorly informed on this matter.

Biotechnology, however, plays only a limited role on the (European) markets where the products of genetic engineering are as good as excluded. Biotechnological tools such as marker selection may be used, yet only to help breeders to decide which animals should be mated. Reluctance of consumers and the continuing lack of studies on the long-term effects of the technologies, lead market access regulations generally to take a precautionary approach.[9] One could say that the 2010 'Eurobarometer' on biotechnology and consumers' acceptance is not subtitled "Winds of change?" without good reason. However, the careful reader of this document will see that "*GM food is still the Achilles' heel of biotechnology*" and that "*Cloning animals for food products is even less popular than GM food with 18 per cent of Europeans in support*".[10] Nonetheless, the recent failure to agree upon whether to allow (or disallow) cloned meat in the European Union – and if it is to be allowed how to label it –

Technical Terms, 6th edition, New York, McGraw-Hill, available at: http://www.answers.com/topic/factory-farming (last visited 21 June 2009)).

[8] "*The main underlying factors that result in some cases in the loss of animal genetic resources are: The focus on a few high-output breeds. The transformation of traditional systems into external input-oriented systems, often by using exotic animal genetic resources that displace local breeds. The indiscriminate cross-breeding with exotic breeds is also rapidly compromising the genetic integrity of local populations.*"

§ 32 of the Global Action Plan for Animal Genetic Resources (Food and Agriculture Organization of the United Nations, *Global Action Plan for Animal Genetic Resources*, Commission on Genetic Resources for Food and Agriculture, adopted at the International Technical Conference on Animal Genetic Resources 3–7 September 2007, hereafter 'Global Action Plan for Animal Genetic Resources', available at: ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf (last visited 7 February 2009).

Furthermore, at § 34 of the Global Action Plan for Animal Genetic Resources: "*Replacement of indigenous breeds could result in the loss of products and services preferred by local people, and the conservation of local breeds must therefore be considered within the broader context of sustaining rural communities and their existing economic foundations. Moreover, such losses now may limit future development options, based on animal products and services from specific breeds, that otherwise could have added considerable economic value as consumer demands become more varied*".

[9] See: M. ENGELHART, K. HAGEN and M.BOYSON, *Genetic Engineering in Livestock: New Applications and Interdisciplinary Perspectives*, Berlin, Springer, 2009.

In this context, it may be mentioned that the European Union, until recently sceptical about biotechnology in food and agriculture, recently allowed, after 13 years, the cultivation of Amflora potato within its territory, as well as the use of the Amflora's starch by-products as feed.

[10] European Commission, *Europeans and Biotechnology in 2010 – Winds of change?*, Brussels, 2010, available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf (last visited 11 May 2011).

is a real indicator of changing attitudes. Cloned meat has been allowed on the US market since 2008.[11] Although we do not take a position on this debate, we have to acknowledge that inventions such as the 'Super Salmon?[12] for instance – real products of genetic engineering; recombinant DNA technology – are unlikely to be kept off the market forever if no evidence of danger – is found. Super Salmon also shows that the technology as such – apart from its safety assessment or consumer acceptance – is ready in many respects.

Against this background, innovation in AnGRFA is partly covered by the patent system. We say 'partly' for two reasons:

- because low-tech innovation may not reach the threshold for patentability or may be excluded subject matter there; and
- because the high-tech (biotech) innovation that does pass this threshold, may be kept off the market.

Although there is no obligation at the international level on the basis of which countries would have to grant patents here,[13] most do (at least the 'industrialised' ones). Inventions in this realm will normally be patentable under the usual conditions (novelty, inventiveness, usefulness and disclosure), but may be subject to specific exclusions or limitations.

In Canada, 'higher life forms', thus including animals, are excluded from patentability.[14] However, their building blocks, cells and gene sequences are patentable and the scope of the patents covering them can extend to the organism in which these building blocks are incorporated.[15] In Europe, 'animal varieties'[16] are excluded from patentability, and processes for modifying the genetic identity of animals will only be patentable if they are not likely to cause animals to suffer without any substantial medical benefit to humans or animals. Also the animals resulting from such processes will be excluded.[17] Finally, essentially, biological processes for the production of

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[11] UNITED STATES FOOD AND DRUG ADMINISTRATION, *Agency Concludes that Meat and Milk from Clones of Cattle, Swine, and Goats, and the Offspring of All Clones, are as Safe to Eat as Food from Conventionally Bred Animals*, press release 15 January 2008, available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116836.htm (last visited 4 August 2009).

[12] US Patent 5 545 808 (16 August 1996) and EP 0 578 635 B1 (18 July 2001).

[13] This is however a matter of debate. The WTO TRIPS Agreement allows 'animals' to be excluded from patentability, yet does not define them. Whether on this basis animal gene sequences and cells may be excluded from patentable subject matter is unclear. It could be argued that this provision only applies to animal organisms as such.

[14] Supreme Court of Canada, *Harvard College v. Canada (Commissioner of Patents)*, 5 December 2002, 4 Supreme Court Records 45 (2002).

[15] Supreme Court of Canada, *Monsanto Canada Inc. v. Schmeiser*, 21 May 2004, 1 Supreme Court Records 902, 2004 SCC 34.

[16] Article 53 (a) of the European Patent Convention.

[17] *"Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes"*.

animals will not be patentable either.[18] As in Canada, 'isolated' animal gene sequences and cells, whose function has been discovered, will however be patentable. Also, as in Canada, these patents will extend to include the organisms in which the gene sequences have been incorporated and fulfil their function. In the United States, none of the above-mentioned exclusions exist.[19]

Patent law thus differs from country to country on the subject. One may however generalise and say that biotechnological progress is protectable and protected in most 'developed' countries; whereas low-tech progress either would not reach the threshold of the 'normal' patentability requirements, or alternatively would be confronted with an exclusion such as that of 'essentially biological processes' or 'animal varieties'.

The main form of 'IP' protection of marketed AnGRFA is therefore the combination of secrecy with hybridisation techniques (mainly the case for poultry and swine).[20] Hybrid animals are the result of cross-breeding and sometimes inbreeding processes. These animals acquire better productivity characteristics than non-hybrids, but are also used because they cannot be reproduced in a stable manner. Farmers and breeders always need to buy new chicks and piglets because only the company controlling the parent and grandparent lines can make the crosses and thus create the hybrid individuals. The sensitive information or material that needs to be kept secret therefore concerns the grandparent and parent lines, nucleus stock and pedigree (and potentially also the (selection) methods applied).

This relies on the incorporation of article 6 § 2 (d) of Directive 98/44/EC. See also Recital 38 EU Biotechnology Directive 98/44: "*Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability*".

[18] Article 53 (b) of the European Patent Convention, and Article 4 § 1 (b) Directive 98/44/EC.

[19] United States Trade Mark and Patent Office Notice, "Animals-Patentability", 1077 Official Gazette 24, 7 April 1987: "*The patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals to be patentable subject matter within the scope of 35 USC 101. The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 USC 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law*".

[20] Hybridisation: "*1. The process of forming a hybrid by cross pollination of plants or by mating animals of different types. 2. The production of offspring of genetically different parents, normally from sexual reproduction, but also asexually by the fusion of protoplasts or by transformation. 3. The pairing of two DNA strands, often from different sources, by hydrogen bonding between complementary nucleotides*".

Definition in: A. Zaid, H.G. Hughes, E. Porceddu and F. Nicholas, *Glossary of Biotechnology for Food and Agriculture*, The Food and Agriculture Organization of the United Nations, FAO Research and Technology Paper N° 9, 2001, available online at: http://www.fao.org/DOCREP/004/Y2775E/y2775e00.htm#Contents (last visited 18 April 2011)).

The question here is whether a *sui generis* system of IP protection would have a positive impact on innovation in the field of AnGRFA. In any case, its absence is considered to be a disadvantage when trying to attract additional investment in AnGR developments.[21]

B. The competition environment

An important element for both innovation and a well-functioning market, is the degree of competition. The number of companies active on a given market does not necessarily constitute the decisive factor, but is an important element or indication. IPRs of the patent type strongly influence the competitive environment of a given market. They allow right holders to exclude others from accessing and using their innovation, and thus to put competitors at a disadvantage. Adjusting a given competition environment, may pass by an adjustment of the IP framework.

For AnGRFA specifically, a separate study would be required to properly analyse this matter. We therefore choose to rely upon a study from (1999 and) 2007, the only one so far published on this field. On the *'industrialised' broilers, hens and turkey* market, a study from 1999 counted up to 10 multinational players.[22] In 2007, Gura showed that the control over genetic material for commercial broilers, layer hens and turkey worldwide is in the hands of only four companies (2 for layer hens, 4 for broilers). As regards *cattle*, the market has few international players; however they control a large market share. The situation is slightly different for *poultry* where other and slightly more names appear. Only five really noteworthy players, in terms of market control, are again to be found in *pig* breeding. Most of these companies are furthermore vertically integrated. They incorporate breeding, growing and processing under the umbrella of the same multinational company.[23]

As we have seen in the discussion on innovation above, this concentration occurred in the absence of strong IP rights. We have furthermore seen that productivity is at the centre of innovation, to the detriment of diversity. The main players not only control the market, but also decide on marketed biodiversity: the oligopoly here is not just one of businesses, but also one of genetic uniformity. Whereas one may say that this is the result of a simple market mechanism, the offer may in fact have contributed to the demand: markets to suit different tastes – for example, for different fat percentages – do appear. Although having more players on the market may not guarantee more diversity on the market, the difficulties experienced by new players trying to enter a market go along with the difficulty for new products to do so. New

[21] W. LESSER, 'Patents, Trade Secrets and Other IPRS', in ROTHSCHILD, F., and S. NEWMAN, S. (Eds.), *Intellectual Property Rights in Animal Breeding and Genetics*, Oxon and New York, CABI Publishing, 2002, p.13.

[22] D.R. Notter, 'The importance of genetic diversity in livestock populations of the future', *Journal of Animal Science* 77, 1999, pp. 61–69.

[23] S. Gura, *Livestock Genetic Companies. Concentration and proprietary strategies of an emerging power in the global food economy*, League for Pastoral Peoples and Indigenous Livestock Development, Ober-Ramstadt, 2007, available at: http://www.pastoralpeoples.org/docs/livestock_genetics_en.pdf (last visited 7 February 2009).

players have no incentive to bring new products to the market and need to compete with cost-efficient industrialised production. It is a legitimate question therefore whether *sui generis* systems for the protection of IP in AnGRFA would have the potential to alter this. It may offer sufficiently strong rights – assets – assuring start-ups, for instance, a stronger position for acquiring the necessary financial credits and thus being able to enter the market in a better position.

C. Conservation (and the creation) of (re-arranged) biodiversity

Leaving the intrinsic value of biodiversity aside, the increasing world population and climate change require the conservation of animal traits capable of adaptation to drought, high temperatures and new diseases.[24] However, the 'erosion of genetic resources' is reported to result in the loss of one livestock breed per month. In FAO's 2008 *State of the World's Animal Genetic Resources for Food and Agriculture,* 20 per cent of the 7616 reported breeds were classified 'at risk'. Between 2002 and 2008, 62 breeds became extinct. This is one breed per month.[25]

The 2007 Interlaken Declaration on Animal Genetic Resources and the Global Plan of Action for Animal Genetic Resources, are the first international texts to address this matter. Little attention, however, has been granted to the analysis of agricultural AnGR diversity *on the market*.[26] Yet, the commercialisation of local agricultural breeds is essential. Commercial value and a sufficiently large and accessible market are direct incentives to conservation here.

The market realities described above thus play against the conservation of agricultural animals. The focus on productivity, the few commercial players offering an almost identical product, the demand for productivity, also in

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[24] "*...maintaining the diversity of animal genetic resources for food and agriculture is essential to enable farmers, pastoralists and animal breeders to meet current and future production challenges resulting from changes in the environment, including climate change; to enhance resistance to disease and parasites; and to respond to changes in consumer demand for animal products. We also recognize the intrinsic value of biological diversity and the environmental, genetic, social, economic, medicinal, scientific, educational, cultural and spiritual importance of breeds of livestock, and our ethical responsibility to ensure genetic resources are available to future human generations*". Food and Agriculture Organization of the United Nations, *Interlaken Declaration on Animal Genetic Resources* (hereafter Interlaken Declaration), Commission on Genetic Resources for Food and Agriculture, adopted at the International Technical Conference on Animal Genetic Resources 3–7 September 2007, § 10, available at: ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf (last visited 7 February 2009).

[25] Food and Agriculture Organization of the United Nations, *The State of the World's Animal Genetic Resources for Food and Agriculture*, Commission on Genetic Resources for Food and Agriculture, Rome, 2007, at p. XXXV, available at: ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf (last visited 7 February 2009).

[26] "*One of the challenges of in situ conservation research is to evaluate how economic development and socio-cultural changes in society are affecting farmer maintenance of diversity so as to account for this process in the implementation of conservation programmes*" (J.E.O. Rege and J. Gibson, 'Animal genetic resources and economic development: issues in relation to economic valuation', *Ecological Economics* 45 (2003) pp. 319–330).

developing countries; all outcompete local breeds and biodiversity[27] and create genetic dilution where the 'productive' animals are being cross-bred with local species.[28] This market failure must be addressed.

A number of options to tackle this situation have been suggested. The European Union for instance fosters agricultural niche markets.[29] EC Regulation 817/2004 promises financial support to farmers who choose to breed "*local breeds indigenous to the area and in danger of being lost to farming*" (as listed by EC Regulation 1257/1999). Similarly, special payments can also be made under EC Regulation 1698/2005 "*for the conservation of genetic resources in agriculture*".[30] Under none of the Regulations however, will payments take into account the probability of extinction among the classified breeds. Furthermore, the payments were often said not to cover the losses triggered by breeding the often less productive, local breeds.[31] The question of inconsistency finally also arises when one considers that European breeds are often promoted in developing countries, triggering the above-described phenomenon of extinction of non-European, yet equally endangered, breeds.

The question is to what extent *sui generis* systems for the protection of IP in AnGRFA be tailored as a tool to incentivise the conservation of existing biodiversity on the market – eventually as a marketing tool – while also offering an incentive to further develop these resources and create 'new' or rather 'rearranged' diversity and breeds. In this context, a US study has shown that in anticipation of the introduction of the plant variety protection in the US (in the 1960s), private R&D investment, notably in soybean varieties, rose

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[27] Food and Agriculture Organization of the United Nations, *The State of the World's Animal Genetic Resources for Food and Agriculture*, Commission on Genetic Resources for Food and Agriculture, Rome, 2007, at p. XXXV, available at: ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf (last visited 7 February 2009): "*among many of the most widely used high-output breeds of cattle, within-breed genetic diversity is being undermined by the use of few highly popular sires for breeding purposes.*" S. Anderson and R. Centonze, 'Property Rights and the Management of Animal Genetic Resources', in 35 *World Development* 9 (2007), pp.1529–1541, at p. 1537: "*Poor households often take decisions that reduce AnGR diversity based on short-term livelihood priorities, rather than emphasizing longer-term aspects of AnGR access and improvement strategies.*"

[28] Cf. § 24 of the Global Plan of Action for Animal Genetic Resources: "*…local breed development may be ignored in favour of the introduction of exotic germplasm, or indiscriminate cross-breeding that will result in the erosion of local breeds*".

[29] Cf. Strategic Priority 6 of the Strategic Priority Area 2 of the Global Plan of Action for Animal Genetic Resources, 'Support indigenous and local production systems and associated knowledge systems of importance to the maintenance and sustainable use of animal genetic resources', Priority 1: "*Support indigenous and local livestock systems of importance to animal genetic resources, including through the removal of factors contributing to genetic erosion. Support may include the provision of veterinary and extension services, delivery of microcredit for women in rural areas,* ***appropriate access to natural resources and to the market****, resolving land tenure issues, the recognition of cultural practices and values, and adding value to their specialist products*".

[30] Article 39 § 1 EC Regulation 1698/2005.

[31] G. Signorello and G. Pappalardo, 'Domestic Animal Biodiversity Conservation: a case study of rural development plans in the European Union', 45 *Ecological Economics* 3, 2003, pp. 487–499.

considerably; while simultaneously attracting more players to the field.[32] Similar effects were recorded in Argentina.[33]

D. (Economic) Development

The above-mentioned issues of innovation in – and conservation of – AnGRFA have a direct impact on the economic development of countries where agriculture constitutes a large percentage of the GDP. Developing and least-developed countries rely heavily on agricultural progress to enable them to grow. Furthermore, an estimated 70% of the world's rural poor depend on livestock.[34]

Accordingly, international recommendations urge the further development of breeds within Production systems requiring low to medium external input.[35] Improving and conserving locally adapted species thereby appears as essential as increasing productivity in industrial breeds and systems.[36] Apart from the necessities of adaptation to climate change, this is also because industrial or 'high-yield' breeds may not necessarily offer a higher productivity in a new environment.[37] The issue is complex. Especially in a developing country context, the introduction of industrial breeds may sometimes be called misleading. Local breeds may indeed offer equal or better productivity. Not all markets are suited for or willing to accept industrial production. Furthermore, consumers in local or export markets might prefer the taste, flavour and fat-quantity of the products of non-industrial agriculture. Not enough attention is given to this aspect. As noted above, short-term priorities lead increasingly to the introduction of industrial breeds, also in developing countries. At the same time, it is in developing countries that the erosion of AnGR strikes the hardest.[38] Most of the animal breeds carrying adaptive traits are at risk. Economic development and conservation may thus go hand in hand. Conservation and the further development of local agricultural breeds may equally go hand in hand. To assure development may thus (also) be to assure local breeds' survival and improvement. In this context, *sui generis* rights to AnGRFA, adapted to this setting, may prove to be an important element.

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[32] Butler and Marion, cited in W. LESSER and M.. MUTSCHLER, 'Lessons from the Patenting of Plants', in ROTHSCHILD, F., and NEWMAN, S. (Eds.), *Intellectual Property Rights in Animal Breeding and Genetics*, Oxon and New York, CABI Publishing, 2002, pp. 103–118, at pp. 110–111.

[33] W. Jaffe and J. Van Wijk, *The impact of plant breeders' rights in developing countries*, Interamerican Institute for Cooperation and Agriculture, 1995.

[34] § 10 of the Global Plan of Action for Animal Genetic Resources.

[35] As well as for assessments of the impact of exotic animal breeds and the development of measures for producers to realize positive impacts and prevent negative impacts – Strategic Priority 4 of the Strategic Priority Area 2 of the of the Global Plan of Action for Animal Genetic Resources, 'Establish national species and breed development strategies and programmes'.

[36] In this sense: J.E.O. Rege and J. Gibson, 'Animal genetic resources and economic development: issues in relation to economic valuation', *Ecological Economics* 45 (2003), pp. 319–330.

[37] In relation to cattle for instance: H. Molinuevo, *Genética bovina y producción en pastoreo***,** Buenos Aires, INTA, 2005.

[38] S. Anderson, 'Animal Genetic Resources and Livelihoods', 45 *Ecological Economics* 3 (2003), pp. 331–339.

II. Animal Breeders' Rights in Practice

In the previous section we have analysed the elements that form the eventual rationale for an Animal Breeders' Right system. This, however, is only one element to be taken into account in the design of such a system. The second element relates to the obstacles and needs of the practice. Together these elements form the basis for our third section, describing how such a system could be designed in concrete terms. In this section, therefore, we first look at whether:

- there are practical difficulties – perhaps of a biological nature – with the application of IP rights of this type to AnGR(FA); and whether
- such a system would actually be used in practice: would the players of the game prefer to (continue to) use other means to protect their innovation?

Needless to say that these elements overlap.

A. Biological obstacles

The literature has addressed the question of *sui generis* IP systems in this area before – although barely.[39] Most concluded that there are biological obstacles to 'Animal Breeders' Rights'.[40] In particular, doubts were expressed as to whether animals are stable enough over the generations.[41] Applicants for IP rights would get an IP right for something they cannot be sure would retain the characteristics based upon which the IP right was granted. Unlike plants, animals may lack the predictability that would be desirable to obtain before covering the subject with an IP monopoly. In comparison, PBR systems on basis of the International Union for the Protection of New Varieties of Plants (UPOV) Convention require 'stability' as a condition for the grant of the right. Authors argue, however, that it is not possible to keep an animal breed stable because of the sexual reproduction: herds evolve. This is different for products that are the direct (first-generation) outcome of biotechnological processes, but for those animals stemming from mating and cross-breeding, stable offspring

[39] Arguing in favour of a *sui generis* system for the protection of animal breeds: N. PEACE and A. CHRISTIE, 'Intellectual Property Protection for the Products of Animal Breeding' 4 *European Intellectual Property Review* 213 (1996).

[40] E.g. LESSER, W., 'Animal Variety Protection: a proposal for a US model law', *Journal of Patent and Trademark Office Society* 76, pp. 697–715.

[41] Two other practical objections to a simple PBR type of system for animal breeds are raised in the literature: the low reproduction rate and absence of an operational designation of an 'animal variety' (W. Lesser, 'Patents, Trade Secrets and Other IPRS', in Rothschild, F., and Newman, S. (Eds.), *Intellectual Property Rights in Animal Breeding and Genetics*, Oxon and New York, CABI Publishing, 2002, at p.13).

are said out of reach.[42] On this basis, there is no agreement as to the extent to which animal breeds are technically suitable for IP protection at all.[43]

To ignore the possibility that animal breeds may be stable, is however to ignore animal breeds as such. After all, breeds such as Holstein cattle and others have been created with 'traditional' means. It appears usual for market approval that genetically modified animals show that the engineered feature is stably inherited: that the phenotype and genotype is consistent and predictable.[44] Perhaps it sets the threshold for protection at a high level, but does not point to the practical impossibility of the system as such. Furthermore, PBRs also protect hybrid plants, although they cannot, by themselves, reproduce stably. However, the right holder will know how to produce the hybrids in a stable manner. This will be equally true of animal breeds.

B. Demand in practice? Prospects of use?

Next to the biological issues comes the question of other practical obstacles and especially that of the *practical need*. Whereas the *theoretical need* was addressed above, this does not guarantee that producers and breeders themselves feel a need for such a system or that they would be willing to use the system if put in place. In particular, we come to the question whether control over 'a breed' is needed to incentivise progress, or whether control over individual animals is enough.

Unlike in plant breeding, the germplasm of superior individual animals will indeed be more important than the breed to which they belong. This would mean that it is enough to physically control the animal to have the 'monopoly', and that IPRs may not be used here simply because they are not needed. The commercial value of one single bull can be immense, whereas it is not the breed he stems from that will guarantee consistent production of such highly performing bulls. In this context, the cloning of bulls combined with secrecy methods can be much more attractive than applying for IP protection of the patent type and acquiring the right over perhaps a new animal breed.

This argument, however, would only be valid for cattle and fails to recognise that animal individuals and their characteristics do not occur in splendid isolation from the breed they stem from. Furthermore, the arguments exclusively turn on productivity. The proposed system rather aims to stimulate the use and improvement of AnGR *diversity* and to incentive a change towards exactly the situation described: the use of individual animals (thus the use of one specific genome) to dominate markets.

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[42] N. PEACE and M. CHRISTIE, 'Intellectual Property Protection for the Products of Animal Breeding', 18 *European Intellectual Property Review* 4 (1996), at p. 224.

[43] A. MÄKI-TANILA, *Is Animal Breeding Trade needing International Guidelines?*, MTT Agrifood Research Finland, Jokioinen, 2008, on file with author.

[44] See for instance: United States FOOD AND DRUG ADMINISTRATION, Department of Health and Human Services, *Regulation of Genetically Engineered Animals Containing Heritable r DNA Constructs – Guidance for Industry*, 18 September 2008.

C. Existing systems

In the context of both biological and practical objections, it must be mentioned that *sui generis* IP systems for animal breeds do exist; in Bulgaria,[45] the Czech Republic[46] and Kyrgyzstan.

Taking the example of the Czech "*Law on the Legal Protection of New Varieties of Plants and Breeds of Animals*", we read that animal breeds shall be granted a "Breeder's Certificate" provided that the breed at stake is ***distinct*** from any other breed commonly known by at least one major trait. Furthermore, the breed must be ***homogeneous*** to an "adequate level" and ***stable*** in its major traits. It must also be ***new***; however this requirement is in the narrow sense that it may not have been sold or offered for sale in the Czech Republic for longer than one year before the date of application or longer than six years in any other state. Finally, the breed must be ***sufficiently large in number for reproduction*** (Article 5). For the purpose of the said law, animal breeds are a population of animals having the same origin and exhibiting characteristic morphological and physiological properties, which is capable of reproducing itself, including hybrids of animals and stocks of poultry.[47]

On this basis, the protection granted is a non-transferable,[48] exclusive right to exploit the breed commercially[49] throughout the duration of the breed.[50] Not only is a right to exploit the breed thus being granted, a right to authorise others to perform such commercial exploitation is included.[51]

In is unclear, however, to what extent these systems are used in practice, or are operationalised (if at all).

[45] Law on the Protection of New Plant Varieties and Animal Breeds, 4 October 1996, *State Gazette* n° 84.

[46] Law on the Legal Protection of New Varieties of Plant and Breeds of Animals, 15 November 1989.

[47] Article 2 (c) Czech Law on the Legal Protection of New Varieties of Plant and Breeds of Animals.

[48] Article 7 Czech Law on the Legal Protection of New Varieties of Plant and Breeds of Animals.

[49] Article 8 Czech Law on the Legal Protection of New Varieties of Plant and Breeds of Animals.

[50] Article 12 (c) Czech Law on the Legal Protection of New Varieties of Plant and Breeds of Animals.

[51] Article § 1 & 4 Czech Law on the Legal Protection of New Varieties of Plant and Breeds of Animals.

III. Animal Breeders' Rights *in Concreto*

When the theoretical needs and practical obstacles are combined; what concrete shape would an Animal Breeders' Rights system have to take?

We have seen that if one considers the implementation of such a system, it should serve to foster innovation and preferential use of local breeds as well as improving them to ensure them a better market position, and possibly to encourage the economic development of agricultural regions. Practically speaking, the system also has to ensure that it actually can be used or is being used by private players; and that it suits the (biological) specificities of AnGRFA. When deciding on the usual elements that form an IP system of the 'patent' type, the following must be considered:

- the subject matter;
- the requirements for eligibility; and
- the scope of the rights.

As mentioned in the introduction, to answer each of these questions, one can derive inspiration from other systems and ask:

- Which elements from PBR systems can be used by analogy (and which elements cannot)?
- Which elements must be added on the basis of the biotech experience?
- Which elements inherent to the field of AnGR must be integrated?

Much may depend upon local needs and political decisions and debate. When designing Animal Breeders' Rights the drafters need to ask what the international level and especially the WTO TRIPS Agreement allows (or prohibits).

A. Subject matter

The question of subject matter forms the basis of the system. One must decide what should be covered *in principle* by the rights, and how to define it concretely. Should the system:

- include biotechnology?
- only apply to what is not yet covered by the patent system (and how to define this)?
- cover animal breeds?
- cover animal breeds 'for agricultural purposes'?
- cover only breeds, only their production methods, or both?
- differentiate amongst different 'types' of animals?

To exclude biotechnology may be to exclude the future. The primary aim of the system, however, would be to cover those areas left out of patent protection. Setting the subject matter on 'animal breeds' may – much as with the PBR system – *de facto* exclude biotechnology anyway since the protection granted would then be inadequate. Biotechnological progress occurs at the 'gene level', protection of the breed only would be too easily circumvented by third parties, by using the gene in isolation. Furthermore, development at the gene level will usually not be limited to a specific breed, nor necessarily create a new one. A system for animal breeds, therefore, almost automatically protects 'traditional' or low-tech progress. Hence one does not need to make a distinction here between breeds that are the outcome of biotechnology and breeds that are not. The definition may be neutral in this respect.

The question arises of whether the system should go beyond the PBR analogy ('plant variety'), to also cover animal gene sequences or production methods. This may then imply dual protection under both sui generis and patent rights in many countries, and no strong proof exists that the patent system is not suited to 'do the job' here. As to production methods, these usually consist of classical processes of mating and cross-breeding. Granting IP rights to these would be to grant rights to known methods without clear justification. The rights granted would represent neither an inventive activity, nor an investment of time and money. We thus tend to stick to the subject matter of 'animal breeds' only.

Then, a decision must be made as to whether only breeds *for agricultural purposes* should be granted protection, or whether protection should be offered to breeds *per se*. A priori, a need for 'a' use is apparent. A system of this kind is not aimed to trigger investment in creating new colours of existing breeds for instance, as is the case in PBR systems. These cover an endless number of new colour combinations applied to tulips, for instance. Although no internationally agreed principle of animal dignity exists, incentivising such activities does appear to have undesirable ethical implications and furthermore does not ensure progress for the purpose of which the system would be designed. Hence it does seems appropriate to require an agricultural use for a new breed to be granted an Animal Breeders' Right. Medicinal uses may however be considered as well.

The subject of 'animal breeds' must also be defined. For the purposes of the Czech law discussed above, animal breeds are a population of animals having the same origin and exhibiting characteristic morphological and physiological properties, which is capable of reproducing itself, including hybrids of animals and stocks of poultry.[52] This definition appears strongly inspired by the PBR system. It is confirmed as a classical definition of animal breeds by the FAO which defines an animal breed as either a sub-specific group of domestic livestock with definable and identifiable external characteristics that enable it to be separated by visual appraisal from other similarly defined groups *within the same species* **or** a group for which geographical and/or cultural separation

[52] Article 2 (c) Czech Law on the Legal Protection of New Varieties of Plant and Breeds of Animals.

from phenotypically similar groups has led to acceptance of its *separate identity*.[53]

A final question would be whether one should – under the umbrella of AnGRFA – differentiate amongst animal (the taxononomical level above breeds), given the different biological and market realities. This is perhaps one of the biggest differences between the regulation of plants and that of animals. Whereas one can relatively easily establish rules in relation to plants in general, it would not be appropriate to do this for animals. Fish are cultivated almost like plants; cattle are monitored in herd-books; poultry production has its own methods; insects – for instance for the production of honey – are also produced and kept in a distinct manner. Furthermore, only in relation to fish production, is genetic engineering said to have a real potential for use in the (near) future.

B. Requirements for eligibility

The next question is what the requirements should be for such animal breeds to be eligible for protection.

- Should the system include a novelty requirement? And, if so:
  - How can enough flexibility be ensured to cover also improved local breeds?[54]
  - Where should the threshold be set between a breed classified as already existing and a new one? Would one consider novelty in the absolute ('patent') sense, or novelty on the market at stake only (UPOV-style)?
- Should one require an inventive step, or rather protect the investment in time?
- Should it embody a criterion of disclosure, and, if so, what should be the subject of the disclosure?
- What criteria would assure that a breed has in fact been created? Should these be the usual PBR criteria of stability, distinctiveness, and uniformity or homogeneity?[55]
- What about a criterion to assure that the breed is viable? As in the above discussed Czech law should one require animals to be sufficiently numerous for reproduction?
- How does one prove an agricultural use as discussed above: should the animal be tested to ensure that it functions as reported before the right is granted?

[53] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, *The State of the World's Animal Genetic Resources for Food and Agriculture*, Commission on Genetic Resources for Food and Agriculture, Rome, 2007, at p. XXXV, available at: ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf (last visited 7 February 2009).

[54] This may also be dependent on whether or not there exist Livestock Keepers' Rights, covering past efforts at breeding and conservation.

[55] For instance: Article 5 of the UPOV 1991 Convention.

- Finally, what about the need for exclusions from eligibility; especially in the case that an application is made for protection of animals which would inevitably suffer from the use to which they will be put?

The decision on the threshold for ***novelty*** seems to be one that must be taken by domestic policy makers. Granting a right for breeds that do not yet exist anywhere in the world appears the most logical from an innovation point of view. However, it may be decided, in order to convince certain players to put their breeds on a given market, to set only a relative novelty criterion: novel = not yet put on the market in that country. A similar reasoning applies to the question of ***inventiveness***. Does one want to reward true innovation, or rather to invest in new breeds?

It appears out of question not to include the requirements of ***stability***, distinctiveness, and ***uniformity***. As in the Czech law, one should also impose the existence of a group of animals ***sufficiently large in number*** for reproduction.

The need for ***distinctiveness*** deserves specific attention in this context. This criterion requires breeds to be sufficiently distinct from other known breeds. Linked to what was said above on the necessity for usefulness of the breeds, distinctiveness must go beyond the usual PBR interpretation that also allows new colours. Instead the important characteristics should be disease resistance, increased nutritional value, and general adaptive traits.

Against this background, it is also apparent that the function should be ***tested*** before the right is granted.[56] The African Model Legislation offers food for thought in this context. It makes a distinction between local varieties and non-local varieties for the grant of IPRs. The proposed system imposes additional, 'multi-locational' variety trials for at least three seasons to prove that the non-local variety being tested does have the characteristics that are claimed (subject to relaxation of the criteria, however, in times of 'exceptional crises in food production').[57] Tests as to their local adaptability would avoid instances where high-yield breeds which are imported and eventually crossed with local species then turn out not to be adapted to the specific local circumstances and hence are unproductive. For newly developed breeds, there appears no reason to grant an IP right of this type if the function that is claimed cannot be proved to work in practice *and* to work ***in the local context***.

Next, comes the question of ***disclosure***. This is not a common requirement under plant breeders' rights systems. In view of the necessity of creating germplasm banks with the aim of conservation, the deposit of genetic material may however be considered as a requirement for protection. It might be a useful tool to counter limitations set by private actores to access AnGR in the

[56] In this respect see also: Article 12 UPOV 1991.

[57] Article 43 of the African Model Legislation.

long run. We might remember that secrecy is the rule today, and the system should also be used to tackle this.

Finally, the issue of ***ethics based exclusions*** must be addressed. The dominant doctrine on animal dignity today is what Francione terms 'legal welfarism'.[58] Legal welfarism calls for better consideration and care for animals, yet within a system of submission to the human will. Reduction of animal suffering is central, yet it is mostly coupled to a balancing and/or necessity test: animals should not suffer without such suffering being necessary to bring a legitimate benefit to humans. This shows the lack of a widely accepted concept of animal dignity, or at least of how it differs from the concept of human dignity. It also shows that the application of private rights on animals is not challenged in its essence. Legal welfarism has also found its expression in European patent law, and we suggest that a similar exclusion should be established in relation to eventual *sui generis* systems as well. Article 6 of the European Union Directive 98/44 excludes from patentability: "*processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes*". [59] One may even consider going a step further, to exclude animals whose alteration bring a physically determined suffering from protectable subject matter, regardless of the benefit they (could) bring to humans.

C. Scope of rights

The subject matter and the criteria for protection having been discussed, it is now necessary to look at how to design the right itself. What will or should the right allow, and what not? This also touches upon the question of which obligations stand in contrast to the rights which would be granted.

- What will the right holder be allowed to exclude others from? Should he or she receive:
    - The exclusive right to 'use'?
    - The exclusive right to 'produce and sell' only?
- Should the right holder be allowed to make any exclusions at all, or should one consider the right as a basis upon which a liability regime is to be implemented?
    - This would mean that the right conferred does not entitle the holder to exclude anyone, yet obliges third parties to compensate the right holder.

[58] G. FRANCIONE, *Animals, Property and the Law*, Philadelphia, Temple University Press, 1990.

[59] Also Rule 23 d to the EPC reads: "*Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes*".

- Should the right cover eventual progeny and until what point (how many generations)?
    - If progeny are to be covered, is there a need for a so-called farmer's privilege allowing the use of progeny for one's own agricultural activity?
- What would be the duration of the right?
- Depending upon the decisions made, it will then be necessary to tailor the exclusions:
    - Farmers' right?
    - Research exemption?
- Furthermore, should there also be a differentiation according to the contribution to the state of the art?
- Could one consider favouring small-scale farming; for instance by implementing a market segmentation mechanism decreasing the strength of the rights to favour small-scale farms – e.g. make the scope of the farmers' privilege dependent on the scale of production?
- Finally, should there be differentiation according to whether or not public funding was involved in the creation of the breed (e.g. public–private partnerships)?

These are the questions. Although it is clear that many of these questions go beyond a legal analysis, we briefly address them below.

The question of the ***rights that should be covered*** is a fundamental one.[60] If the right to exclude others from 'using' the subject matter is granted, the right becomes very strong. In this constellation, a ***research exemption*** enabling the use of the breed for research purposes must be considered, as well as a farmers' privilege, enabling farmers to use the progeny on their own farms for instance. If however only the right to 'produce and sell' is granted, a research exemption, for instance, may already be implied.

[60] In this respect, under the 1991 Act of the UPOV Convention the following acts require the prior authorisation of the rights holder: producing or reproducing (multiplying); conditioning for the purpose of propagation; offering for sale; selling or other marketing; exporting; importing; stocking for any of the above purposes (Article 14 (1) of the UPOV 1991 Convention).

Under the African Model Legislation, any person or farmers' community can, despite breeder's rights being established on a given plant variety, nonetheless: *"a) propagate, grow and use plants of that variety for purposes other than commerce; b) sell plants or propagating material of that variety as food or for another use that does not involve the growing of the plants or the propagation of that variety; c) sell within a farm or any other place at which plants of that variety are grown any plants or propagating material of that variety at that place; d) use plants or propagating material of the variety as an initial source of variation for the purpose of developing another new plant variety except where the person makes repeated use of plants or propagating material of the first mentioned variety for the commercial production of another variety; e) sprout the protected variety as food for home consumption or for the market; f) use the protected variety in further breeding, research or teaching; g) obtain, with the conditions of utilization, such a protected variety from genebanks or plant genetic resources centres"* (Article 31 § 1).

The idea of a ***liability regime*** comes from Jerome Reichman. He suggests that a third party is allowed to access and use the protected subject matter without requiring permission from the owner. However, the third party is then obliged to reasonably compensate the right holder for any such use.[61] Animal Breeders' Rights could be the first field to actually test his theory.

The next question – of extending the scope of the rights to include ***progeny*** - is in fact existential. It is necessary to enable a return on investment. Without this, the system would be useless, since second generations (or later ones) could be used to produce the protected breed in parallel and nullify the effect of the IP right. Protection would thus have to last as long as the subsequent generations continue to express the (essential) protected characteristics. This right may however be 'eased' by the implementation of a ***farmers' privilege***, as mentioned above. Enabling farmers to use the protected breeds for further breeding – on their own farm for instance – would bring the system (more) in line with classical ownership rules in the AnGR field (where the genetic resources and the possibility of using them are transferred and included in the price). Yet, it would not endanger the recoup of investment in the same way as the exclusion of the next generation from the scope of the IP right would.[62]

The question of ***duration*** of the right is essentially a non-legal one. It may be linked to the actual ***contribution that is made to the state of the art***. Inventions in the low-tech area (more so than biotechnology) will build upon classical methods, previous endeavours of farmers[63] and natural evolution.[64] Although it will be difficult to define the criteria upon which to base such an assessment, the idea may nonetheless merit further thought. In this context, one could also consider specific means either to reward the ***original community*** on whose breeds the improvements have been based, or grant them certain participatory rights.

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[61] On the idea of introducing compensatory liability rules for small-scale inventions see Reichman J. H., Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovations, 53 Vanderbilt Law Review 1753, 2000. Also on the same topic but on the example of traditional knowledge see in Reichman J. H. and Lewis T., Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to traditional knowledge, in Maskus K. E., and Reichman J. K., International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime, Cambridge University Press, Cambridge, 2005, pp. 337–366.

[62] Plant breeder's rights as established under the African Model Legislation are further subject to yet another series of exceptions, established to redress eventual post-grant failures to the public interest: *a) where problems with competitive practices of the Rights holder are identified; b) where food security or nutritional or health needs are adversely affected; c) where a high proportion of the plant variety offered for sale is being imported; d) where the requirements of the farming community for propagating material of a particular variety are not met; and e) where it is considered important to promote public interest for socio-economic reasons and for developing indigenous and other technologies.*

[63] Cf. in relation to plants; Article 9 § 1 ITPGRFA – Farmers' Rights: **"***The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world*".

[64] In this sense: M.W. Tvedt and M. Finckenhagen, 'Scope of Process Patents in Farm Animal Breeding', 11 *Journal of World Intellectual Property* 3 (2008), pp. 203–228, at p. 215.

Finally, a number of additional features to improve the access of farmers to the newly developed breeds, and further incentivise investment in innovation can be envisaged. In particular, the above-mentioned ***market segmentation mechanism*** decreasing the strength of the rights to favour small-scale farms – e.g. a larger farmers' privilege depending on the scale of production. In relation to incentivising investment, one must take into account the new structures of many research ventures. Especially in agricultural and medicinal research, many projects are set up in what is called a ***public–private Partnership*** (PPP)[65]. Although the degree of collaboration may vary depending on the specific venture, the involvement of public money must be considered when deciding on the strength of the IP rights on the outcome of these projects. While features to attract PPPs in this field may be envisaged, access to the inventions that are the outcome of PPPs must be enhanced, given that consumers will have already paid a part of the cost (through the public money involved).[66]

[65]Cf. Strategic Priority 16 of the Global Action Plan for Animal Genetic Resources, 'strengthen international cooperation to build capacities in developing countries and countries with economies in transition', proposed action 1: "*Build or strengthen technical cooperation and establish facilities for technology transfer and exchange of experience*".

As well as § 40 of the Global Action Plan for Animal Genetic Resources: "*There is a need to promote the provision of technical assistance, especially to developing countries and countries with economies in transition, either bilaterally or through appropriate national and international Organisations, with the objective of facilitating implementation of the Global Plan of Action for Animal Genetic Resources. There is also a need to promote the transfer of technologies relating to sustainable use, development and conservation of animal genetic resources, which should be facilitated, consistent with relevant international obligations and relevant national laws*".

And ibid. at § 63: "*Countries should promote the implementation of the Global Plan of Action for Animal Genetic Resources, in particular through national actions and by international cooperation, in order to provide a coherent framework for exchange of information, access to and transfer of technology and capacity building*".

[66] In this sense, see: B. Karapinar and M. Temmerman, 'Benefiting from Biotechnology: Pro-poor IPRs and Public-Private Partnerships', 27 *Biotechnology Law Report* 189 (2008).

Conclusion

The hypothesis stated at the beginning suggested that the success of an Animal Breeders' Rights system may be subject to how it is received and used in practice, yet that *its need is intrinsic and the opportunity apparent*. The analysis presented in this paper tends to support the hypothesis. However, there are many 'coulds', and the right is reserved to be hesitant on the 'woulds'. The system *could* be beneficial to innovation in the field, *could* improve the competition environment, *could* positively affect the use and conservation of AnGR diversity, and *could* contribute to the development of agricultural regions. Whether it *would*, however, has yet to be tested in practice.

Sui generis systems can fill the 'IP protection'-gap that is left in relation to promoting low-tech innovation and thus to fostering research on within-species diversity in the field of AnGRFA. The necessity for action in this regard is motivated by the genetic uniformity that characterises many AnGRFA markets, and is linked to the erosion of AnGR and climate change. It reflects the increasing need to keep and develop distinctive traits of adaptation to environmental conditions and diseases – traits that are rapidly eroding.

Sui generis rights could tackle the genetic uniformity that stems, for instance, from overexploiting *individual animals*; to give *breeds* a stronger position from which to enter the (concentrated) markets. Whereas existing players may not be incentivised to use newly created IP protection systems for AnGRFA and may instead continue to operate a secrecy-based strategy, eventual new players may consider it an essential tool for enabling them to enter the market successfully: as an asset necessary for obtaining financial credits.

Much of the effectiveness of the eventual system will also depend on the concrete shape of the system. Here, the opportunity is offered to draft an IP system from scratch, taking into account all the issues and debates that have taken place in recent decades in the biotechnology context, as well as in the general context of innovation and economic development. One can for instance envisage specific features for PPPs; link the strength of the rights to the contribution that is made to the state of the art; co-reward the original community that has conserved and developed the basic breed upon which the new one is based; establish ethical limitations on the creation of animals destined to suffer; require that the breeds are adapted to the local environment; create farmers' privileges linked to market segmentation; or *carrément* implement a liability regime instead of the usual 'right to exclude'.

The options are open.