MICHELANGELO TEMMERMAN

Intellectual Property and Biodiversity

RIGHTS TO ANIMAL GENETIC RESOURCES

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Love, peace and world trade.(?)

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List of Abbreviations

ABS	Access and Benefit Sharing
ACTA	Anti-Counterfeiting Trade Agreement
AIPO	African Intellectual Property Organisation
AnGR	Animal Genetic Resources
AnGRFA	Animal Genetic Resources for Food and Agriculture
CBD	Convention on Biological Diversity
CIPO	Canadian Intellectual Property Office
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CPC	Community Patent Convention
DNA	Deoxyribonucleic Acid
EFTA	European Free Trade Association
EGE	European Group on Ethics in Science and New Technologies
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FTA	Free Trade Agreement
EST(s)	Expressed Sequence Tag(s)
GATT	General Agreement on Trade and Tariffs
GATS	General Agreement on Trade in Services
GI	Geographical Indication
GR	Genetic Resources
GMO	Genetically Modified Organism
GURTs	Genetic Use Restraint Technologies
ICAR	International Committee for Animal Recording

ILA	International Law Association
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
NAFTA	North American Free Trade Agreement
NGO	Non-governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PBR(s)	Plant Breeders' Right(s)
PGR	Plant Genetic Resources
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
PPP(s)	Public-Private Partnership(s)
R&D	Research and Development
SPLT	Substantive Patent Law Treaty
SPS (Agreement)	Agreement on the Application of Sanitary and Phytosanitary Measures
TK	Traditional Knowledge
TM	Trademark
TRIPs (Agreement)	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	Union Internationale pour la Protection des Obtentions Végétales
US(A)	United States (of America)
USC	United States Code
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WTO	World Trade Organization

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Introduction

At the centre of this book is the question of control over, and thus access to, animal genetic resources (AnGR).[1] It focuses – from a legal standpoint – on how intellectual property rights (IPRs) and especially patents (can) affect a number of factors in this field specifically, such as agricultural ownership traditions, animal ethics and biodiversity.

The query is motivated by a number of changes that have occurred in the realm of AnGR over the past decades, while a striking lack of specific analysis is simultaneously being witnessed. Although literature on patent law and how it applies to biological or genetic material is abundant, AnGR are only rarely the specific focus.[2] At best, conclusions drawn in relation to plant genetic resources (PGR), or even to agriculture at large, are being generalized to also include AnGR.

Although many differences between animals and plants are obvious and do not need explanation, it nonetheless appears necessary to briefly emphasize them at the outset. This is essential in order to see in which cases an analogical regulation as developed in the realm of plants – where a substantial body of case-law and literature already exists – can be applied, and in which case it cannot. The background of AnGR, when compared to PGRs, is indeed different in

1. 'AnGR'.
2. Especially in the past years a number of articles have been published however: S. Biber-Klemm and M. Temmerman (eds), *Rights to Animal Genetic Resources for Food and Agriculture*, NCCR Trade Regulation Working Paper No 2010/05, 2010, available at: http://www.nccr-trade.org/publication/rights-to-animal-genetic-resources-for-food-and-agriculture/; Tvedt, M.W. and Finckenhagen, M., 'Scope of Process Patents in Farm Animal Breeding', 11 *the Journal of World Intellectual Property* 3 (2008), pp. 203-228; Sommer, T., 'Patenting the Animal Kingdom? From Cross-Breeding to Genetic Make-Up and Biomedical Research', 39 *International Review of Intellectual Property and Competition Law* 2 (2008), pp. 139-161; and Rothschild, M.F., Plastow, G. and Newman, S., *Patenting in Animal Breeding and Genetics*, Oxon and New York, Cabi Publishing, 2003.

terms of the biological reality, ethical load, market structure, conservation needs, ownership traditions and practical needs in general.[3] These differences will be further explained in – and accompany most of the chapters of – this book.

In term of biological differences and their impact on intellectual property (IP) regulation, a number of examples can already be given at the outset. Animals – first – are less stable in their traits over the generations than plants. This may amongst others lead to problems in identifying the characteristics that would constitute the description standard of a breed, when considering an IP protection system for animal breeds analogical to Plant Breeders' Rights (PBR).[4] In relation to plants, only asexually reproduced plants[5] have been amenable for IP protection until 1970 in the United States for instance.[6] However, asexual reproduction is not possible for animals, nor is (self-)pollination. Countries like South-Korea[7] still only set asexually reproduced plants patentable. Second, the reproduction process of animals is much slower and more complex than that of plants. Animals have a much longer 'interval period'.[8] Camels for instance only assure progeny every second year. Hence the impact of the extension of patent rights over the progeny of patent protected animals is a priori stronger. Thirdly, the germplasm of superior individual animals will be more important for animal breeding. The commercial value of one single bull can be immense, whereas it is not (only) the breed he stems from that guarantees this. This is never the case with plants. For those bulls, simple control suffices: patents are not needed.

Not only literature seems to lag behind. Also the attention of regulators – at both domestic and international levels – seems to have developed at a slow pace. On the international level, one for instance had to wait until the year 2007 to see a 'Global Plan of Action for Animal Genetic Resources'[9] and a corresponding

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3. '[. . .] there are some intrinsic differences between plant and animal resources and the way they can be managed. Such differences relate to reproduction, storage and transport, ownership, and costs associated with genetic improvement programmes', A. Ingrassia, D. Manzella, E. Martyniuk, *The Legal Framework for the Management of Animal Genetic Resources*, FAO Legislative Study 89, Rome, Food and Agriculture Organisation of the United Nations, 2005, available at: ftp://ftp.fao.org/docrep/fao/009/a0276e/a0276e00.pdf (Last visited 22 May 2011), at p. 97.
4. 'PBRs'.
5. Traditionally, *asexual* reproduction occurs by grafting, budding, or like. It produces an offspring with a genetic combination that is identical to that of the single parent, which basically could thus be called a clone.
6. See: United States Supreme Court, *J.E.M. Agricultural Supply v. Pioneer Hi-Bred International*, 10 December 2001, 534 US 124, 60 USPQ2d 1865.
7. Article 31 of the Korea Patent Act, cited in WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Review of the Provisions of Article 27.3 (b)*, 18 February 2003, IP/C/W/273/Rev.1., at p. 17.
8. This goes with certain exceptions. 'Aquaculture genetic resources' and fishes in particular actually have a high rate of reproduction, as well a short interval period between reproductive phases.
9. Food and Agriculture Organisation of the United Nations, *Global Plan of Action 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, available at: ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf (last visited 22 May 2011).

'Interlaken Declaration on Animal Genetic Resources'[10] – two instruments of soft-law issued by the Food and Agriculture Organisation of the United Nations (FAO).[11] IPRs are however remarkably absent in recent international undertakings on AnGR. It is only vaguely referred to:

> Policy development should take into account the increasing role of *intellectual property rights* in the sector... (emphasis added).[12]

> A range of policies and legal instruments have direct or indirect effects on the use, development and conservation of animal genetic resources. These instruments often pursue different objectives, such as economic development, environmental protection, animal health, food safety, consumer protection, *intellectual property rights*, genetic resources conservation, and access to and equitable sharing of benefits arising from the use of animal genetic resources (emphasis added).[13]

Specific to patent law, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPs) Agreement[14] leaves the patenting of animals up to domestic regulation in analogy to plants[15]; the World Intellectual Property Organizations Draft Substantive Patent Law Treaty[16] has not made a specific analysis in relation to AnGR (and is still under negotiation), and its Paris Convention[17] stems from the pre-biotechnology area.

10. Food and Agriculture Organisation 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, available at: ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf (last visited 22 May 2011).
11. 'FAO'
12. § 40 of the Global Action Plan for Animal Genetic Resources.
13. Strategic Priority 20 of the Global Plan of Action for Animal Genetic Resources.
14. Agreement on Trade Related Aspects of Intellectual Property Protection, Annex IC to the Agreement Establishing the World Trade Organisation, Marrakesh, 15 April 1994, 33 *International Legal Material* 1197 (1994) – hereafter 'TRIPs Agreement'.
15. 'The scope of protection in the TRIPs Agreement is not adapted to the field of animal breeding – so these consequences are probably not foreseen in the WTO', Tvedt, M.W., et al., *Legal Aspects of Exchange, Use and Conservation of Farm Animal Genetic Resources*, Fridtjof Nansens Institutt, FNI Report 1/2007, available at: http://www.fni.no/doc&pdf/FNI-R0107.pdf (last visited 16 November 2008), at p. 18.
16. World Intellectual Property Organisation, Standing Committee on the Law of Patents, *Draft Substantive Patent Law Treaty*, SCP/10/4, 14 May 2004.
17. Convention for the Protection of Industrial Property, Paris, March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979, 828 *United Nations Treaty Series* 303, Administered by WIPO (hereafter 'Paris Convention').

I. BACKGROUND ELEMENTS

Despite – and perhaps also because – the lack of attention so far, a specific analysis seems justified. On the one side, AnGR are different in many respects from other biological resources, and it must be seen to what extent this should be translated into different regulatory approaches. On the other side, certain events occurred that either are specific to animal genetics, or still were not assessed in dept in the specific context of AnGR and intellectual property protection:

- the entry of biotechnology and genetic engineering;
- the so-called 'erosion of AnGR';[18]
- climate change;
- the globalization of the marketplace; and
- a strong concentration of market players in certain fields.

Amongst these elements, biotechnology can have a central impact on all others, while it is also biotechnology that has brought patents into the field of AnGR. Biotechnology facilitates trade in AnGR and opens perspectives for increased productivity as well as for increased adaptation of breeds to diseases and environmental factors (including climate change). It can be an effective tool for the conservation of resources and has a direct potential to the economic development of agricultural regions. Biotechnology however also raises a number of questions and may alter many traditions and habits, especially in agriculture. It is at the heart of heated debates on ethics,[19] development, safety, and on the control over the technologies – to cite but a few.[20]

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18. Around 20% of breeds reported in the FAO *State of the World's Animal Genetic Resources for Food and Agriculture* are classified *at risk*, Food and Agriculture Organisation of the United Nations, The State of the World's Animal Genetic Resources for Food and Agriculture, Rome, 2007.

    This is attributed to several factors, among which the largely established marketing of high-yield, genetically uniform breeds. At stake is the intensification, mechanization and industrialization of agriculture and animal production, along with the loss of rangeland grazing resources and the loss of the pastures and common property resources that form the foundation of the production systems in which local breeds developed. Large-scale promotion of uniform high-yielding breeds and cross-breeding; inappropriate breeding policies and practices in general, including the inappropriate introduction of exotic breeds; policies and developments that disadvantage ethnic minorities; conflicts and wars; natural disasters; and diseases outbreaks play a role as well.

19. For instance: Oliver, M., *Biotechnological Inventions: Moral Restraints and Patent Law*, Aldershot, Ashgate Publishing, 2005.

20. Despite these newer debates, biotechnology comes in a long tradition of human intervention into animal life. Animal breeding has in fact always been based upon human intervention into genetic structures (albeit in a less predictable, precise and far reaching war). The first domesticated species, animal species that have been controlled and subsequently modified by breeding methods in order to better suit certain purposes, are estimated to have lived 12 000 years ago. Today there are around 7000 'domestic animal breed populations' (see § 10 (2) of the Global Plan of Action for Animal Genetic Resources). It comes to investigate which elements of change biotechnology brings and requires from the regulatory framework, in the specific context of AnGR.

The term *biotechnology* can cover a wide range of different conceptions. Whereas it is often linked to the discovery of deoxyribonucleic acid (DNA) by Crick and Watson in the 1950s – mostly called the start of *modern biotechnology* – elder work with micro-organisms for instance can equally qualify as biotechnology in its dictionary definition.[21] *Genetic engineering*, apparently a term with a narrower coverage than 'genetic manipulation', has emerged in the 1970s and only and points more directly at what many people have in mind when considering biotechnology: modifying the genotype (the genetic constitution of an organism), and hence the phenotype (the external, visible characteristics of an organism), by transgenesis (the introduction of a gene or genes into cells[22]).[23] Translated into the 'AnGR practice', animals which for instance are the outcome of a process of marker selection[24] can be called 'biotechnological' but the animals themselves have not been 'genetically engineered'. This introduces the increasingly blurred borderline between what one would call 'traditional'[25] agriculture and 'biotechnology' driven farming.

On the one side, whereas genetic engineering plays only a minor role on the markets of AnGR for food and agriculture[26] – so far[27] – biotechnology nonetheless has a certain influence. It usually comes in through processes and tools such as sexing,[28] cloning,[29] artificial insemination or marker selection. Marker selection, sexing and especially artificial insemination can even be considered 'traditional' in most developed countries' agricultural systems already. Their use is moreover likely to increase in the future, for instance in relation to artificial insemination in pig breeding. The situation is a little different for cloning. The cloning of bulls

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21. 'The explanation of biological processes for industrial and other purposes, esp. genetic manipulation of micro-organisms' – Concise Oxford English Dictionary, Oxford University Press, Ninth Edition, 1995, at p. 128.
22. Which leads to the transmission of the input-gene (transgene) to successive generations.
23. 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 22 May 2011).
24. A common tool to identify the animals in which certain genes considered to enhance productivity occur naturally. By this is achieved a better result in mating and breeding.
25. 'Of, based on, or obtained by tradition'; whereby 'tradition' is defined as: 'a custom, opinion or belief handed down to prosperity esp. orally or by practice', Concise Oxford English Dictionary, Oxford University Press, Ninth Edition, 1995, at p. 1478.
26. 'AnGRFA'.
27. Although for instance Avigenics is reported to be producing genetically altered chicken for the past four years already, 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, at p. 16.
28. The process of 'sexing' or 'semen sexing' separates x and y-sperms so as to enable a choice on the gender of unborn animals.
29. Cloning has been successfully applied to sheep, cattle, pig and horses (Suk, J., 'Dolly for Dinner? Assessing Commercial and Regulatory trends in cloned livestock', 25 *Nature Biotechnology* 1 (2007), pp. 47-53).

for instance appears promising, but is not yet applicable in a successful manner. Ethical objection raise[30] and on European markets:

> GM food is still the Achilles' heel of biotechnology[31]

> Cloning animals for food products is even less popular than GM food with 18 per cent of Europeans in support.[32]

Although cloned meat has been allowed on the US market since 2008,[33] even here it will probably stem from animals which are the 'natural' offspring of cloned 'originals'. The direct products of cloning processes are still too expensive to be used on a commercial scale today.

On the other side, transgenic animals – the results of genetic engineering – have so far not entered the agricultural markets and are not the subject of strong research and development (R&D) investment, although the possibility to genetically engineering animals has for the first time been concretized in the early 1980s already.[34] An exception may be the fish industry, where 'Super Salmon'[35] and further developments are prospected to receive larger investments in the future. However, today, also these still face a strong reluctance by consumers and market access regulations.[36] This is different in relation to animals engineered to be used for medicinal purposes. Both consumer reluctance and safety issues are less strong here, and investment appears to be commercially interesting.

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30. European Group on Ethics in Science and new Technologies to the European Commission, *Ethical aspects of Animal Cloning for Food Supply*, Opinion No 23, 16 January 2008, available at: http://ec.europa.eu/european_group_ethics/activities/docs/opinion23_en.pdf (last visited 4 January 2009).
31. 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).
32. *Ibid.*
33. 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 11 May 2011).
34. When scientists reported on the development of genetically modified mice in 1982 (Palmiter, R.D., Chen, H.Y. and Brinster, R.L., 'Differential Regulation of Metallothionein-Thymidine Jinase Fusion Genes in Transgenic Mice and Their Offspring', ***Cell*** 29 (1982), pp. 701-710). Later, in 1986, these principles where tuned to fit rabbits and pigs as well (Hammer, R.E. (ed.), 'Genetic Engineering of Mammalian Embryos', *Journal of Animal Science* 63 (1986), pp. 269-278, available at: http://jas.fass.org/cgi/content/abstract/63/1/269 (last visited 8 March 2009).
    The first patent on a transgenic animal was issued in the US in 1988: the Harvard Oncomouse (US Patent 4 736 866, Harvard College, 12 April 1988).
35. US Patent 5 545 808 (16 August 1996) and EP 0 578 635 (18 July 2001).
36. Engelhart, M., Hagen, K., and Boyson, M., *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 skeptical on 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.