

Animal Genetic Resources and Intellectual Property Rights – The Issues

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Précis

International multilateral agreements among nations currently operating are designed to ensure mutual recognition of formalities of proprietary rights, the standards and formalities of proprietary applications, the continuation of the legal certainty regarding ownership and the ensuing necessary legal certainty of trade at an international level of genetic resources and the commodities these resources generate. However, whilst there is mutual recognition of some of the formalities², there is not uniform mutual recognition of proprietary rights themselves.

The question is whether the current agreements will meet these objectives for the future without amendment.

Genetic resources and their usage form part of humans' daily existence, from the food ingested to the medicine used to cure ailments to the advancement of standards of human health and well-being. Scientific research and commercial application, particularly with regard to the genetic manipulation of DNA, have permitted these advancements to be made. However, the legal

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² The Patent Cooperation Treaty provides a unified system of rights to apply patent protection enabling a single application to be filed in member countries for international patents. Each member country may require individual differences with applications electronically filed. The Patent Law Treaty seeks to address administrative issues relating to the patent system, particularly the harmonization, on a global basis, of formal patent procedures. These procedures include standard forms and simplified procedures for the maintenance of patents.

constructions currently in operation are not appropriate to fully recognize these with the necessary certainty both in the short and long term, particularly if increased disclosure obligations are required or the requirements of novelty or inventiveness are no longer compelled to be components of proprietary protection. Should the requirement of additional disclosure be included this would introduce legal uncertainty to the system and to the trade in such resources and the commodities that they generate.

Coupled with these scientific advancements or achievements are the issues of associated traditional knowledge concerning genetic resources and their subsequent use, particularly for the purpose of commercialization. These technically cultural concerns do not fit within the legal paradigm currently in operation at an international level and raise questions relating to the equity of existing arrangements. However, a large proportion of traditional knowledge is currently within the public domain and to offer legal protection to this knowledge would create legal uncertainty. The issue, of which traditional knowledge requires protection, public or private domain, requires clarification. If international legal protection is granted to the body of traditional knowledge currently held within the public domain, the resultant effect would be a creation of a level of legal uncertainty regarding the exchange and use of genetic resources for both research and commercial purposes.

The question is whether these equity issues are best answered at the international legal level concerning the formalities of proprietary protection, or by each nation on a domestic legal footing by legislation containing as its object the recognition of indigenous land rights in the form of native title to ensure tenure by the current possessors of the land.

Sources of Law

Whilst these international debates continue concerning the global recognition and possible legal advancement of the key constructions of traditional and associated knowledge in conjunction with access and benefit-sharing as they relate to genetic resources, signatory nations to some international conventions³ have been charged with the obligation to enact domestic provisions. These provisions capture the intention to regulate and

³ These agreements include: *Convention on Biological Diversity*, *International Treaty on Plant Genetic Resources for Food and Agriculture*, *International Union for the Protection of New Varieties of Plants* and the *International Plant Protection Convention*.

control genetic resources within their jurisdiction, both in their original form and as they may be used for scientific research, commercial development of commodities and the ensuing trade in such at domestic and international levels. This obligation has been discharged by a number of nations within a continuum that represents the diverse range of interpretation and legal applications of the central concepts of title of property, access to property, purpose of property use, proprietary protection in both a normative and cultural sense, royalty thresholds and other benefit-sharing schematics from the commercialization of property. Some of these nations have enacted domestic provisions which seek to regulate on an access only basis, whilst others have delineated between the usages of the genetic resources. This usage may either be for research or commercialization; for instance, pure scientific research concerning analogue derivatives, as opposed to the commercialization of the genetic resource in the form of tradable commodities.

The enactment of domestic provisions by some nations to discharge perceived obligations under international agreements has raised concerns regarding the legal certainty of current obligations under the existing intellectual and other proprietary rights agreements. These include; the impact of Articles 27, 29, 35 and 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁴, the disclosure obligations under the Patent Cooperation Treaty (PCT) and the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purpose of Patent Procedure (Budapest Treaty)⁵, and the current standards and formalities regarding international applications, particularly Articles 2, 5 and 10 of the Patent Law Treaty (PLT).

⁴ Article 27 'Patentable Subject Matter' provides that patents 'shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application' (Article 27.1) Debate has ensued concerning Article 27.3(B) and the four rules of patentability that it contains, particularly the issue of *sui generis* protection for plant varieties. Various developing nations have called for a review of this particular provision to avoid conflict with the Convention on Biological Diversity as TRIPS is silent on the concepts of traditional knowledge and biodiversity. This represents a call for a major refocus on substantive legal obligations. Article 39 charges TRIPS member countries with the protection of undisclosed information. Whilst this provision was originally aimed at the protection of traditional industrial trade secrets, it has been debated that the three requirements of Article 39 could be met by traditional knowledge, thus allowing nations to enact domestic legislative provisions to protect such knowledge consistent with the provisions of TRIPS.

⁵ The Budapest Treaty provides for the deposit of micro-organisms in an international depository authority where a deposit is necessary to satisfy descriptive requirements of patent legislation for inventions involving micro-organisms or the use of micro-organisms. Under the Treaty, a Member State which allows or requires the deposit of micro-organisms for the purpose of patent procedure must recognize the deposit regardless of the location of the facility.

The issues of mandatory disclosure of associated traditional knowledge; the characterization of the concept of benefit flow being distinct from royalty and conditional to disclosure; the removal of the concept of control from property ownership when defining associated traditional knowledge⁶; the application of legal forms of protection for associated traditional knowledge only in situations of commercialization, not research initiatives; the compliance obligations that would ensue if amendments to disclosure provisions were made and the interface between contract law and the patent system are currently under consideration.

The impact of these issues on the legal certainty of patents over genetic resources and products made from or using them and the ability to provide the necessary certainty in ensuing commercial transactions, both at a domestic and international level, has a broad reach. This is particularly compounded when placed adjacent to the cardinal objective of international trade law of the World Trade Organization (WTO) that of economic development through open and free trade.⁷ This liberalization of the international trade agenda by the WTO has as its cornerstone the reduction of barriers to trade, which could be dramatically curtailed if the resolution of these impact issues is resultant domestic legislation that is prohibitive or restrictive to open and free trade between nations. The existence of barriers to trade was recognized in the preamble to the WTO Agreement, with the reference 'by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations'.⁸ Although at the time of drafting, it was recognised that the lack of protection offered to innovators was a barrier to free and open trade on an equitable footing⁹, the inclusion of domestic proprietary protection legislation seeking to offer legal protection to technically cultural concerns may not have featured amongst these perceived barriers. Domestic legislation, given that it is at the discretion of the nation State, may include components that are incompatible with international

⁶ Associated traditional knowledge has been the subject of considered debate concerning the definitional understanding of such a term when it is applied to the subject of genetic resources. The term has the capacity to be interpreted broadly to encompass any knowledge held by any member of an indigenous population concerning the genetic resource in any form; or to be interpreted narrowly to confine this knowledge to that not previously held in the public domain and only the specific, previously undisclosed knowledge being utilized for the purpose of the commercialization of the genetic resource.

⁷ Islam, M.R. *International Trade law of the WTO*, Oxford University Press, Hong Kong, 2006

⁸ Agreement Establishing the World Trade Organization, 15 April 1994

⁹ TRIPS was drafted to address this trade barrier and to encourage investment within a system that offered protection to inventions or innovative processes.

systems and as such, these would have the potential to be used as barriers to trade.

Issues under consideration

At issue are a suite of concerns ranging from the agreement of a baseline definitional understanding of the concepts through to the commercial application in a legal paradigm that is able to demonstrate both an equitable distribution and the necessary certainty in terms of ownership. Coupled with this is the interface of these concepts with the existing intellectual and other property rights structures with regard to legally enforceable proprietary rights that a natural person or other legal entity may possess and seek to exercise. An adjunct to this interface is the complex issue of associated traditional knowledge and the legal space that this may or may not occupy in the proprietary structure at an international legal level. This is the juncture at which environment and trade appear to be juxtaposed.

This juncture is one that is fraught with conceptual difference, particularly with regard to the usage of genetic resources and the inclusion of cultural concerns as legitimate legally enforceable proprietary rights. If existing international agreements, such as TRIPS, the PCT, the Budapest Treaty, the PLT, UPOV and the WTO's arrangements for the trade of commodities generated from genetic resources are to continue substantive amendments may be required. Should these amendments be contemplated in the form of new normative measures, these would need to display the required legal certainty to guarantee the continuation of international trade. This introduction may also generate a need to amend existing international conventions to accommodate these changes.

However, before such a decision can be drawn, the legal interface with public international law, private international law and property law in the domestic jurisdiction will require examination. In particular, the role of industry sector codes of ethical conduct and their interface with the legal schematic will require deliberation to ensure all elements of a mutually supportive regime have been considered.

Questions raised by the issues being considered

The issues currently under consideration raise a number of complex and

challenging questions that will require resolution:

1. What is the future for genetic resources currently held by private individuals and other legal entities?
2. Are genetic resources within the jurisdictional boundaries of domestic nations and under their control and management?
3. Should any proposed amendments encompass the issue of mandatory disclosure for traditional and associated knowledge of the genetic resources utilized? If so, what form of protection would this disclosure provide?
4. Does mandatory disclosure resolve the current perceived impediments and provide scope to encompass future technological and scientific advancements with regard to genetic resources?
5. What legal principles would such disclosure be based on, given the technical cultural delineation in the current intellectual and other proprietary rights legal systems?
6. If genetic resources are subject to nation specific jurisdictional provisions, what impact does this have on the necessary legal certainty of commodities based on combined or modified genetic resources that are traded under bilateral or multilateral agreements?
7. Would any alteration to the current international legal paradigm place proprietary rights currently held in legal uncertainty?

Animal genetic resources – the place they occupy in the schematic

The space in the existing international legal schematic occupied by animal genetic resources is one that rests primarily in property law. Any animal genetic resources are normally traded as simple property transactions, with title passing to the purchaser on the completion of the transaction. Any trading of patented animal genetic material is normally conducted under a license agreement, but supply agreements are not normally entered into in

relation to the produced or engineered commodity that results. Even at its most simple transactional level, that of a subsistence farmer, the trade in animal genetic resources still remains a simple property law transaction.

However, the ensuing international legal debate concerning the regulation, protection and usage of animal genetic resources would institute a change in this essentially simple transactional arrangement, particularly at the public law level. It would be difficult, unless domestically enacted, to extend any jurisdictional change to private sector ownership and trade in these resources and the commodities that they generate without the issue of compensation being raised for loss of title and continued use. It may also generate a high level of uncertainty for all transactions, even that of the subsistence farmer, if such domestic jurisdictional reach were to come into existence.

Current issues of concern

The continued availability of animal genetic resources for the purpose of sustainable agricultural production is a matter of concern for both developing and developed countries. Coupled with this concern are the issues of the conservation of the locally adapted breed populations developed by agriculturalists, the continued access to and sharing of the benefits derived from these resources, the importance of Livestock Keepers' Rights and the implications of intellectual property rights protection in various forms of these resources.¹⁰ As an adjunct to these issues is the use and protection of transgenic animals for the purposes of modeling human diseases and the production of human pharmaceuticals for commercial purposes.¹¹ These are all components of a wider governance structure for the regulation and control of the usage of these resources for a variety of purposes, including that of agricultural production.

Any governance structure concerning animal genetic resources will need to consider the interconnectedness of the various national domestic legal systems with the current international legal schematic to ensure the continued access, trade and development of these resources. In particular, the ability to acquire proprietary protection for animal genetic resources in

¹⁰ 'Managing Animal Genetic Resources in Africa: Strategies, priorities, livestock keepers' rights, and the way forward' Executive summary of a workshop held in Addis Ababa, Ethiopia, on 24-25 May 2007

¹¹ Woessner, W.D. 'Patenting Transgenic Animals' 2000

selected domestic jurisdictions¹² as a precursor to international proprietary protection will require substantial deliberation if an international system of mutual recognition of domestic legal regimes is to be envisaged.

Prior to the institutionalization of any governance structure, the objective and intent need to be formulated. Is it the intention to institute a system of governance for the conservation of animal genetic resources to halt the decline in available livestock breeds¹³, or is it the intention to regulate all livestock breeds currently situated in the jurisdiction of the national domestic governments of each nation State¹⁴, or is it the intention to regulate all dealings in animal genetic resources whether in the public or private domain?

The objective of the governance structure would also require clarification. Is it the objective of the instituted system to regulate all dealings in animal genetic resources regardless of use of purpose¹⁵, or is it the objective to regulate all dealings in animal genetic resources for the purpose of agriculture only?

One central issue of intent that must be resolved prior to the institutionalization of any governance structure is the treatment of traditional and associated knowledge. Is it the intention to respect the domestic jurisdictions of nation States to enact or otherwise regulate the protection and usage of this knowledge; or is it the intention to formally recognize, at an international level, the concept in a legal framework that could only operate within the public law domain? Where would the concept of Livestock Keepers Rights best be addressed, within an international legal paradigm or at a nation State domestic jurisdictional level?

Until clarity of these intentions and objectives is achieved, any instituted governance structure is at risk of being incongruous with existing international arrangements. This would not be inline with the original tenets of the Charter of the United Nations that all international agreements should be mutually supportive and non-conflicting in the areas of coverage that they

¹² This occurs primarily in the United States of America in relation to transgenic animals (mice, pigs, sheep, cattle and goats) used for the purposes of pharmaceutical research and development.

¹³ FAO Report Part 5 'Needs and challenges in animal genetic resources management'

¹⁴ This intention would recognize the sovereign jurisdiction of nation States to their genetic resources as envisaged by the Convention on Biological Diversity.

¹⁵ This holistic objective would include research, agricultural purposes and pharmaceutical purposes.

seek to claim.¹⁶

Lessons from the plant world

Given the issues under consideration with regard to animal genetic resources have, in some manner, been considered by the international community in relation to the proprietary protection of plant genetic resources, this depth of consideration may offer some guidance.

The main proprietary protection and benefit-sharing mechanisms concerning plant genetic resources are UPOV and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Both of these conventions utilize a different approach to proprietary protection and benefit-sharing; with one being an example of a *sui generis* system as envisaged by Article 27 (3) (b) of the TRIPS agreement, whilst the other is a creation of a new multilateral system for the purposes of the 64 listed genera held under the management and control of the national governments of parties and utilized for the purposes of food and agriculture only.

This dichotomy of proprietary protection and benefit-sharing may prove to be of assistance regarding the issue of proprietary protection of animal genetic resources. Both of the conventions regarding plant genetic material seek to facilitate access and continued development of the original genetic material without being restrictive. Even if intellectual proprietary protection is attached to these plant genetic resources it is not to restrict or prevent access to and the development of these resources.¹⁷

Concluding comments

The institution of any new governance structure for animal genetic resources for food and agriculture will need to carefully consider the issues with due reference to the intent driving the agenda for change. Each nation State depends on the availability of these resources for safe food through to economic development and trade expansion. The task is not an easy one and not one to be rushed. It will require extensive consultation with all relevant

¹⁶ Charter of the United Nations: Article 1(3) 'To achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character' and Article 1(4) relating to the United Nations being 'a centre for harmonizing the actions of nations in the attainment of these common ends.'

¹⁷ UPOV has the breeders' exemption, whilst the ITPGRFA actively encourages the development of genetic material placed in the multilateral system, whilst still adhering to any proprietary rights exerted.

stakeholders particularly as, unlike plant genetic resources, the bulk of the animal genetic resources are held within the private domain.

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