

Regulatory options for exchange, use and conservation of animal genetic resources: a closer look at property right issues¹

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Summary

Three main areas for further development of policies or regulatory options for animal genetic resources (AnGR) were identified in a study on the exchange, use and conservation of AnGR (Hiemstra *et al.*, 2006):

1. how to halt the further erosion of genetic diversity and promote sustainable breeding and use,
2. whether there is a need to further regulate the exchange of genetic material and
3. how to balance different systems of property and use rights.

This paper provides an in-depth analysis regarding the third challenge, that of addressing the problems and options available for balancing the different property right systems for AnGR.

Résumé

On a identifié trois domaines principaux pour le développement futur de politiques ou règlements pour les ressources génétiques animales (AnGR) dans une étude sur l'échange, l'utilisation et la conservation des AnGR (Hiemstra *et al.*, 2006):

1. Comment empêcher l'érosion de la diversité génétique et promouvoir une amélioration et utilisation durable.
2. Quand est-il nécessaire de réglementer les échanges de matériel génétique.

3. Comment harmoniser les différents systèmes de propriété et droits.

Cet article présente une analyse détaillée du troisième point, c'est à dire, comment approcher les problèmes et quelles sont les options disponibles pour harmoniser les différents systèmes de droits de propriété dans le domaine de AnGR.

Resumen

Se han identificado tres áreas principales para futuros desarrollo de políticas o reglamentos para los recursos zoogenéticos (AnGR) en un estudio sobre el intercambio, la utilización y conservación de AnGR (Hiemstra *et al.*, 2006):

1. Cómo impedir la erosión de la diversidad genética y promover una mejora y utilización sostenible.
2. Cuando es necesario reglamentar el intercambio de material genético.
3. Cómo armonizar los distintos sistemas de propiedad y derechos.

Este artículo presenta un análisis detallado del tercer punto, es decir, cómo enfocar los problemas y cuales son las opciones disponibles para armonizar los distintos sistemas de derechos de propiedad en el campo de AnGR.

Keywords: AnGR, Regulatory options, Patent, Sui generis, Breeders' rights and livestock keepers' rights

¹ This paper summarizes the main findings on property right issues of a study by Hiemstra *et al.* (2006) entitled "Exchange, use and conservation of animal genetic resources: policy and regulatory options". The study was commissioned by FAO and funded by the Government of the United Kingdom of Great Britain and Northern Ireland, through DFID. The views expressed in the study and in this paper are the sole responsibility of the authors. The full report is downloadable from: www.cgn.wur.nl/UK/CGN+Animal+Genetic+Resources/Policy+advice/
www.cgn.wur.nl/UK/CGN+General+Information/Publications/2006/
www.fao.org/ag/againfo/subjects/en/genetics/documents/ITWG-AnGR4/AnGR_policy_and_regul.pdf

Introduction

The analysis of different property right and legal systems (in this paper) forms part of a larger study by Hiemstra *et al.* (2006) into how exchange practices regarding AnGR affect the various stakeholders in the livestock sector.

The study's main objective was to identify policies and regulatory options for the global exchange, use and conservation of AnGR (Hiemstra *et al.*, 2006 and Hiemstra *et al.*, this issue). The background for FAO to commission this study was a recommendation from the Intergovernmental Technical Working Group on Animal Genetic Resources (see: CGRFA/WG-AnGR-3/04/REPORT, paragraph 24). The analysis of policy and regulatory options available is based on literature surveys, scenarios analysis and stakeholder consultations (Hiemstra *et al.*, 2006; Drucker *et al.*, this AGRI issue).

Different legal systems and types of property rights are relevant to AnGR. The current legal framework shapes the freedom to use, breed and sell AnGR on national, regional and global levels. For farm animals and thus also for AnGR, private ownership is the rule and public domain the exception. The principal point of departure is that the owner of the individual animal has the right to use the genetic resources in further breeding or even to sell genetic material (for a more profound discussion of ownership of AnGR, see Hiemstra *et al.* 2006, pp. 15–16; Tvedt *et al.* 2007, pp. 8–10).

The right to use the animal in breeding is often specified in a (formal or informal) contract between the seller and the buyer of the animal. The contract or informal agreement determines the scope of what is transferred and which rights still belong to the seller (if any). Contracts imply a dynamic element in establishing (or transferring) rights from one owner to the other. The most important limitation of the use of a contract is that it only applies between two parties, and has limited legally binding effects for third parties (For a more detailed discussion of contracts, see Tvedt *et al.*, 2007, p. 11–12).

Intellectual property rights are also used in the animal sector. Currently, the most familiar is a trademark. A trademark is a “*sign, or any combination of signs, capable of distinguishing the goods or services*” that may add value to a product by distinguishing the product from other similar products in the market (TRIPS Article 15).

Thus a trademark does not target the AnGR *per se*, but products developed from animals. Geographical indications can protect “*indications which identify a good as originating in the territory of a*

Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin” (TRIPS Article 22, paragraph 1). Similar to trademarks, geographical indications do not protect the breed or genetic material *per se*, but may add commercial value to the animals or breeds produced in a particular region. A third type of intellectual property right which is relevant for AnGR are patents (see Section A below).

This paper addresses the problems of, and options available for, balancing different property right systems for AnGR. Three groups of regulatory options can be identified:

1. Patent law and animal breeding.
2. *Sui generis* protection in animal breeding.
3. Livestock keepers' rights.

Section A explains the current situation regarding patent law as applied to the animal breeding sector. Section B identifies possible *sui generis* systems, which could be (further) developed for AnGR. Section C elaborates further on the specific issue of livestock keepers' rights (or farmer's rights). Finally in Section D we summarize our main conclusions and highlight key issues to be discussed in international forums.

Section A. Patent Law and Animal Breeding

Patent law is general in scope, applying to all fields of technology and innovation [for a more in-depth analysis of how patent law applies to animal breeding and AnGR, see Tvedt (2007, forthcoming) and Nuffield Council on Bioethics (2001) regarding an analysis how patent law applies to genes in general]. Consequently, it does not necessarily take into account the specific needs and challenges of AnGR or the animal breeding sector (Tvedt 2007, Rothschild and Newman 2004 and Rothschild and Newman 2002). The main legitimacy of this existing legal framework rests in its contribution to innovation, research and development. If patent law is not contributing to increased research and development in this field, the time-limited monopolies can hardly be justified. One concern for AnGR is that a high number of claims, as is common for patent applications in the plant sector, may lead to the establishment of a significant body of exclusive rights with substantial impact upon the use of AnGR by researchers, breeders and farmers. The potential consequences are yet to be seen.

In the plant breeding sector, the main rule is that Plant Genetic Resources (PGR) are in the public domain and open to use by everyone. This is quite different from the case of AnGR, which are often in individual or communal private ownership. It may well be that the need to maintain a viable public domain for AnGR is not as important as it is for plants (For an analysis of public domain for genetic resources in general, see Tvedt 2005). However, if patent protection is granted with a low requirement of inventiveness and novelty (potential examples are in fact in the process of being granted (see Fitzgerald 2005), and if granted broadly in terms of scope, research and breeding activities which were previously widely possible might become more restricted. In some cases this could even impact traditional uses in the country of origin. Due to the short history of applying patents to AnGR, there is an absence of case law and scholars commenting on how these general principles of law will be applied in this particular area. In this context, this study has identified the following questions that may raise particular problems in the future.

Patentability in the animal sector

The question of what types of inventions are eligible for patent protection was previously left to the discretion of each country. This was radically altered by the Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement) under the WTO, which establishes a comprehensive scope of patentability by requiring all member countries to provide for patent protection in all fields of invention, save for some narrow exemptions: Countries are allowed to exempt patent protection of animals other than micro-organisms, and for essentially biological processes (TRIPS Agreement 27, paragraph 3).

The TRIPS Agreement essentially creates opportunities for exempting animals other than micro-organisms from product patent protection in national patent law. The practical implications of this exemption depend upon the interpretation of the legal concept 'other than micro-organisms'. There is no definition or any agreed understanding of the term 'micro-organisms' among the parties to the TRIPS Agreement. Thus, countries have significant discretion as to whether to include or exclude animals, animal-proteins, genes and cells under patent protection in their national patent

system, which may have a significant impact on biotechnology. One linguistically possible interpretation of this term is that countries have the freedom to exempt product patent protection for every category of animal-related biological invention except those being clearly recognised as micro-organisms in a biological sense [Correa (2007, p. 293); Westerlund (2001) takes the opposite position and argues that the exemptions should be interpreted narrowly, see also de Carvalho (2005)].

Consideration of the patent applications received under the WIPO Patent Cooperation Treaty system shows that process patents are highly relevant for the animal sector (Tvedt, 2007) and that countries are highly likely to grant process patents in the field of animal breeding. The TRIPS article 27 paragraph 3 opens for countries to exempt "...essentially biological processes for the production of [...] animals", but obliges countries to delimit such an exemption and provide for patents to "other than non-biological and microbiological processes". The essential question is what is an "essentially biological process"? A WIPO official, de Carvalho, argues that this wording should "... be read in a restrictive manner...", since it is an exemption and maintains that: "...there are processes which are biological, to the extent they comprise some phase in which biological reproduction is employed, yet their most important steps consist of acts of human direct interference. These processes, in essence, are not biological" and must therefore, according to him, be patentable according to his understanding of the TRIPS Agreement (de Carvalho 2005, pp. 217-218). Correa notes that "...its main aim in the TRIPS Agreement context is probably to limit the exclusion of patentability to traditional breeding methods [...]" (Correa 2007, p. 293). Note that neither of them are discussing this issue particularly within the context of the animal breeding sector. As the TRIPS agreement does not specify the legal concept further, countries have some discretion to implement a broad or narrow definition and practice of the concept of essentially biological processes for the production of animals. The experience from the EU Directive on the legal protection of biotechnological inventions (EC/98/44) shows that this discretion has in fact been used to implement a narrow exemption from patentability in Europe (Tvedt, 2007). We may therefore expect differences among countries with regards to the scope of patentability both for product and process patents, but as a general rule patent protection can be expected to become widely available in the field of animal breeding.

Prior art

The concept of 'prior art' relates to what is considered to be a body of information which cannot be patented. In principle, everything already known should be considered part of prior art and thus ineligible to meet the patent criteria. However, this is only a formal point of departure as the national patent office must put this principle into practice. For an activity where the current practices or prior art are not necessarily published in a sufficiently formal manner, there is a concern that common knowledge could conceivably become patent protected. To avoid such occurrences, measures could be taken to ensure that all relevant sources be covered during the prior art search process. Such a measure could be implemented by expanding the check-list for patent offices when they search for prior art.

Although preventive publishing is often put forward as a strategy to ensure that common knowledge will be considered prior art, it should be taken into consideration that such publishing only prevents patents from being granted in relation to that specific and particular form of published information. This means that preventive publishing may prove to be less effective in protecting against small adaptations to what was originally published. The large number of patent applications for different breeding methods which are currently being considered by patent offices is already increasing the challenge of identifying relevant prior art.

Novelty and inventiveness

The novelty of an invention is considered by comparing the prior art with the invention described in the patent claims. If these two textual sources are identical the novelty criterion is not met and the patent should not be granted. In technical areas where extensive publication is not the norm, the chance of meeting the novelty criterion is higher than for areas where there is an extensive body of publications. The livestock sector might thus be exposed to many patent applications meeting the patent criterion even if they are not particularly novel in a practical sense. The same items of prior art are used to assess inventiveness. If a low level of inventiveness is required, a granted patent may include what was de facto already known or in practice. Practical measures to deal with these problems include the development of specific

guidelines for patent offices relating to how such assessments should be conducted. Such specific guidelines would of course have to comply with the requirement in the TRIPS Agreement, which states that patent protection is granted without discrimination among the various technological fields. Specific regulation of aspects of biotechnology patents is already accepted by the EU Directive on Biotechnological Patents (EC/98/44), so the TRIPS Agreement does not close the door to adapting special guidelines for single areas of invention. The general conclusion with regard to AnGR issues is therefore that an important gap needs to be addressed in order to ensure that methods already in existence do not become patented due to a lack of formal publications.

Scope of the granted right

After a patent is granted, the next task is to determine the scope of the exclusive right that the claims would confer to the patentee. According to the TRIPS Agreement, Article 28, the scope of a process patent protection is:

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

The process patent covers an exclusive right to the use or application of the described method. But the scope of protection extends also to cover at least the product obtained directly by that process. This means that the scope of process patent protection in the TRIPS Agreement requires countries to provide for indirect product patent protection that covers the outcome from the use of a patented method. Using a patented process might therefore give the patentee a legal position in relation to the offspring from the application of the process. This is highly relevant for the breeding sector as the next generations of animals bred by applying a patented method might become subject to the exclusive right.

In addition to concerns regarding the above principles and the granting of patents, the application of the principle of equivalence may create further difficulties when applied to livestock sector issues. The scope of what is covered by a patent is described in the patent claims. While interpreting the written patent claims, in some countries the scope of patent protection is made

even broader than it appears from a reading of the patent claims. The invention as described in the patent claims might be interpreted to become wider to also cover inventions that are so-called 'equivalent' to the invention described in the patent claims. If such an expansive 'doctrine of equivalence' is applied, there is a possibility of restricting someone else's potential to carry out breeding and/or research activities. Little attention has been given to this principle in patent law and none for the area of animal breeding. It is nevertheless an important issue, as it might become a significant factor in establishing broad exclusive rights. This will have unforeseeable consequences for AnGR. Since there hardly is any case-law dealing with these questions in the livestock sector, there is a need for a thorough, systematic legal analysis related to assessing how general patent law rules will apply to AnGR and breeding (for further details, see Tvedt 2007).

Exemptions to patent protection

An additional measure for supporting the adaptation of patent law could involve the identification of useful exemptions that would lead to a more balanced application of patent law vis-à-vis the livestock sector (for an analysis of the balancing of property rights in the aquatic sector, see Rosendal 2006). In this context, it is important to note that although a patent grants the exclusive right to use an invention as it is described in the patent claim, Article 30 of the TRIPS Agreement specifies that "countries have discretion to implement exemptions in the right conferred by the patent on a general level in the patent act". One example of such an exemption applies to plants in Europe, where the EU Patent Directive Article 11 implements a version of the 'farmers' privilege' – i.e. the right of the farmer to reuse his harvest as seeds under certain specific conditions even if those seeds contain a patented gene. There is a similar opening for EU countries to implement an exemption in the animal sector according to the directive and a wide discretion for all countries according to the TRIPS Agreement. Nevertheless, surprisingly few developing countries have implemented such legitimate exemptions in their patent legislation.

Finally, it is also worth considering the degree to which patent protection is needed in practise to promote breeding, research and development in this sector. While the issue of increased bureaucracy is often raised as a counter argument to the

implementation of CBD-based access legislation, it should also be taken into consideration that the patent application process and subsequent enforcement are also time-consuming, expensive and heavily dependent upon the involvement of lawyers. It would therefore be useful to assess what the potential benefits of patent protection might be for breeding, research and development in this sector, taking into account the fact that the investments of breeders and others need to be protected. This would need to be weighed against any potential costs, e.g. increased costs of breeding material and reduced exchange and use of AnGR.

Section B. *Sui Generis* Protection in Animal Breeding

The term '*sui generis*' is not a clearly defined legal term or concept in international intellectual property law. The TRIPS Agreement talks about "an effective *sui generis* system" for the protection of plant varieties as an alternative to providing patent protection to the same subject matter. But the TRIPS Agreement does not itself define such a system 'of its own kind' – a *sui generis* model for plant variety protection. One example of such a *sui generis* system for the protection of plant varieties are the plant breeders' rights under the different versions of the UPOV Convention. *Sui generis* systems for traditional knowledge have also been on the agenda at the World Intellectual Property Organisation (WIPO) for some years, but agreement on such an international system is still far off. If a *sui generis* system for AnGR were to be developed, it is crucial that the differences between plants and animals are carefully taken into account.

For AnGR it is not immediately apparent which subject matter requires further intellectual property protection. Where such a subject matter is identified and could be protected within the context of a *sui generis* system, then there is still a need to clarify *inter alia* i) who needs protection, ii) which entity should be the holder beneficiary to the right, iii) what should be the criteria for achieving protection, and iv) what should be included under the exclusive right. In the following section four options for *sui generis* protection are discussed:

Animal variety or breed protection

In considering the application of an intellectual property right such as a *sui generis* system for

AnGR or the breeding sector, defining the precise subject matter that should be protected by the right is clearly important. Compared to plant variety protection, providing intellectual property protection for 'animal varieties/breeds' would not make much sense due to biological reasons. The variety/breed is probably not the most relevant entity in animal breeding, but rather the individual breeding animal or its germplasm. Furthermore, the concept of an animal variety/breed is not easily defined. Such considerations mean that in terms of development of a *sui generis* system for the livestock sector, it would be difficult to identify characteristics that could serve as a standard description of the 'subject matter'. Further work is required to clarify the relevant subject matter for protection.

Establishment of breed associations

A *sui generis* system could be linked to eligibility for being included in a particular register or herd book (managed by a breed association). Under such a *sui generis* protection system, registration would lead to the establishment of a right and the criteria for being granted that right are those required for being registered. The difficult question here is what the rights (and legal consequences) conferred by such a registration should entail. For example, should such registration give any exclusive rights to the genetic material? One alternative could be that registration gives rights to the individual animal. However, such registration would not add much in addition to the already held physical property right over the animal plus the complete genome of the particular animal in question. A second alternative could be that registration of individual animals also confers an exclusive right to single genes or alleles in the registered animals. This alternative is however problematic, as single genes or alleles often occur in a similar form in different individual animals and there is a need to avoid creating competing exclusive rights to the same gene. A third alternative could be that only those farmers and breeders with animals registered by the breed association have the right to use the name or brand of the breed. Such a '*sui generis* protection' would be more similar to a regular trademark approach. Establishment of breed associations or herd book registration (governed by breeding laws) combined with trademark protection could therefore be a good option for breed conservation and property right protection.

Rights to genetic material of individual animals

One might also think about establishment of a *sui generis* right to the genetic material of the individual animal. With reference to the second alternative in the preceding paragraph, the first problem associated with such a right is the parallel occurrence of similar or identical genes and alleles in other animals. This would either undermine the exclusivity of such a right or result in competing property right claims. In addition to the problems related to identifying such genes, establishing a general *sui generis* right to the genes of the individual animal would probably not add anything new compared to ownership of the animals.

Geographical related properties

A *sui generis* protection could also be linked to special geographical related properties and characteristics of the animals or their products (geographical indications). A final alternative for a *sui generis* system would be to leave it to the breeder to characterise in a sufficiently precise manner as to what s/he claims as an exclusive right. This could then be used to establish a system for securing rights to technological developments and provide, for example, protection for a single gene when isolated and described. Such protection is however already provided by the existing patent system.

Summing up options for *sui generis* systems

To sum up, there are a number of relevant subject matters for intellectual property protection:

- At the level of the individual animal – protection is conferred by physical ownership of that animal and/or its offspring. Rights transferred during the purchase/sale of individual animals can be protected through the use of contracts.
- At the breed level – protection through the establishment of breed associations (or herd books) and the use of trademarks may be appropriate
- At the allelic, gene or protein level – protection is provided by patent law.

- Technical inventions relevant for breeding - protection would be covered by current patent law.

The conclusion on *sui generis* intellectual property rights in the animal sector is that it is not easy to identify the subject matter which needs to be protected. If a *sui generis* system were to be developed there would be a need for a more profound theoretical analysis in close cooperation with breeders to identify the subject matter that needs further intellectual property protection. Such an analysis would also need to identify the necessity of stimulating breeding and innovativeness by using such a legal system.

Section C. Livestock Keepers' Rights

Livestock keepers' rights or farmers' rights to animals are unexplored legal or political concepts in the livestock sector. The term 'farmers' rights' is mentioned in Article 9 of the ITPGRFA (FAO International Treaty on Plant Genetic Resources for Food and Agriculture). Farmers' rights 'recognize the enormous contribution' farmers have made regarding plant genetic resources (PGR). Responsibility for realizing such rights rests with national governments and there is a clause specifying that Article 9 shall not limit any already existing 'rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law'. From a legal point of view, these 'rights' are not formulated in a legally binding sense, which raises issues about their enforcement in practice.

Implementing a version of farmers' rights for livestock keepers (e.g. as formulated in such documentation as the 'Karen Declaration', which includes support for indigenous knowledge remaining in the public domain and that AnGR needs to be excluded from IPR claims) would first require similar international recognition of their crucial role and contribution to AnGR.

Different strategies have been suggested for securing livestock keepers' rights, and these include codifying the customary laws that relate to the management of AnGR. A first step in this direction would be to review and analyse relevant customary law in order to identify which principles need to be included. Given that grazing rights are crucial to

maintaining pastoral societies and are thus closely linked to conservation both at a breed level and at an allelic level, livestock keepers' rights could include production and grazing rights, as well as the protection of traditional knowledge.

Mechanisms to strengthen livestock keepers' understanding of AnGR issues, their negotiating capacity and access to legal support would also necessarily be a crucial element of a strategy for developing livestock keepers' rights.

Obstacles to the implementation of livestock keepers' rights include the fact that they could conflict with other intellectual property rights. For example, if a patent on a particular gene existed, the consent of the patent holder could be required when animals that express that gene were used for further breeding. Addressing this potential conflict is not however an insurmountable problem. For example, India has developed a Farmers' Rights law which carefully balances these rights for crop seeds. Similarly, where livestock keepers' rights could potentially conflict with other intellectual property rights, there would be a need to have rules governing how these interests should be taken into account within the highly specified and enforceable body of patent law. One approach would be that livestock keepers' rights could *inter alia* be relevant for inclusion both when assessment of the patent criteria is carried out, as well as during enforcement. However, since livestock keeper practises are typically not published in a manner qualifying as prior art according to the patent system, this might expose them to patenting even if not new in a *de facto* sense. Two alternative approaches might also be considered:

1. either single countries could implement exemptions to intellectual property rights for livestock keepers; or
2. standard exemptions could be developed at a regional or multilateral level.

It is also possible to imagine some form of a *sui generis* protection system for livestock keepers' rights. This concept would have to be developed further on a theoretical level, but could include a model for benefit sharing or could combine individual and community rights over AnGR. A crucial issue in the development of such a concept would be whether a *sui generis* system should include a positive right to exclude others or whether

it should be geared towards being a negative right aiming at preventing misappropriation of what is in use by livestock keepers.

Section D. Conclusions: How to Balance the Rights of Stakeholders in the Livestock and Animal Breeding Sector

'Classical ownership' of AnGR includes physical ownership and communal 'law of the land' affecting livestock keeping and breeding. The existing use of contract law in a more or less explicit manner is functioning rather well in the area of animal breeding. There is, however, an increasing tension with developments in the realms of biodiversity law and intellectual property rights protection. Demarcation of these different rights systems and maintaining equity among different stakeholders is crucial to avoiding conflict and increased transaction costs. In this context, it is important to consider the rights of livestock keepers vis-à-vis national level sovereign rights, as well as obligations between patent holders and breeders/livestock keepers. Balance is not easily achieved as breeders have a need to protect their new investments as well the current practices which are functioning and thus need not to be altered.

There are several potential options that could be explored in order to better balance the rights of different stakeholders in the livestock sector under a range of future scenarios. For example specific exemptions in patent law as applied to the animal sector could be implemented. This is already a well-known strategy from in the crop sector. Key issues related to the patent system also could be considered and these include: up-dating the prior art search practice, reviewing patent criteria for assessing potential innovations relating to AnGR, and/or implementing exemptions for livestock keepers and breeders.

Sui generis protection options for AnGR could also be explored, including through protection of breeds via the establishment of breed associations, defining livestock keepers' rights and assessing other strategies to secure investments. Note also that since livestock keepers' rights are in an early phase of development as a legal concept, further development is likely to require the identification of the needs of livestock keepers and how these needs can be addressed through the use of international policy or legal instruments.

The overall conclusion of this paper is that property rights need to be adequately adapted to the field of AnGR to be conducive to the exchange, conservation and sustainable use of AnGR. A second main observation is that for these purposes the balancing of property rights may not also be easily achieved. This is because breeders have a need to protect their new investments, while current practices are functional and thus do not need to be altered. Exploration of the options discussed in this paper may however assist in this task.

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