Intellectual property rights (IPR) issues in livestock biodiversity –Indian perspective

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ABSTRACT

Commercial interests in the new developments in biotechnology led to pressure being exerted on World Trade Organization (WTO) member states to provide better patent protection in livestock agriculture. Harmonization of national laws, particularly dealing with intellectual property rights in different areas including animal agriculture is one of the major impacts of GATT/WTO. Convention on Biological Diversity (CBD) recognizes the sovereign rights of nations over their genetic resources, including the capacity to establish conditions of access and fair and equitable sharing of benefit from the use of such resources. In spite of great economic and biological importance, even today a legal framework for animal genetic resources comparable to International Treaty on Plant Genetic Resources doesn't exist. Such a legal framework should contribute to global food security, and also benefit biodiversity rich under developed and developing countries".

Keywords: IPR, Livestock biodiversity, traditional knowledge

Agriculture in general and livestock agriculture in particular is unique because of its diversity and location-specific requirements. Livestock sector may be considered as driving force for food security and sustainable agriculture in India. The value of output from livestock at current price without considering the indirect contributions during 2006-07 was Rs 2,10,629 crores which is 26.6 per cent value of output of agriculture sector. Without high growth in livestock sector, it is difficult for India to achieve 7-8 percent GDP growth annually. Rapid progress in science and the number of applications of proprietary rights has led to an unprecedented growth in private sector investment in livestock agriculture particularly in animal biotechnology research in developed countries. All applications of biotechnology are potentially the subject of intellectual property claims.

Livestock biodiversity an asset: Indian subcontinent is a rich source of diverse animal germplasm, and only very few countries have such a large number of breeds of farm animals with such a wide genetic diversity. Majority of crop growing and livestock rearing areas in India are dry land areas with low and medium input production systems which favors maintenance of animal genetic diversity. On the contrary intensive systems of animal agriculture with high input, largely practiced in industrialized countries, erode genetic diversity. Locally adapted breeds enable these vast areas to be used in sustainable manner. The production and market requirements will inevitably be different in the future from what they are today because of likely changes in consumer needs, physical environment etc. Therefore, maintaining a wide genetic resource base is analogous to taking out insurance against an undefined need in the future.

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The loss of animal genetic diversity puts in jeopardy the sustainability of animal agriculture and the ability of the sector to respond to changing environmental conditions, such as disease, climate, production systems as well as future consumer preferences and food security particularly during disaster. Presently we are facing the problem of failure to match the genetic resources to the production environment. Rising human population leads to higher demand for food which can be met by more and more use of dry land – which can be used effectively only for raising livestock breeds that are well adapted to these conditions. Since 1950s, world human population has doubled and reached to 5.4 billion while the number of livestock has grown from 2.3 billion to 4 billion. In India decline in the ratio of human: livestock is much more sharp, for example the cattle: human ratio has declined from 430 per thousand in 1961 to 170 in 2003 and is expected to further drop by 20 per thousand by the year 2011. Worldwide rising income leads to rising demand for specialized food generated by diversification of animal production systems (Oldenbroek, 1999). Pastoralists in semi-arid areas are losing their livelihood because their grazing areas are being used for other purposes: irrigated cropping, rain-fed farming, nature reserves and wildlife parks (Vivekanandan and Paulraj, 2002). Pastoralists, small and marginal livestock farmers conserve livestock genetic diversity and thus provide a service to humanity that is currently not rewarded by market forces. An international legal framework on animal genetic resources could provide support and incentives to those conserving genetic diversity.

Indigenous cattle are bestowed with many unique characteristics. Identification of genes for unique characteristics like disease resistance, heat tolerance, ability to survive and thrive under stressful and low input conditions etc. in local breeds will go in a long way not only in the advancement of science and livestock

production, but also pave the way for patenting of gene sequences for these unique traits. If an appropriate and internationally accepted legal system is developed with respect to use of animal genetic resources, patenting of novel genes will bring about economic benefit to the livestock keepers through benefit sharing.

Animal genetic resources with high diversity are essential for food security, to utilize environment unsuitable for crop agriculture and to respond to changes in production systems and market demand. Industrialization of livestock agriculture is resulting in loss of valuable breeds developed over centuries. Biodiversity of farm animal genetic resources has been rapidly declining. As per FAO, about 690 of the 7616 recognized breeds have become extinct during the last 100 years and another 1491 breeds are at risk. One-third of these became extinct between 1985 and 2000 (FAO, 2001). Livestock species are unlikely at danger of extinction themselves. The level of biodiversity, which is of concern here, is that of breeds and even populations within breeds. In fact, within breed, diversity accounts for 50 to 70% of total genetic variance (Hammond and Leitch, 1996). Many of the indigenous breeds of livestock in India are in the threat of extinction. It is difficult to save all of them, unless they are made economical under the prevailing production systems. For example, the dual-purpose breed Krishna Valley found in Maharashtra and Karnataka is on the verge of extinction due to change in the agricultural production system and lack of efforts to make the breed to respond to the changing production system (Ramesha et al. 2000).

For decades India could get along without a strong IPR policy in the area of agriculture and allied sector because it relied exclusively on its own public sector scientists and government extension agents, rather than private investors or international private companies, to stimulate innovation in the area of agriculture and allied sector. India operated without a plant variety protection law, and its 1970 Patent Act specifically excluded patenting of life forms including plants. As a result of New Seed Policy (1988) multinational seed companies began making significant investments through India's own private sector companies.

Patents and Plant Variety Protection (PVP) provide exclusive monopoly rights over the creation (such as new plant variety) for commercial purposes for a limited period. The provision for patenting on life form is the most contentious issue within TRIPS. A patent is a right granted to an inventor to prevent all others from making, using and/or selling the patented invention for 20 years. The criteria for a patent are novelty, non-obviousness and utility. PVP provides patent like rights to plant breeders. The Protection of Plant Varieties and Farmers' Rights Act, 2001 and PVP and FR Rules 2003 of Govt. of India provides for well-defined breeder's rights as well as strong and proactive Farmers' rights. The Indian Protection of Plant Varieties and Farmers' Rights Act has many unique features such as opportunity for registration of extant varieties, registration of farmer's traditional varieties by communities of NGOs on their behalf and constitution of National Gene Fund.

For protection of new varieties of plants, the sue generis system was created by International Convention for Protection of New Varieties of Plants (UPOV). During the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) for the first time agricultural trade was fully considered. The principal outcome was the Agreement on Agriculture (AoA). Fish and fishery products are not covered by the Agreement on Agriculture but are treated as industrial goods in the context of international trade. The International Treaty on Plant Genetic Resources finalized in 2001 and signed by more than 80 countries aims to maintain and conserve the plant genetic resources. In spite of great economic and biological importance, even today a legal framework equivalent to International Treaty on Plant Genetic Resources doesn't exist for animal genetic resources, although the issues at stake are of equal importance.

The majority of the developing countries, during the Trade Related Intellectual Property Rights (TRIPs) negotiations, demonstrated their objection to the notion of the patentability of biological resources. TRIPs is the first international instrument to provide IPR protection for life forms. However the obligation at present is limited to microorganisms and plant varieties. India is a signatory to both TRIPS and Convention on Biological Diversity (CBD). In order to fulfill the obligations under WTO, the Patents (Amendment) Ordinance- 2004 was issued by the Indian Govt. on December 27, 2004 and became operative from January 1, 2005. The most important aspect is to assess the possible implications of the new IPR regime on the various stakeholders in the field of livestock agriculture. The Ordinance amends the Indian Patents Act, 1970 for the third time to introduce product patent protection for drugs, food and chemicals. The knowledge intensity of livestock agriculture has to go up if it has to become competitive globally, and at the same time, responsive to the urges of local communities, which actually maintain and conserve genetic diversity.

Convention on Biological Diversity (CBD): The CBD is a legally binding international instrument, applying to all biological diversity, including plant and animals. It recognizes the sovereignty of nations over their genetic resources, including the capacity to establish conditions of access and fair and equitable sharing of benefit from the use of such resources. CBD recognizes sovereign rights of States to conserve and preserve their biological diversity. Article 8 states that each contracting party shall as far as possible and as appropriate subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application

with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices. Animal genetic resources have not been the objects of much specific consideration within the CBD, and no consideration has been given to arrangements that meet the special nature and distinctive features of livestock sector.

In January 2000 in Montreal, 130 nations agreed the legally binding Cartagena Biosafety Protocol to the CBD. It aims at protecting the environment from risks posed by the transboundary transport of genetically modified organisms (GMOs) created by modern biotechnology. It specifies obligations for the international transfer of GMOs and sets out risk-assessment, risk-management, advance informed agreement, technology transfer, and capacity-building measures. Pharmaceuticals (including recombinant vaccines) are exempted from the Protocol.

Trade Related Intellectual Property Rights (TRIPS) : Any country ratifying the Global Agreement on Trade and Tariffs (GATT) and becoming a member of the World Trade Organization (WTO) is required to establish minimum intellectual property rights (IPR) standards. Under TRIPS Article 27.3, members must provide various forms of intellectual property, many of which are relevant to animal genetic resources and animal products, including indications of geographical origins, trademark, trade secrets and patents. It provides that member countries must grant patents on all products and processes, except that they may exclude from patenting plants, animals and essentially biological processes, other than microbiological ones. Provision is made for plant variety protection under patents or a sui generis system, or a combination of both. However, there is no comparable system for animals. In the animal sector, contractual arrangements, trade secrets and trademarks are so far more important for animals than patenting. Animal patenting, even in countries where it is permitted, is so far largely a phenomenon of medical and pharmaceutical research, rather than of livestock agriculture, though this may change with the introduction of transgenic production animals. Patents and trade secrets are relevant to animal biotechnology research and development. It is advantageous to patent innovations of major value while trade secret is highly useful for protection of process / strain / know how improvements which are often non-patentable.

In developing countries including India there is limited public investment in animal biotechnology and only modest support for more conventional livestock research and development to improve productivity, nutrition and the health of farm animals. At present very few livestock breeding programmes exist in India where there is possibility of applying molecular marker assisted selection and gene based selection as an aid in selection of superior breeding stock. Additional public sector investment is especially required, in developing and applying biotechnologies strategically in the characterization, sustainable use and conservation of animal genetic resources, where private sector investment is unlikely to be commercially attractive in the short and medium term. However in the modern IPR regime, there exists possibility of private funding for research in the area of improved diagnostics and therapeutics, particularly vaccines against the major livestock diseases, where information coming from the study of pathogen genomes can help in developing more effective disease control measures. There is an urgent need to establish Animal Genetic Resources Authority of India and legislation on similar lines as for plants. There is scope for regional co-operation in the harmonization of regulatory systems, and the development of regional capacities, legal instruments and regulatory procedures.

Necessity for protection of Traditional Knowledge (TK): As regards protection of knowledge, innovations and practices associated with biological resources, these do not seem to fall within the conventional legal systems of IPR protection. These conventional forms of IPRs are inadequate to protect indigenous knowledge essentially because they are based on protection of individual property rights whereas traditional knowledge associated with animal genetic resources is by and large collective, developed over a period of time and may either be codified in texts or retained in oral traditions over generations and often held in parallel. The conditions of novelty and innovative step necessary for grant of patent are therefore not satisfied.

Nevertheless, the development of an appropriate form of protection for the knowledge of local communities is of great interest to countries, which are rich in biodiversity and also rich in traditional knowledge such as India. Traditional knowledge (TK) associated with biological resources is an intangible component of the resource itself. TK has the potential of being translated into commercial benefits by providing leads for development of useful products and processes. The valuable leads provided by traditional knowledge save time, money and investment of modern biotech industry into any research and product development. Hence, a share of benefits must accrue to creators and holders of TK. To secure this, suggestions have been made by India in international fora under the aegis of CBD as well as WTO that applications for patents should disclose the source of origin of the biological material utilized in their invention and should also be required to obtain prior informed consent of the country of origin.

Need for an International Treaty on Animal Genetic resources: Livestock biodiversity is a valuable asset and is a matter of insurance and investment necessary to sustain and improve livestock production and to keep open future options as a buffer against environmental changes and as a raw material for scientific innovation. Since the signing of the International Treaty on Plant Genetic Resources, there have been attempts to negotiate an equivalent agreement for animal genetic resources with an aim to provide level

playing field between low to medium input systems which conserve genetic diversity without any additional benefit and intensive system of rearing which erode genetic diversity.

The need for a legally binding instrument was discussed during the World Food Summit in June 2002. During the 3rd Session of the Inter-governmental Technical Working Group on Animal Genetic Resources in spring 2004, a number of developing countries proposed initiating negotiations on an international treaty on animal genetic resources (FAO 2004). Due to the resistance from industrialized countries, starting of negotiations have been postponed until the First Report on the State of the World's Animal Genetic Resources is completed, which has been achived in 2008.

Without internationally recognized legally binding instrument, billion of dollars is being spent worldwide in the area of livestock genomics and proteomics research with a aim to identify novel genes, expressed sequence tags (ESTs), single nucleotide sequences (SNPs) etc. Livestock keepers' have the risk of losing their intellectual property rights, while biotechnology firms require a legal framework to operate. Thus, there is an urgent need for internationally recognized legally binding instrument which gives right to livestock keepers including rights over associated indigenous traditional knowledge.

Livestock Keepers' Rights: In November 2003, representatives of indigenous livestock breeding communities met in Karen, Kenya and issued a statement requesting FAO to start negotiations towards Livestock Keepers' Rights (Köhler- Rollefson and Wanyama, 2003). Kohler-Rollefson (2005) argued that the Livestock Keepers' rights should include:

- The right to continue to use their knowledge on the conservation and sustainable use of animal genetic resources, without fear of its appropriation. The right to participate democratically in making decisions on matters related to the conservation and sustainable use of animal genetic resources.
- The right to access, save, use, exchange, sell their animal genetic resources for food and agriculture, unrestricted by Intellectual Property Rights and (modification through) genetic engineering technologies that may alter the integrity of these genetic resources.
- The right to have their breeds recognized as products of their communities and indigenous knowledge, and therefore remain in the public domain.
- The right to benefit equitably from the use of animal genetic resources in their own communities and by others.

Seventeen countries including India that are home to 70% of the world's "biological resources" have formed a group known as the Like-Minded Mega diverse Countries. They are in the process of developing a common negotiating position towards developed countries, such as a 20% royalty of the revenue from any product developed from their biological resources. It might be worth giving attention to the need and possibility for developing a "clearing-house" mechanism to operate at the Dept. of Animal Husbandry and to the possibility of conducting an IPR audit. It is not only formal IPR measures which need to be addressed (patents, variety protection, copyright, trade secrets etc.) but also the system needs to come to grips with the protection, and recognition, of "informal" innovation and indigenous traditional knowledge. The issues relating to ownership, access, benefit sharing, farmers' rights and intellectual property relating to animal genetic resources need immediate attention.

Economic evaluation of Animal Genetic Resources: Free exchange of germplasm is breaking down and system requiring some compensation mechanism for animal genetic sources is emerging. Importance of economic evaluation of AnGR derives from its role in developing effective breeding programmes, breed conservation programmes and from the interest in benefit sharing (Mendelssohn, 1999). Strengthening laws for intellectual property protection of germplasm and signing of the International Convention on Biological Diversity (CBD) in the year 1992 have increased the importance of establishing the value of genetic resources. Drucker (2004) explained the methodological approaches and knowledge gap in valuation of animal genetic resources. Lack of recognition of the value of animal genetic resources (AnGR) is a major cause of inappropriate management and erosion of genetic resources (Drucker, 2004). Linear programming and farm simulation models, dynamic models estimating the value of research and development and econometric models estimating the demand for breed characteristics have been used for economic evaluation of animal genetic resources (Roosen et al., 2005).

In view of rapid developments in areas of intellectual property rights, benefit sharing in agricultural sciences including animal science, increasing role of private sector in agricultural research and development of transgenic plants and animals, there is urgency for economic evaluation of animal genetic resources. This has to be done by harmonizing the different approaches of the Convention on Biological Diversity on the one hand and the TRIPS Agreement on the other hand as the former recognizes sovereign rights of States over their biological resources and the latter treats intellectual property as a private right. India being signatory to both CBD and WTO, is obliged to implement the provisions under both the instruments. In case of wrong patenting, the process of revoking is very expensive. Protecting our traditional knowledge particularly associated with biological resources is difficult unless proper documentation is done. Patents are granted under national patent laws and have territorial application only.

CONCLUSION

Globalization in trade and investment through harmonization of laws relating to intellectual property rights is one of the major impacts of GATT/WTO. Even in the present IPR era the state of legal instruments regarding animal genetic resources may easily be termed as chaotic. Therefore there is an urgent need for evolution of a suitable system that is beneficial to the whole mankind. It is necessary to establish Animal Genetic Resources Authority of India to protect the interest and rights of all stakeholders and for sustainable use of vast animal genetic resources available in India.

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