

*Interpretation and Application of International Legal
Obligation in a National Legal System:
Taking Seriously Benefit Sharing from the Utilization
of Genetic Resources in India*

**Interpretación y aplicación de una obligación
internacional en el sistema jurídico nacional:
considerando seriamente la división
de beneficios de la utilización de recursos
genéticos en la India**

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SUMARIO: I. *Introduction*. II. *Cases*. III. *Necessity of a Law and Rules*.
IV. *Conclusion*. V. *Bibliography*.

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ABSTRACT: In taking seriously the interpretation and application of international obligations on sharing of benefits equitably on genetic resources, India has decided for a law, rules and guidelines to define equitableness as well as a “case by case” assessment. In doing so, lessons from various cases in which (un)successfully benefits have been shared as well as the rule of application of Article 15.7 of the Convention on Biological Diversity (rules should be enacted as well as policies and “other measures”) were considered in a national Act on this subject. The process of law creation as a consequence of incorporation, therefore, is a dual process: interpretation (of a general international legal rule to determine specifically the national requirements to fulfil vague terms used in the rule) and, at the same time, application of these international rules (by enacting national legal rules defining the objects of legal regulation established by the treaty). Interpretation and application of article 15.7 in India has been defined ruling beyond obligation establishing legal objects and subjects, equitableness, fairness of sharing benefits and standards for a final amount, basically, detailing legal requirements and defining “equity” and “justice” as distribution, synallagma and procedure.

Key words: Equity and Justice, benefits sharing, genetic resources, India, interpretation and application

RESUMEN: Al considerar seriamente la interpretación y aplicación de las obligaciones internacionales sobre la división equitativa de los beneficios derivados de la utilización de los recursos genéticos, India se ha decidido por leyes, reglas y guías a fin de definir equidad así como una evaluación “caso a caso”. Esta evaluación se debe a consecuencia de casos ocurridos en India que hicieron que la ley sobre la materia no sólo incluyera el mandato del artículo 15.7 de la Convención sobre Diversidad Biológica, sino también los razonamientos productos de los casos mismos. El proceso de generación de ley producto de la incorporación es en este caso dual, es decir, producto de la norma jurídica internacional y de la obligación internacional de aplicación de la misma al sistema jurídico nacional así como de las “experiencias” nacionales aunque en el caso de India, ella ha regulado más allá de la norma jurídica internacional y ha definido justicia y equidad distributiva, sinalagmática y procedimentalmente.

Palabras clave: equidad, justicia, división de beneficios, recursos genéticos, India, interpretación y aplicación.

RÉSUMÉ: Après avoir sérieusement réfléchi sur l’interprétation et l’application des obligations internationales en ce qui concerne le partage équitable des bénéfices générés par l’exploitation des ressources génétiques, l’Inde a opté d’abord pour la mise en place de lois, de règles et de guides afin de redéfinir la notion d’équité puis pour une évaluation «au cas par cas». Cette dernière résulte d’un ensemble de cas qui se sont produits dans ce pays et qui ont permis la modification de la Loi en la matière : au mandat visé par l’article 15.7 de la Convention sur la diversité biologique, s’ajoutèrent alors les raisonnements occasionnés par lesdits cas. Le processus législatif, qui a pris en compte cet ajout, est donc ici duel: il résulte à la fois de la norme juridique internationale, dont l’application dans le système juridique national est obligatoire, mais également «expériences», de faits vécus sur le plan national. Toutefois, en ce qui concerne l’Inde, ce pays a été au-delà de la régulation de la norme juridique internationale et a redéfini la justice et la répartition équitable de manière synallagmatique et procédurale.

Mots-clés: équité, justice, partage des bénéfices, ressources génétiques, Inde, interprétation et application.

I. INTRODUCTION

One of the main points in taking seriously genetic resources from plants, animals and microorganisms¹ is interpreting and applying² international le-

¹ Obviously the misconception of being Decisions of the Conference of the Parties of the Convention on Biological Diversity mandatory is a classical mistake without taking seriously the convention, *cf.* Normand, Valerie, “Implementación nacional”, en Hodges, Timothy and Soberón, Jorge, *Taller internacional de expertos sobre el acceso a los recursos genéticos y distribución de beneficios*, Cuernava, Conabio-Environment Canada, 2004, p. 65. Another problem are generalizations on this issue properly from a course and of a research: *cf.* Rodríguez, Marcia, *Aspectos jurídico internacionales del acceso a los recursos genéticos que componen la diversidad biológica*, Girona, Universitat de Girona, 2003. The “Bonn Guidelines” were not considered in this research article because they were officially established by the Conferences of the Parties of the Convention on Biological Diversity in 2002 but they were not officially “published” until the end of 2002 or in 2003 and these are “guidelines”. Above all, in the draft of the Indian Biodiversity Act no evidence of influence of these guidelines in the legal rule were officially established and conversation in India and with Indian representatives would not suggest that they used the guidelines as source of the Act. Negotiations on the final rules in the Act were more a national negotiation between different representatives and groups under the obligations of the CBD, particularly Article 15 paragraph 7. Further, the Indian Biodiversity Act was enacted in February 2003 and the Bonn Guidelines have been broadly known in 2003. For consultation on this point, Secretariat of the Convention on Biological Diversity, *Handbook on the Convention on Biological Diversity*, London, Earthscan, 2001, pp. 165 and 166. These guidelines might have influence on administrative rules after 2004 and particularly on certain percentages but in the Act and the rules and after the rules on the Nagoya Protocol nothing suggests influence, Dhar, Biswajit, James, T. C., Pandey, Vinayak, *National Study on ABS Implementation in India Commissioned by the ABS Capacity Development Initiative in collaboration with the Government of India*, New Delhi, Research and Information System for Developing Countries, 2014, p. 15.

² The hierarchical structure of the legal order is the main issue here. International legal rules are on the top of this hierarchy but not strictly inside the legal system. Therefore, a process of interpretation and a process of application is common for these rules, on one hand to define the sense and on the other the form in which this international legal obligation will be honoured. Being a whole legal system the one that should honoured this international legal obligation every legal rule is suitable to fulfil the obligation and every single State’s organ should be able to create and obey these rules. Kelsen expresses this in the following way: “Among those norms one is of special importance, known as the principle *pacta sunt servanda*. It authorizes the states as the subjects of the international community to regulate by treaty their mutual behaviour of their own organs and subject in relation to the organs and

gal rules³ with international obligations into national law by national legislative, administrative and judicial powers⁴ by a juridical act:⁵ focus of this article is the Convention on Biological Diversity⁶ (Convention) and Nagoya Protocol (Protocol),⁷ the obligation of applying equitableness and fairness in sharing benefits from genetic resources.

Interpretation of international legal obligations stated in international legal rules (a Treaty and a Protocol) provokes a question: What kind of national legal rules and national sub legal rules will be enacted by the national legal system providing for the interpretation and application of this international obligation (benefits share equitably when they arise from genetic resources from plants, animals and microorganism)?⁸ The process of

subjects of other states". Kelsen, Hans, *Pure Theory of Law* (transl. M. Knight), New Jersey, The Lawbook Exchange, Ltd., Clark, 2005, p. 323.

³ Interpretation of rules have been following the issue of genetic resources and sharing benefits from these natural resources, in the case of India, World Trade Organization, *The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge, Technical observations on the United States submission IP/C/W449* by Bolivia, Brasil, Colombia, Cuba, India and Pakistan, IP/C/W/459, Geneve, World Trade Organization, 2005. Other discussion on the same problem, *cf.* World Trade Organizations, *Article 27.3(B) relationship between the TRIPS agreement and the CBD, and the protection of traditional knowledge and folklore*, IP/C/W/469, communication of the United States of America, Geneve, World Trade Organization, 2006, McMannis, Charles, "Biodiversity, biotechnology and traditional knowledge protection: Law, science and practice", in McMannis, Charles, *Biodiversity and the Law*, London, Earthscan, 2007, pp. 2 and 3 including creation of artificial discussions beyond the words of the convention or a description without explaining everything included in the title, *cf.* Miller, James, "Impact of the Convention on Biological Diversity: The lessons of Ten Years of Experience with Models for Equitable Sharing of Benefits", in McMannis, Charles, *Biodiversity and the Law*, London, Earthscan, 2007, pp. 58-67.

⁴ "...international law delegates to the national legal orders the task of identifying the individuals by whose behaviour the obligations established by international law are fulfilled or violated, and the rights established by international law are exercised". Kelsen, Hans, *op. cit.*, note 2, p. 327.

⁵ Kelsen, Hans, "Was ist ein Rechtsakt? (¿Qué es un acto jurídico?)", *Isonomía*, no. 4, abril 1996 (trad. U. Schmill), pp. 65-76, particularly at 66.

⁶ United Nations, Secretariat of the Convention on Biological Diversity, *Convention on Biological Diversity*, New York, United Nations, 1992.

⁷ United Nations, Secretariat of the Convention on Biological Diversity, *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity*, Montreal, United Nations, 2011.

⁸ We answer in the affirmative to the question put forth by Kelsen, "In defining the relation between international and national law, it is important, above all, to answer the ques-

interpretation and application seems to be different for a treaty as well as a Protocol in a national legal system due not only peculiarities but the current legal problems face in the legal system.⁹ Interpretation and application will be by interpreting words like “benefits”, “sovereignty”, “share”, “genetic resources”, “traditional knowledge”, expressing them in legal acts (laws, guidelines, by laws, rules) in national legal systems stating the ways in which international legal obligations will be honoured.

The Convention asserts the obligation for implementation of legal rules in Article 15, particularly, paragraph 7.¹⁰ All countries should comply with this obligation at national level.¹¹ As pointed out by scholars in international law and theory of law new legal rules into national legal systems introduce new interpretations and applications of the current legal rules.¹² Grounds

tion whether there can be an insoluble conflict between the two systems of norms”. Kelsen, Hans, *op. cit.*, note 2, pp. 328-329. It is possible to find difficulties between rules from one to another system, my proposal is to solve the problem by interpretation of the rule that will be applied. However, this interpretation should be based on the monistic view but on the “national legal order” viewpoint, Kelsen, Hans, *op. cit.*, note 2, p. 333.

⁹ In this case India recognizes the validity of international law tacitly, by its application, eg. Kelsen, Hans, *op. cit.*, note 2, pp. 333, 334.

¹⁰ It is interesting to note that implementation should be not only by legal rules, eg. Article 15 paragraph 7 of the Convention on Biological Diversity and in international and national environmental law, Wilson, Peigi *et al.*, “Emerging trends in national environmental legislation in Developing countries”, in Craig, Donna *et al.*, *Capacity Building for Environmental Law in the Asian and Pacific Region*, vol. I, Asian Development Bank, Philippines, 2002, pp. 181-183.

¹¹ A different issue is the discussion and interest behind the interpretation and application of this article e.g. Stoll, Peter-Tobias, “Access GRs and Benefit Sharing-Underlying Concepts and the idea of Justice” in Kamau, Evanson and Winter, Gerd, *Genetic Resources, Traditional Knowledge and the Law*, London, Earthscan, 2009, pp. 5, 10, 15 in which the author proposes an interpretation relating genetic resources with biotechnology recognizing the sovereign rights of the State and a form of transaction *iustitia commutativa* than the distributive or procedural justice. Winter, Gerd, “Towards regional common pools of GRs-Improving the effectiveness and Justice of ABS” in Kamau, Evanson and Winter, Gerd, *op. cit.*, p. 24 in which contracts is suggested as a legal interpretation of article 15 paragraph 7.

¹² Crawford, James, *Brownlie's Principles of Public International Law*, Oxford University Press, Oxford, 2012, p. 11. The reference to the work of J. Finnis is extremely interesting including the viewpoint on Philosophy of Law in International Law and the nature and effects of International Law into National law, an issue studied in European Union Law, Philosophy of Law and Jurisprudence. On these last two disciplines e.g. Besson, Samantha and Tasioulas, John, *The Philosophy of International Law*, Oxford University Press, Oxford, 2010, p. 9 and on the European Union Law and national law are a single legal system, Tiltonson, John and Foster,

for the interpretation and application of international legal rules into national legal systems¹³ vary in accordance to different reasons, in the case of this article, cases and legal obligations.¹⁴

India, one of the supporters of the Convention,¹⁵ is active in the implementation process of an equitable system for sharing of benefits arising from utilization of genetic resources.¹⁶ A research on India is interesting because of the features of the Indian legal system and the serious consideration to the interpretation and application of this international obligation.¹⁷ Moreover, in India this legal problem has been important to solve before and after the entry into force of the Convention: illegal extraction of genetic resources created problems during the last 30 years. The process, however, started earlier with the “Neem tree” and “Basmati rice” cases and the movement for a Biodiversity Law.¹⁸

The search for institutions providing a balance between parties and protecting this balance seems to be one of the outcomes of the Indian Law on Biodiversity. In this legislation, India has been trying to achieve Access and Equitable Sharing of Benefits. As Dr. Sarath Babu Gidda from the Ministry of Environment of India has stated:

Nigel, *Text, Cases and Materials on European Union Law*, London, Cavendish Publishing Limited, 2003, p. 161.

¹³ The content of the legal rule, aw, should be interpreted and applied. Kelsen expresses this: “If law is to be applied by a legal organ, he must determine the meaning of the norms to be applied: he must “interpret” these norms. Interpretation, therefore, is an intellectual activity, which accompanies the process of law application in its advance from a higher to a lower level”, Kelsen, Hans, *op. cit.*, note 2, p. 348.

¹⁴ Besson, Samantha and Tasioulas, John, *op. cit.*, note 12, p. 12.

¹⁵ The support of India to the interpretation and application of the Convention vis á vis the Trade Related Intellectual Property Rights Agreement is historic, Curci, Jonhatan, *The protection of biodiversity and traditional knowledge in international law of intellectual property*, Cambridge, Cambridge University Press, 2010, p. 183.

¹⁶ Probably, one of the reasons is medicines and food for its population, as well they have invested in biotechnology for plants, Watanabe. Kazuo, Pehu, Eija, *Plant biotechnology and plant genetic resources for sustainability and productivity*, Austin, R. G. Landes Company, Amsterdam, 1997, pp. 1, 19.

¹⁷ In this sense it should be same content without considering the kind of construction because all rules of law have a content and the content remains the same, Kelsen, Hans, *op. cit.*, note 2, p. 345.

¹⁸ Bridges, “Granting of Basmati Patent To US Firm Raises Traditional Knowledge Concerns”, vol. 5, num. 29, July 15, Geneva, 2001.

India is one of the 12th Megadiverse countries and India is a country rich in biological diversity and in traditional knowledge. And the Convention on Biological Diversity facilitates to realize equitable sharing of benefits arising from these rich resources and the traditional knowledge. One of the obligations of the Convention on Biological Diversity and also the interest of the country is to realize the benefits from those resources, we need this legislation.¹⁹

II. CASES

In this research cases were analysed, the first two representing refutations to equitableness and the third one signifying equitable division of gains from Genetic Resources.²⁰ They have triggered awareness on the legal issue within the country and, at the same time, connotations from them have been included in the Indian Biodiversity Act.

1. *The Basmati rice case*

*Basmati is a “long grain aromatic rice grown only in India” (Uttar Pradesh, Haryana, Punjab) has belonged to Indian regions from immemorial times.*²¹ *The company RiceTec was granted a patent by the United States Patent and Trade Office (USPTO) in 1997 on this rice. However, the patent rights seemed to entitle RiceTec to call its rice Basmati within USA and label it Basmati for its exports. Patent number 5663484 on Basmati rice lines and grains stated: “[T]he invention relates to novel rice lines and to plants and grains of these lines”.*²²

Some of the criticisms against the patent are as follow: It includes plants that have been transported from India and cultivated in other parts of the

¹⁹ Babu, Sareth, *Interview*, (25.06.03), New Delhi, 2003.

²⁰ As pointed out by Graham Dutfield India is the source of various of the most important crops of the world, Dutfield, Graham, *Intellectual property, Biogenetic resources and traditional knowledge*, Earthscan, London, 2004, p. 166.

²¹ Addewumi, Jolayemi, “Basmati, TED Case Studies”, Washington, American University, 1998), <http://www.american.edu/TED/basmati.htm>.

²² IPSNEWS, *Basmati Rice Patent Battle*, New Delhi, IPSNEWS, August 20, 2001.

World (North, Central or South America or the Caribbean Islands).²³ It would be difficult to market rice grains having similar or identical characteristics in those places where this patent has been granted.²⁴ The rice lines of the invention have been obtained by crossing a selected Basmati seed with a semi-dwarf variety of long grain rice.²⁵ All these seeds from Basmati lines seem to be obtained from the World Germplasm Collection, Beltsville, USA owned by the United States of America Department of Agriculture.²⁶

It is necessary to consider that until now India is in a discussion on a multilateral system of access and benefit sharing based on international treaties and experiences like Basmati²⁷ and many Indian researchers still consider agreements as the base for benefits sharing and considering laws as guidelines²⁸ and not as mandatory rules.²⁹

The government of India urged the USPTO to re-examine the claim for a patent on Basmati because RiceTec wanted to grow and sell rice under the Basmati brand name.³⁰ At the same time, a high-level inter-ministerial group of representatives of the Indian Government were asked to examine the case”.³¹

²³ Addewumi, Jolayemi, *op. cit.*, note 21.

²⁴ *Idem.*

²⁵ United States Patent and Trade Office, “Basmati Rice Lines and Grains, US 5663484,” Washington DC, USPTO, 1997, <https://www.google.ch/patents/US5663484>; Robinson, Daniel, *Confronting Biopiracy*, London-Washington D.C., Earthscan, 2010, p. 48, citing USPTO Patent Number 5663 484, Patent Facilitating Centre, New Delhi, Basmati Rice Lines and Graines, 2016 <http://www.pfc.org.in/info/basmati.htm>.

²⁶ United States Patent and Trade Office, *op. cit.*, Patent Facilitating Centre, *Ibidem.*

²⁷ Paroda, Rabeth, “Implementing the International Treaty to address current concerns about managing our plant genetic resources” in Halewood, Michael *et al.*, *A roadmap for implementing the multilateral system of access and benefit sharing in India*, New Delhi, Bioversity International, Rome; ICAR, NBPGR, 2013.

²⁸ Suneetha, M. S, Balakrishna, P., Kumar, S., *Framework for benefit sharing guidelines for India*, Asian Biotechnology and Development Review, Vol. 11, No. 2, pp. 55-88.

²⁹ Hart, Herbert, *The concept of Law* (Second Edition), Oxford, Clarendon Press, 1994.

³⁰ Ramchandran, Rabindranath, “Challenging the basmati patent”, *The HINDU India's National Magazine*, volume 17- Issue 10, may 13-16, 2000, <http://www.frontlineonnet.com/f1710/17100790.htm>.

³¹ See Addewumi, Jolayemi, *op. cit.*, note 21.

The Indian agency that filed the petition for examination on behalf of the government was the APEDA. It argued that the patent was invalid on technical grounds of novelty, usefulness and non-obviousness. This patent was difficult to change from a scientific and techno-legal viewpoint, because it was skilfully drafted and it covered as many as 20 claims and extremely broad parametric ranges in the attributes that basmati rice varieties are associated with”.³²

Nevertheless, scientists participating in the Technical Committee set up by the Ministry of Commerce and Industry believed that the evidence assembled from research publications and the different varieties under cultivation demonstrated beyond a doubt that the claims are not at all new. R. A. Mashelkar,³³ Director-General of the CSIR, heading the high-level inter-ministerial committee constituted to solve the Basmati patent issue, stated that the “patent might be challenged in two phases”: at first, those claims that can be conclusively defeated will be challenged; later, on the basis of the outcome and the strength of evidence presented by the defense, the remaining claims will be challenged.³⁴

2. Possible mistakes and misconception in the Basmati rice case

In the Basmati rice case the information distributed by newspapers and Non Governmental Organization seemed to be wrong, according to some lawyers. The first mistake seems to be that Rice-Tec had patented the name “Basmati” at the USPTO. On the other hand, names or trademarks cannot be patented under any Law; they can only be registered as a trademark and a word appearing in the title of a patent application or granted patent does not confer any monopoly right.³⁵

The second mistake, seem to be that as a result of patenting the name “Basmati”, Indian manufacturers, growers and exporters will not be able to export, sell or even grow Basmati rice in India and Indian consumers will

³² See *idem*.

³³ Mashelkar, Raghunath A., *Interview*, New Delhi, India (electronic mail), 2003.

³⁴ See Ramchandran, Rabrindranath, *op. cit.*, note 30 above, see Mashelkar, Raghunath A., *op. cit.*, note 33.

³⁵ Dewan, Niti, “Basmati Rice patent issue”, RK. Dewan and CO, New Delhi, 2000, <http://www.rkdewan.co.in/et/epage69.htm>.

be forced to eat only RiceTec's Basmati rice.³⁶ A reading of the claims of this Patent showed that the claims ask for protection of a method of breeding a new type of rice grain and lines, asserting a right to the new rice grain or line produced in accordance with this method. This patent has nothing to do with the commercialization of Basmati in India.³⁷

The third mistake is related to the claim of a method of predicting the cooking and starch properties of the rice grain. Any Indian manufacturer, grower or exporter of Basmati rice is allowed to conduct his traditional activity as a result of this patent because the patent and legal protection is granted on chemical characteristics of Basmati.³⁸

The fourth mistake seems to be that the patent of "Basmati" was possible because the Indian Patent system has defects such as slackness or because of lapses on the part of the Indian Government. However, a patent application is processed only by the system of the country in which the patent application is filed. Patent laws in India or the Indian Government had no bearing on either the processing or the granting of a Patent in the USA or vice versa.³⁹

The fifth mistake seemed to be the claim against the Government of India on the moment to put forth a claim a USPTO. There are no provisions for opposition before a patent is granted by the USPTO. All interested parties are mere spectators.⁴⁰

Laws in India seem to protect against the misuse of brand names. In India the "Trade and Merchandise Marks Act, 1958, provide adequate criminal remedies against any person wrongly describing products as Basmati Rice".⁴¹ Nevertheless, it must be pointed out that any Law, nevertheless strong or weak, will have no bearing on the use or protection of a name or trademark in the USA⁴² or any other foreign country.⁴³

³⁶ Balasubramanian, D., "Basmati-identity crisis solved", New Delhi, The Hindu, 2002, <http://www.thehindu.com/seta/2002/05/09/stories/2002050900070200.htm>.

³⁷ United States Patent and Trade Office, *op. cit.*, note 25, Dewan, Niti, *op. cit.*, note 35.

³⁸ Dewan, Niti, *op. cit.*, note 35.

³⁹ Dewan, Niti, *op. cit.*, note 35.

⁴⁰ Dewan, Niti, *op. cit.*, note 35.

⁴¹ Dewan, Niti, *op. cit.*, note 35.

⁴² It is still competing with other rice that have similar sound in their names: "kasmati", Dutfield, Graham, *op. cit.*, note 20, p. 170.

⁴³ Dewan, Niti, *op. cit.*, note 35.

3. *Neem tree case*

The Neem tree, a tree from India, has adaptable qualities: Its foliage and woof have been used to treat diseases such as leprosy, ulcers and diabetes and have also been used to make pesticides.⁴⁴ These qualities can be traced back to the Upananivod, a very old Sanskrit treatise dealing with farming. In 1988, a USA wood corporation sold a patent on Neem tree germ to W. R. Grace, another USA company. Later in 1992, W. R. Grace secured its rights to the formula that used the emulsion from the Neem seeds to make a powerful pesticide. Some 200 organizations from various countries have mounted an extraordinary legal challenge at the USPTO against the patent granting the exclusive use of a pesticidal extract from Neem seed. “The substance of the challenge is that the pesticidal extract in question has long been known to and used by the Indian people for protecting their crops”. The knowledge of the substance was therefore well known and publicly available at the time of patenting and the difference between it and the patented product was “obvious” or known.⁴⁵

The European Patent Office in Munich faced objections from the Green Group in the European Parliament to a patent granted in 1994 to the aforementioned company. The same is possible to say to the Department of Agriculture of USA for the “claimed invention of the fungicidal properties of the Indian Neem tree”.⁴⁶ The Examining Division held that the technique used was well known to local farmers, lacked any inventive step, and concluded

⁴⁴ A large amount of plant species are used for medicine, around 8,000, Dutfield, Graham, *op. cit.*, note 20, p. 169, Sonalkar, Manisha, Kagalkar, Amrita, Sachin, Nitave, “Review on Neem Plant”, *World Journal of Pharmacy and Pharmaceutical Science*, Volume 3, Issue 4, 2014, pp. 590-598.

⁴⁵ Goodhealthnyou.com, “A case history of Biopiracy”, New Delhi, India, 2001, <http://www.goodhealthnyou.com/library/reading/neem/chap10.php3>, Shiva, Vandana, *Interview*, February 27, Tokyo, 2003.

⁴⁶ Sheridan, Cormac, “EPO neem patent revocation revives biopiracy debate”, *Nature Biotechnology* 23, (2005), pp. 511-512, Bullard, Linda, *A Briefing paper on the first legal defeat of a biopiracy patent: The Neem case*, Research Foundation for Science, Technology and Ecology, New Delhi, India, The Green European Free Alliance in the European Parliament, International Federation of Organic Agriculture Movements, NWRAGE, Portland, 2005, Greens, “European Patent Office rejects Neem Tree Patent”, *Syntesis/Regeneratio* 23, Brussels, Bull, 2000.

that such indigenous knowledge can therefore not be patented.⁴⁷ As pointed out before, the patent was rejected by the European Patent Office.⁴⁸

Jeevani case

“Jeevani” is an anti-fatigue agent. It is based on the “medicinal plant *arogyapaacha (trichopus zeylanicus)*”.⁴⁹ Kani tribal members divulged the identity of the fruit to Indian scientists. The Kani “tribal people live in the forests of the Thiruvananthapuram district of Kerala in Southern India”.⁵⁰ The traditional structure of the community was that of “a highly coordinated unit under the control of a tribal chief, called Muttukani” and the tribal doctor, Plathi.⁵¹ Traditionally, the Muttukani combined the roles of lawgiver, protector and dispenser of Justice, physician and priest.⁵²

This perennial plant is a small “rhizomatous, perpetual herb distributed in Sri Lanka, Southern India and Malaysia”.⁵³ In 1996, the Tropical Botanical Garden and Research Institute (TBGRI) “filed two-process patent application for the manufacture of an herbal sports medicine, based on the

⁴⁷ Shiva, Vandana, “The Neem tree- a case history of biopiracy”, New Delhi, TWN Third World Network, 2002, <http://www.winside.org.sg/titlepit-ch.htm>, Action Aid, *Trade Related Intellectual Property Rights (TRIPs) and Farmer Rights*, London, Action Aid, 1999, Addewumi, Jolayemi, *op. cit.*, note 21.

⁴⁸ Sheridan, Cormac, *op. cit.*, note 46; Bullard, Linda, *op. cit.*, note 46.

⁴⁹ Gupta, Anil K., *WIPO-UNEP Study on the role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge*, Geneva, World Intellectual Property Organization, 2004, p. 111; Kiene, Tobias, *The “legal” protection of Traditional Knowledge in the Pharmaceutical Field, An intercultural problem on the International Agenda*, Münster, Waxmann Verlag, GMBH, 2011, p. 18.

⁵⁰ Nair, GM, “TBGRI-KANI Model of Benefit Sharing”, Pacha Palode, Thivurananthapuram, Tropical Botanic Garden and Research Institute Kerala, 2005, p. 6.

⁵¹ World Bank, *World Bank Case Study Two: Value addition to local Kani tribal knowledge: patenting, licensing and benefit-sharing*, Washington DC, World Bank, 2003, p. 110.

⁵² Anuradha, R., *Sharing with Kanis: A case study from Kerala*, New Delhi, Kalpvriksha Mimeo, 1998, Anuradha, R., *Bio-prospecting and Benefit-Sharing: Some issues and Prospects Novartis and UNED (UK)*, New York, Report of a UNED-UK/Novartis Workshop hosted by the Rockefeller Foundation, 1999.

⁵³ Pushpangadan, P. K., “Arogyapacha (Trichopus Zeylanicus), The Ginseng of Kani Tribes of Agasthyar Hills (Kerala) for Evergreen Health and Vitality”, *Ancient Sciences of Life* 7, 1998, pp. 13-16; P. K. Pushpangadan et al., *P. Ancient Science of Life*, TBGRI Publication 1995, New Delhi, TNGRI, 1998, pp. 13-16.

compounds isolated from *arogyapaacha*".⁵⁴ Scientists isolated 12 active compounds from *arogyapaacha* and developed the drug "Jeevani".⁵⁵ The technology was "then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer".⁵⁶ Scientists established a Trust Fund pursuing sharing benefits from the aforementioned drug.⁵⁷ The application described the invention as "a novel, safe herbal sports medicine, having anti-fatigue, anti-stress and stamina boosting properties".⁵⁸ The application recorded that "the therapeutic effect of this plant has been established by detailed pharmacological studies and it specified that the physical appearance and characters of this plant matched the description of 'Varahi' described by various books and scientists."⁵⁹

4. *Benefit Sharing in Jeevani Case*

In November 1997 a Trust was registered and named: "Kerala Kani Samudaya Kshema Trust" with nine members, all of whom were members of the tribe with a president and vice-president of the Trust (two Kanis) who communicated the traditional knowledge regarding *arogyapoacha* to TBGRI. Fourty Kanis in a meeting decided to create this Trust.⁶⁰ Objectives of the Trust were: welfare and development activities for Kanis in Kerala, preparation of a biodiversity register to document the knowledge of the Kanis, evolving and supporting methods to promote sustainable use and conservation of biological resources.⁶¹

5. *Discussions and reactions to the cases of illegal extraction and contracts*

In every case, it is possible to find different discussions arising from the conflicts. The discussions are organized according to each case provoking legal

⁵⁴ Nair, G. M., *op. cit.*, note 50, p. 8.

⁵⁵ Nair, G. M., *op. cit.*, note 54, p. 8.

⁵⁶ *Idem.*

⁵⁷ *Idem*, p. 8.

⁵⁸ Pushpangadan, P. K. *et al.*, *op. cit.*, note 53.

⁵⁹ *Idem.*

⁶⁰ Gupta, Anil K., *op. cit.*, note 46, pp. 111-114.

⁶¹ See Pushpangadan, P. K. *et al.*, *op. cit.*, note 53.

consequences on the current legislation as well as on the legal view points of Indian government on the subject.

6. *Basmati rice case*

India was defeated in this case

Some commentators stated that “We [India] have resoundingly lost the Basmati rice”, particularly because some of the claims were not rejected by the USPTO.⁶² Some of the criticisms that rose after the rejection were:

7. *India challenged only the grain quality*

Grain quality was not the essence of the patent and trade is related to the chemical compounds in the genes. Non Governmental Organizations considered that at that moment (2001) India challenged three or four claims and RiceTec Inc. withdrew all of them.⁶³ If India had challenged all the twenty claims, they claim, this patent would not have stood.⁶⁴

8. *Future claims at the USPTO against the patent will not be possible*

USPTO’s rules of procedure and USA patent law closed future claims for any appeal. Some explain that other national courts will be too expensive in terms of lawyer’s interventions and time consuming that it would be practically impossible to present a new claim.⁶⁵ Comments like that have appeared in various Indian newspapers criticizing the government for its idea of a victory against RiceTec Inc in relation to Basmati Rice case.⁶⁶

⁶² Sahai, Sumat, *Interviewed by Ramesk Menon*, New Delhi, Rediff.com, 2001, <http://cgi.rediff.com/money/2001/aug/27inter.htm>.

⁶³ Addewumi, Jolayemi, *op. cit.*, note 21.

⁶⁴ Sumat. Sahai, *op. cit.*, at note 62.

⁶⁵ Sumat. Sahai, *op. cit.*, at note 62.

⁶⁶ Addewumi, Jolayemi, *op. cit.*, n. 21.

9. India only succeeded in withdrawing few of patents claims

“We have succeeded in forcing Rice Tec to withdraw four out of twenty claims. The claims now withdrawn would have adversely affected India’s commercial interests in future exports of Basmati Rice,” said an APEDA statement.⁶⁷ But a leading food security activist claims that by “withdrawing four crucial claims, Rice Tec had foiled India’s attempts to strike down the patent”.⁶⁸ According to Devinder Sharma, “Rice Tec withdrew these claims because it realized its claims pertaining to “novel rice grains would not hold in light of the re-examination sought by the APEDA” with the USPTO “Of the 20 claims, only four are specific to the characteristics of the rice grain”. Others are concerned with “novel rice lines”, which detailed “breeding techniques, characteristics and properties for cultivation outside the Indian sub-continent,” Sharma said.⁶⁹ There is, nevertheless, a problem with the number of claims that was withdrawn by RiceTec Inc. According to other sources based on information on Indian Government officials, the number of claims withdrawn by RiceTec amounted to fifteen.

10. Increasing infringement of national Sovereignty of India

Pakistani anti-biopiracy campaigner, Uzma Jamil described the Basmati and turmeric patents as “manifestations of the increasing infringement of the economic and national Sovereignty of the South by the North.” According to Jamil, who is with the “South Asia Commission on Environmental, Economic and Social Policy”, Rice Tec’s claims were clear violations of the 1992 Convention, which recognizes the Sovereignty of a State over its Natural Genetic Resources.⁷⁰

⁶⁷ Devraj, Ranjit, “‘Basmati’ patent win not final, say food security experts”, New Delhi, Twinside, 2003, http://www.twinside.org.sg/title_basmati.htm.

⁶⁸ Sharma, Devinder, “Basmati Patent-Rice tech upstages India”, Asia Pacific Biotech Journal, Vol 4, No 2000, p. 419.

⁶⁹ Devraj, Ranjit., *op. cit.*, at note 67, See Ramchandran, R., *op. cit.*, at note 30.

⁷⁰ Devraj, Ranjit., “US Corporate ‘Biopirates’ Still Staking Claim on Basmati Rice”, New Delhi, Inter Press Service, 2000, <http://www.commondreams.org/headlines/100900.htm>.

11. *Ignorance of the contributions of local communities*

Moreover, Uzma Jamil considered that, “The manner in which Rice Tec established its patent, demonstrates that it has ignored the contributions of local communities in the production of Basmati and that it does not intend to share the benefits...”⁷¹

12. *Violation of Agreement on Trade Related Intellectual Property Rights*

Rice Tec’s Basmati patent also violates rules of the Trade Related Intellectual Property Rights agreement concerning ‘geographical indications’, say anti-*biopiracy* activists. Under this, for example, the term ‘champagne’ can only be used to describe wine that has been produced in the Champagne region of France and ‘Scotch’ whisky can only be applied to the spirit produced in the Scottish highlands. Basmati Rice is also governed by this rule since it has a “closely linked, exclusive relationship with its place of origin on the Indian sub-continent,” accordingly to Devinder Sharma. But, India has failed to claim TRIPs protection of Basmati rice, Darjeeling tea and other products, Sharma says.⁷²

Others also claim that the Basmati case is a clear violation of the geographical indication clause of 1994 Agreement (Article 22), which covers the protection of goods whose “quality, reputation or other characteristics” are “essentially attributable” to their geographical origin. India is now in the position to make all-out efforts to protect its products of specific geographical indications such as Basmati rice through the legal framework available under the recently adopted Geographical Indications Act. On the other hand, qualified protection under 1994 Agreement Article 23 is only granted to wines and spirituals although Article 24, paragraph 1 provides for renegotiations of Article 23 in order to expand its protection to further geographical indications. But according to food security experts, such extensions to products such as Basmati and Darjeeling tea “...have so far been opposed by the developed countries”.⁷³

⁷¹ Devraj, Ranjit., “Repeating/Development-South Asia: ‘Basmati’ Patent Win Not Final, say Food Security Experts”, Delhi, InterPress Service News Agency, 2000, <http://www.ip-news.net/2000/10/repeating-development-south-asia-basmati-patent-win-not-final-say-food-security-experts/>.

⁷² Devraj, Ranjit, *op. cit.*, at note 67.

⁷³ ICTSD Internal Files, “Granting of Basmati Patent To US Firm Raises Traditional

13. *Basmati Rice case was a triumph for India*

USPTO refused to grant a patent for the generic and pseudo-generic strains of Basmati.

Others say that India has not lost the Basmati rice case. Anil Swarup, chairman of the Agricultural and Processed Food Products Export Development Authority, clarified that, “contrary to reports, India has won the legal battle against Texas-based Rice Tec Inc for exporting Basmati rice to the USA. In a recent ruling, the United States Patent and Trademark Office, while granting RiceTec Inc a patent for three strains of superfine rice developed by it, has not granted a patent for the generic and pseudo-generic strains of Basmati”.⁷⁴

14. *Freedom of trade in Basmati Rice*

Furthermore, Anil Swarup asserted, “In fact, now no one can deprive us of selling our rice as basmati... What the US Patent Office has now done is to accept APEDA’s objections and has restricted the patent to only those three rice strains which do not impinge upon India’s interest in exporting basmati rice to the United States”.⁷⁵

15. *Indian regulation for certification of names will be possible*

The same source Mr. Anil Swarup claimed, “...With the Geographical Indications Act finally in place, within a month we hope to finalize the regulation for certification of basmati varieties with geographical indications”. He continued, “The claims, which were subsequently withdrawn by RiceTec,

Knowledge Concerns”, volume 5, number 29, 31 July 2001, p. 5, <http://www.ictsd.org/week-ly/01-09-11/story4.htm>.

⁷⁴ Dhar, B., *Interview*, 23.06.03, New Delhi, 2003; Saha, R., *Interview*, New Delhi, June 20, 2003; Nayar, L., “India wins basmati rice battle against US. Firm”, New Delhi, REDIFF, 2001, <http://www.rediff.com/money/2001/aug/21rice3.htm>; Rai, Saritha, “India-US Fight on Basmati Rice is mostly settled”, New York, New York Times, 2001, <http://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-is-mostly-settled.html>.

⁷⁵ Dhar, B., *op. cit.*, at note 74.

were broadly worded so that they included 90 percent of rice germplasm and even traditional rice”.⁷⁶

16. *No trademark right on Basmati rice to any company*

A more moderate evaluation came from Madan Diwan, World Agricultural Forum, India. Diwan argued that the USPTO “has given a ‘varietal patent’ to a Texan company for selling its three varieties of Basmati rice but this in no way prevents India from cultivating and selling its own Basmati”.⁷⁷

Diwan also said that India had not lost the Basmati case, “as it does not prevent India from selling improved strains of the grain”. He asserted that “India can also develop its own variety of Basmati rice and exports it”.⁷⁸

17. *Neem tree case*

Rights of companies to conduct research based on Natural Genetic Resources.

Afterwards various discussions arose, for example on the rights of companies to conduct research using patents, “what the United States of America companies are calling discoveries are to some considered as the actual stealing and pirating of the indigenous practices and knowledge of its people”.⁷⁹

18. *Patentability of the Neem Tree*

Another discussion is on the patentability of Neem Tree, since it is a product of nature, therefore, “not a result of innovation and discovery”.⁸⁰ Nev-

⁷⁶ Dhar, B., *op. cit.*, at note 74.

⁷⁷ Reddiff.com, “US firm wins patent for basmati rice varieties”, New Delhi, REDDIF, 2001, <http://www.reddiff.com/money/2001/aug/21rice.htm>.

⁷⁸ Rai, Saritha, *op. cit.*, note 74, Reddiff.com, *Ibidem*.

⁷⁹ Hasan, S., “The Neem Tree, Environment, Culture and Intellectual Property Rights”, American University, Washington, 2003 <http://www.american.edu/TED/neemtree.htm>; V. Shiva, *op. cit.*, note 44.

⁸⁰ Hasan, S., *op. cit.*, note 79.

ertheless, W R Grace does not have a patent on the tree itself, but “on the process of making the emulsion of pesticides”.⁸¹ The company believes that this process “is a discovery because it entails manipulation yielding greater and better results”.⁸² In other words, discovery seems to have both old and new definitions.⁸³

19. *Use of novel scientific advances on traditional Indian techniques*

According to V. Shiva,⁸⁴ director of Research Foundation for Science, Technology and Natural Resource Policy in India, “corporate processes are supposedly novel advances on Indian techniques”. She stated that the “reluctance of scientists in India to patent agricultural and pharmaceutical creations might be an effect of their acknowledgment that the immensity of labor had earlier been consummate by cohorts of nameless Indian persons”.⁸⁵ She mentioned “Dr. R P Singh of the Indian Agricultural Research Institute that asserted that: ‘Margosan-O is a simple ethanol extract of Neem seed kernel. In the late sixties we discovered the potency of not only ethanol extract, but also other extracts of Neem’”.⁸⁶ Shiva⁸⁷ added that the discovery of Neem’s characteristics and the means of processing the extract were not “obvious” but rather evolved from first to last extended systematic development in non-Western cultures.⁸⁸

20. *Negative elements*

Patent rise objections from Indian people.

Grace’s aggressive interest in Indian Neem tree provoked objections from farmers, political activists and Indian scientists asserting that “multi-

⁸¹ *Idem.*

⁸² *Idem.*

⁸³ *Idem.*

⁸⁴ Shiva, Vandana, *op. cit.*, note 44.

⁸⁵ *Idem.*

⁸⁶ Hasan, S., *op. cit.*, note 79.

⁸⁷ Shiva, Vandana, *op. cit.*, note 44.

⁸⁸ Hasan, S., *op. cit.*, note 79.

national companies have no right to expropriate the fruit of centuries of indigenous experimentation and several decades of Indian scientific study”.⁸⁹

The patent seems to be an attack against people’s traditional and local knowledge.

The patent on Neem tree pertains to the process “of pulling out the natural chemical in the form of a stable solution: a conventional process used for millennia for making Neem based products”.⁹⁰

Common knowledge and common use of Neem was “one of the primary reasons given by the Indian Central Insecticide Board for not registering Neem products under the Insecticides Act, 1968”.⁹¹ The Board argued that “Neem materials had been in extensive use in India for various purposes since time immemorial, without any known deleterious effects”.⁹² It is also venerated in the culture, religions, and literature of the region⁹³. A legal rule was enacted in the Biological Diversity Act to define “prior approval” to application to intellectual rights.⁹⁴

21. Abuse of rights

The Neem patents are just part of a “whole large catalogue of Genetic Resources originating in the South over which intellectual property rights are being asserted by a few multinational corporations originating, for the most part, in the North”.⁹⁵ The Northern patent system was not intended to recognize or reward as inventive the products of community innovation processes such as those, which created the various uses of Neem today.⁹⁶

⁸⁹ Erklarung von Bern, *Background paper on the Neem patent challenge*, (22.09.00), http://www.evb.ch/index.cfm?page_id=448>%.

⁹⁰ Hasan, S., *op. cit.*, note 79.

⁹¹ *Idem*.

⁹² *Idem*.

⁹³ Erklarung von Bern, *op. cit.*, at note 89.

⁹⁴ Suneetha, M. S., Balakrishna, P., Kumar, S., *op. cit.*, note 28.

⁹⁵ Koul, Opendar, Wahab, Seema, “Neem Biotechnology-A Synthesis”, in Koul Opendar, Wahab, Seema, *Neem: Today and in the new Millennium*, Berlin, Springer, 2004, pp. 251-252.

⁹⁶ Erklarung von Bern, *op. cit.*, note 89.

22. *Positive elements*

A. *Benefits for Indian Economy*

W. R. Grace and P. J. Margo claim that their projects benefit the Indian Economy. It does so, they say, by “providing employment opportunities at the local level and higher remuneration to the farmers as the price of Neem seeds have gone up in recent times because value is being added to it”.⁹⁷ “Over the last 20 years the price of Neem seed have gone up from 300 Rupees a ton to current levels of 3,000-4,000 Rupees a ton”.⁹⁸ However, such argument cannot support the acquisition of Neem seed.

B. *Converting waste to wealth*

P. J. Margo claims that this is “a classic case of converting waste to wealth and beneficial to the Indian farmer and its Economy”.⁹⁹ This statement is, in turn, “a classic example of the assumption that local use of a product does not create wealth but waste and that wealth is created only when corporations commercialize the resources used by local communities”.¹⁰⁰

23. *Jeevani case*

There has been some criticism of the Trust and the mode of sharing benefits.

Lack of information.

There is a grievance of several Kanis about their lack of awareness of the Trust, the new medicine being developed, and the future program of development.¹⁰¹

⁹⁷ Shiva, Vandana, *op. cit.*, note 47.

⁹⁸ Shiva, Vandana, *North-South Conflicts in Intellectual Property Rights*, Peace Review, 12:4, 2000.

⁹⁹ Shiva, Vandana, *op. cit.*, note 47.

¹⁰⁰ *Idem.*

¹⁰¹ John, J. and Menon, S., “Kerala Tribe Accuses Indian Biologists of Stealing Knowledge”, London, PANOS Biopiracy, 1998.

24. *Problems with Intellectual Property Rights*

The Director of the Kerala Institute for Research, Training and Development of Scheduled Castes and Scheduled Tribes (KIRTADS) complained that local tribes were not seeking intellectual property rights and instead rights were being granted to private entities.¹⁰² There was a suggestion about enacting new laws, which would also protect intellectual property rights of Kanis instead of only official scientists or outsiders.¹⁰³ Many observers have overlooked the fact that the patent applications by TBGRI only involved the process of making drugs, because Indian patent law has not permitted product patents until then:¹⁰⁴ nobody's right was affected adversely by the patent applications in any real sense, because what was in the public domain will remain so before and after such patents have been granted.¹⁰⁵ "But as is well known, the Indian patent office takes a long time to issue patents and applications made in 1996 have been processed in 2000" but they have to consider the Biological Diversity Act.¹⁰⁶

25. *Participation*

Some argue that, it is true that the process of trust formation can have been participatory within the settlements from which Kanis were included. TBGRI did accept the help of some regional Non Governmental Organizations in creating trust and generating awareness, but it was not adequate. On the other hand, the fact that Kanis dared to protest against the Forest Department when they were not allowed to collect leaves *arogyapaacha*, shows that they were losing the capacity to participate actively in the decision making

¹⁰² Chaturvedi, Sachin, *Kani case, A report for Gen Benefit*, New Delhi, Research and Information System for Developing Countries, 2007, p. 10.

¹⁰³ *Idem*.

¹⁰⁴ *Idem*.

¹⁰⁵ Gupta, Anil K., *op. cit.*, note 46, p. 117; Chaturvedi, Sachin, *op. cit.*, note 102, p. 10.

¹⁰⁶ Gupta, Anil K., *op. cit.*, note 46, p. 117, Republic of India, "The Biological Diversity Act, 2002, (No 18 of 2004), New Delhi, Gazette of India, February 5th, 2003", in Andhra Pradesh Biodiversity Board, *The Biological Diversity Act, 2003, The Biological Diversity Rules, 2004, Andhra Pradesh Biological Diversity Rules, 2009*, Andhra Pradesh, Andhra Pradesh Biodiversity Board, 2013. Other legal rules have been enacted at the national level but are on administrative aspects of the Biological Diversity Act 2002.

processes which affect their traditional knowledge. Furthermore, the rights of informants and those of the community needed to be distinguished in the benefit-sharing arrangements.

26. Biodiversity Law

The Biodiversity Law passed the Rajya Sa on 11 December 2002 and is now in force.¹⁰⁷ It is India's legal implementation of the topic of Access and Benefit Sharing established by the 1992 Convention is reflected in the Biodiversity Act 2002.¹⁰⁸ Moreover, various institutions expressed that the Act tried to comply with the international obligations of India, *vis-à-vis* the Convention on Biological Diversity.¹⁰⁹ This national legal rule, and other national and subnational legal rules work on the accomplishment of international legal obligations but in the interpretation and application process the international obligations change their "ordinary meaning" considering the current needs of the country and considering the broadness of the terms.¹¹⁰

III. NECESSITY OF A LAW AND RULES

The "state of the environment report" prepared for India broadly covers five priority issues pertaining to the Environment to which biodiversity

¹⁰⁷ The Biological Diversity Act of 2002 is in force since the 5th of February 2003.

¹⁰⁸ See Babu, Sareth, *op. cit.*, n. 19, Cullet, Phillip, *Interview* (via electronic mail), 15 of June, Geneva, 2003, Suneetha, M. S., P., Balakrishna, S. Kumar, note 28, Balakirshna, Pisu-pati, "Foreword", in Republic of India, National Biodiversity Authority, *Annual Report, 2011-2013*, Chennai, National Biodiversity Authority, 2012, p. 3; Republic of India, National Biodiversity Authority, "Annual Report, 2011-2013", Chennai, National Biodiversity Authority, 2012, p. 9; Republic of India, "Biodiversity", Ministry of Environment, Forestry and Climate Change, New Dehli, Government of India, 2015 <http://envfor.nic.in/division/biodiversity>.

¹⁰⁹ Choudhary, B., "Legislation for genetic heritage", *Biotechnology and Development Monitor*, No. 48, December, 2001, Gupta, Anil, *Value addition to local Kani tribal knowledge: patenting, licensing and benefit-sharing*, New Delhi, SRISTI, 2003, <http://www.sristi.org/pub.html>, Cullet, Ph., *Ibidem*.

¹¹⁰ As pointed out by Underfalk, interpretation of a treaty has different view points, Underfalk, Ulf, *On the interpretation of treaties*, Berlin, Springer, 2007, p. 29. One is international and other national. Vagueness, "open texture" is a common characteristics of legal rules, Hart, Herbert, *op. cit.*, note 29, p.124. Law has to refer to classes of acts and persons, otherwise general standards of conduct will not be able to be communicated.

has a central role.¹¹¹ The report expresses concern over the loss of biodiversity because of lack of clear legislation and policy, institutional mechanisms for biodiversity conservation, participation of communities, clear perspective on intellectual property rights leading to international patents on Indian biodiversity. A comprehensive legislation on biodiversity conservation and uses should be promulgated.¹¹² Other legal rules are Patent Act of 1970 amended in 1999, 2002 and 2005, Protection of Plant Varieties and Farmer's Rights Act of 2001 and Geographical Indication and Registration of Goods Act of 1999.¹¹³ Among other "stakeholders" Non Governmental Organizations took an active role in the discussion process of the Biodiversity Act. After consultations, these organizations and legal experts provided a first draft for a Biological Diversity Act and they mobilized political support to pressurize the Ministry of Environment and Forests to start the process of finalizing a Biodiversity Law for India ruling access for foreigners, Indian citizens, local people and communities.¹¹⁴ Gene Campaign was a member of the Expert Committee that finalized the National Biodiversity Act¹¹⁵ and in Law and Rules have been enacted.¹¹⁶

1. Salient features of the Biodiversity Act and Biodiversity Rules

In accordance to the Law¹¹⁷ in 2004 the Rules of the law¹¹⁸ have been enacted and since then various applications have been solved by applying these

¹¹¹ See Babu, Sareth, *op. cit.*, note 19.

¹¹² Sethi, Pia, Kumaran, Lakashmi, *Interview*, New Delhi, Teri, 2003.

¹¹³ Ramanna-Pathak, A., *Benefit sharing in India: Brief overview of Current Status*, New Delhi, SRISTI, 2013, Suneetha, M. S., Balakrishna, P., Kumar, S., *op. cit.*, note 28.

¹¹⁴ Suneetha, M. S., Balakrishna, P., Kumar, S., *op. cit.*, note 28.

¹¹⁵ Gene Campaign, "Influencing National policy and Drafting National Legislation", Ottawa, Gene Campaign, 2003 <http://www.genecampaign.org/activities4.htm>.

¹¹⁶ Criticism was just at the entry into force of the Rules: faulty process, faulty content, Gram Panchayats and gram sabhas of Chattisgarth, P. *et al.*, *Community control over Biodiversity, Memorandum to the Government of India*, DDSINDIA, New Delhi, 2004, http://ddsindia.com/www/Biodiversity%20rules%20rally%20report_link%20MoEF.htm.

¹¹⁷ Babu, Sareth, *op. cit.*, note 19.

¹¹⁸ Republic of India, *Biological Diversity rules 2004*, (entry into force 15 of April 2004), New Dehli, Indian Gazette, 2004.

rules.¹¹⁹ However, criteria for equitably benefit sharing is still under discussion (and criticism) because they should be solved on a “case by case basis” in accordance to the Rules in article 20.4 but still is necessary to formulate guidelines as well as the benefit sharing formula in the Indian Gazette in accordance to article 20.1 therefore a coordination between criteria, guideline, formula and cases need to be considered.¹²⁰ However, the interpretation of equitableness and justice in sharing benefits includes everything discussed not only in India but around the world on matters of benefits as considered in articles 20 numbers 2, 4 and 5.¹²¹ As well in in 2005 the State of West Bengali and 2009 the State of Andra Pradesh enacted the Biological Diversity Rules and other States of India.¹²²

2. Sovereignty over Natural Genetic Resources

– Obligatory registration

Only Indian citizens, “corporate associations or organizations registered in India or which are registered in India with Indian citizen participation in Equity or Management, are allowed to obtain any biological resource occurring in India and/or associated knowledge for research, commercial utilization, or bio-survey and bio-utilization” without prior approval of the National Authority (Article 3 paragraphs.1 and 2, and Article 4).¹²³

¹¹⁹ Suneetha, M. S., Balakrishna, P., Kumar, S., *op. cit.*, note 28.

¹²⁰ Kalpavriksh, “The Biological Diversity Act 2002 and the Rules 2004, Concern and Issues”, New Delhi, Kalpavriksh, 2015, p. 2 in which “weaknesses” has been raised like exemption to plants registered under the Protection of Plant Varieties and Farmer’s Rights Act of 2001, no possibility for citizens to stay in Court, Indian companies should be obliged to ask for permission from National Biodiversity Board, among others. It is not the process of application the main issue of this paper but the kind of interpretation of an international legal rule to comply with international obligations, therefore further criticism we will be explained.

¹²¹ Republic of India, *op. cit.*, note 118.

¹²² Republic of India, *West Bengal Biological Diversity Rules 2005*, Kolkatta, Kolkatta Gazette, 2006, Republic of India, *Andra Pradesh Biological Diversity Rules, 2009* in Andrah Pradesh Biodiversity Board, *The Biological Diversity Act, 2003, The Biological Diversity Rules, 2004, Andra Pradesh Biological Diversity Rules, 2009*, Andra Pradesh, Andra Pradesh Gazette, 2013.

¹²³ Republic of India, *op. cit.*, note 106; Gupta, Anil K., *op. cit.*, note 46, p. 105, Gupta refers to a Draft, not to the Law.

Citizens of “India who stay abroad face obligatory registration in case they want to export Indian Biological resources” (Article 2b).¹²⁴ Only “collaborative research involving transfer or/and exchange of biological resources and information relating to these between institutions including government sponsored and similarly placed institutions in other countries will be exempted”.¹²⁵

It is necessary to define the amounts of money for those violating the application for the National Biodiversity Board or for those unlawfully taking genetic resources without permission of the Board.¹²⁶

– Registration of local people’s knowledge

Measures that include registration of knowledge at local, State and national levels, and development of, and adjustment in, “a *sui generis* system for intellectual property protection of such knowledge can advance the protection of and respect for local people’s knowledge as recommended by the National Biodiversity Authority to the Central Government” (Article 36 paragraph 5).¹²⁷

– Imperative authorization by the Indian National Authority for any research results

The Biodiversity Act established the obligation of authorization for “any result transfer arising from research on Indian biological resources (their genetic information or knowledge associated with those resources) by any citizen, body, corporate association, or organization registered in India” (Article 4). If a “scientific publication contains results of scientific investigation from Indian Natural Genetic Resources, it should follow the government’s guidelines”. In this manner, it can be published.¹²⁸

¹²⁴ Republic of India, *op. cit.*, note 106.

¹²⁵ Babu, Sareth, *op. cit.*, note 19, Republic of India, *op. cit.*, note 106.

¹²⁶ University of Pune, *Compliance with provision of the Biological Diversity Act, 2002, The Biological Diversity Rules, 2004 and the Maharashtra Biological Diversity Rules, 2008*, Pune, University of Pune, 2015, p. 2.

¹²⁷ Babu, Sareth, *op. cit.*, note 19, Republic of India, *op. cit.*, note 106.

¹²⁸ Babu, Sareth, *op. cit.*, note 19, Republic of India, note 106.

- Possibility for National Biodiversity Authority to oppose any intellectual property right

The National Biodiversity Authority may, “on behalf of the central government, take measures to oppose intellectual property rights granted outside India on any biological resource or associated knowledge taken out of India (Article 18 paragraph 4).¹²⁹

3. *Prior Informed Consent*

- Prior permission for application on intellectual property rights inside or outside India

The Law on Biodiversity requires prior permission for any “form of intellectual property rights” inside or outside India.¹³⁰ This permission should be granted from the Indian National Authority according to the form established by law. The authority may grant permission but it can also “impose benefit-sharing fees or royalties or conditions on the financial benefits arising out of the commercial utilization of such rights” (Article 6).¹³¹

- Prior intimation to State Biodiversity Board

In case Indian citizens or a “body corporate” want to explore biodiversity in India, they will have to give “prior intimation to the State Biodiversity Board in the prescribed manner” (section 24 paragraph 1).¹³² The State Biodiversity Board may establish a prohibition or restriction on any such activity after receiving such intimation if it is of the opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or Equitable Sharing of Benefits arising out of such activity (Article 24 paragraph 2).¹³³

¹²⁹ Republic of India, *op. cit.*, note 106.

¹³⁰ Babu, Sareth, *op. cit.*, note 19; Republic of India, *op. cit.*, note 106.

¹³¹ Babu, Sareth, *op. cit.*, note 19; Republic of India, *op. cit.*, note 106.

¹³² Republic of India, *op. cit.*, note 106.

¹³³ Babu, Sareth, *op. cit.*, note 19; Republic of India, *op. cit.*, note 106.

4. *Mutually Agreed Terms*

- Joint-collaborative research

It is apparent from the above review of the Biodiversity Act that Indian nationals are not subject to the constraints imposed on international biodiversity-prospectors. In the case of “joint or collaborative projects” among State institutions, prior clearance will not be needed, even though international researchers may be involved. This is relevant to the present case. The Act stipulates that no study outputs can be transferred to anyone outside the country without prior approval of the competent national authority. A whole range of incentive measures is suggested (both monetary and non-monetary) to meet the “expectations of genetic resource and/or knowledge providers” (Paragraph 1, 2, and 3 of Article 5).¹³⁴

5. *Equitable Sharing of Benefits*

- Direct protection of Equity

On one hand Chapter 1 article 2 paragraph “g” defines “equitable sharing of benefits” and on the other hand, the National Biodiversity Authority ensures (“secures”) various important aspects related to the implementation of Article 15 of the Convention on Biological Diversity.¹³⁵ A list of benefits including joint-ownership of intellectual property rights (Basmati, Neem and Jeevani cases), “transfer of technology, location for research and development, venture capital fund and direct monetary compensation, as well as other non-monetary compensations” in paragraph 2 of Article 21.¹³⁶ As well, “claimers” of benefits include those that “conserve the biological resources, by products, creators and holders of knowledge and information”, the definition of equitableness has to be determined by the National Biodiversity Authority in accordance to article 18 and in accordance to article 21 has to consider almost all elements related to benefits. The State Biodi-

¹³⁴ Republic of India, *op. cit.*, note 106.

¹³⁵ *Idem.*

¹³⁶ *Idem.*

versity Board of India includes “persons that have experience in equitable sharing of benefits” as determined in Article 22.4¹³⁷ and in some of the “functions of the Board equitable sharing of benefits plays a very important role” as included in article 23 letter “a”.¹³⁸ The Authority has an obligation for advising the Central Government on matters related to Equitable Sharing of Benefits in accordance to article 12 of the Biological Diversity Rules and organize by mass media a “comprehensive program” on this subject. Section 20 of the Rules establishes “Criteria for equitable sharing of benefits” as pointed out before clearly drafters do not know how to define this criterion because of insertion of a number of elements means not including anything. Further, the focus is on benefits not on equitableness in number 6 of article 20 of the Rules.¹³⁹

In interpreting and applying Article 15 of the Convention on Biological Diversity, India has included almost all elements of sharing benefits without establishing the kind of determination of the equitableness because an authority defines equitableness (in a distributive manner) but considering agreed terms (retribution) in a procedure (procedural manner).

6. Practices associated with their use, application and knowledge

The knowledge associated with those resources through the approval of the terms and conditions of any transaction related to this issue.¹⁴⁰

– Enforcement of Equitable Sharing of Benefits

The Law created a National Biodiversity Fund and any benefit shall be deposited in this Fund in accordance with the rules on equitable sharing agreed by the parties.¹⁴¹ It requires that the payment of these benefits would be made directly to the sources when “the biological resources or knowl-

¹³⁷ *Idem.*

¹³⁸ *Idem.*

¹³⁹ *Idem.*

¹⁴⁰ Babu, Sareth, *op. cit.*, note 19; Republic of India, *op. cit.*, note 106.

¹⁴¹ Ahuya, Viba, *Interview*, The Indian Bioindustry Association, New Delhi, 2003, S. Babu, S., *op. cit.*, note 19.

edge are a result of access for a specific individual or group of individuals or organizations in accordance with the terms of agreement and in such a manner as it deems fit” (Article 21 paragraph 3).¹⁴²

– Creation of Funds for sharing benefits

The Biodiversity Act created two funds, the National Biodiversity Fund (Articles 26 to 30) and the Local Biodiversity Fund (Articles 42 to 47). The National Biodiversity Fund aims at “channelling benefits to benefit claimers, conserving biological resources and developing areas, where such biological resources or knowledge associated thereto have been accessed and socio economic development of areas where biological resources or knowledge associated thereto in consultation with the local bodies concerned” (Article 26).¹⁴³

At the same time, the Law on Biodiversity has a Local Biodiversity Fund that will be used for the benefit of communities in so far as such use is consistent with the conservation of biodiversity (paragraph 2 of Article 44).¹⁴⁴

7. Evaluation to the Indian Biodiversity Act

According to some commentators, the Biodiversity Act of 11 December 2003 is weak and confused.¹⁴⁵ The Act does not consider old laws and in some cases will run counter to them. There is no reference to “the kind of intellectual property rights applicable to traditional knowledge associated with biological resources or to the biological resources themselves”¹⁴⁶ and with the approval of the National Biodiversity Authority of rights on intellectual creation. The Act runs counter to the large debate (at the national and international level) on life forms patents. Other Indian legislation on the issue of bio resources took a clear position, for instance: the Plant Variety Protection and Farmers Rights Act 2001 guarantees that no patents

¹⁴² Ahuya, Viba, *op. cit.*, note 141; Republic of India, *op. cit.*, note 106.

¹⁴³ Republic of India, *op. cit.*, note 106.

¹⁴⁴ Ahuya, Viba, *op. cit.*, note 141; Republic of India, *op. cit.*, note 106.

¹⁴⁵ Sahai, Suman, *India's Biodiversity Bill is weak and confused*, November 11, New Delhi, Genecampaign, 2002, <http://www.genecampaign.org/newsfolder/PVP-FR-long/analysis/20II.doc>.

¹⁴⁶ *Idem*.

will be allowed on plants and animals but only on micro-organisms. At the same time, the Biodiversity Acts “set up parallel institutional structures. For example, in the case of protected areas one of the main problems is the possibility of two institutions governing these areas”.¹⁴⁷ Therefore overlap in meanings and criteria can arise from such mismanagement.¹⁴⁸

The current Act might be researchers’ problem due to bureaucratic requirements to be fulfilled by these researchers as well as a contravention to the Convention on Biological Diversity.¹⁴⁹ Publications and dissemination of information will have to followed guidelines and research proposals should be approved by the Authority.¹⁵⁰ The possibility for legal opposition by local communities to patents granted when they were based on knowledge on genetic resources taken from them is not clear.¹⁵¹ Corporate bodies might have the capacity to abuse of the rights conferred by the Act with the approval of the Government. In addition, they expressed that the government of India is described as an alliance between bureaucrats and “politicians without a conscience, sub- serving the interests of private industrial capital, including the MNCs [Multinational Companies]”.¹⁵² Finally, they pointed out that the final outcome of the legislation would be the appropriation of the rich biodiversity by Multi National Companies through the connivance of civil servants.¹⁵³ The Act, nevertheless, has some good features, such as the effort to decentralize the decision making process on Natural Genetic Resources.¹⁵⁴

The Act provides in section 3 that non-citizens, non-residents as well as corporate bodies not registered in India, cannot obtain any biological resources or associated knowledge whose source is in India. This includes research for commercial utilization, or for bio-survey and bio-utilization without special permission given by the National Biodiversity Authority. On the other hand, this general prohibition “neatly bypassed” a different

¹⁴⁷ Sahai, Suman, *op. cit.*, note 145.

¹⁴⁸ *Idem.*

¹⁴⁹ *Idem.*

¹⁵⁰ *Idem.*

¹⁵¹ *Idem.*

¹⁵² Devi, Suha, *Interview*, New Delhi. 2003.

¹⁵³ *Idem.*

¹⁵⁴ Sahai, Suman, *op. cit.*, note 145.

provision that allows collaborative study in accordance with the policy guidelines issued by the Government of India.¹⁵⁵

The proposed Biodiversity Act does not end with opening the door to “collaborative research” with foreign parties. Section 6 paragraph 3 states that “the provisions of this section shall not apply to any person making an application for any rights under any law relating to protection of plant varieties enacted by Parliament”.¹⁵⁶

The Act leaves the door wide open to multinational companies to exploit the Indian farming community to the fullest. This implies that the global seed industry, Cargill, Monsanto and others, can freely claim patents or “breeders’ rights”, to take Indian seeds and tinker with them, and exploit the Indian farming community to maximize their profits, much to the detriment of the bulk of Indian farmers.¹⁵⁷

“No suit, prosecution or legal proceeding shall lie against any officer or other employee of the Central government or the State government for anything which is done in good faith in pursuance of this act or the rules made there under,” reads Article 52 of the Act.

V. Shiva¹⁵⁸ pointed out that the Biodiversity Act is against accountability to bureaucracy and, as such, is a threat to democracy and people’s rights in any context but in this case with serious implications. “The immunity of the bureaucracy combined with power and unaccountability of the multi-nationals can easily work to usurp the resources and knowledge of the people”.¹⁵⁹

It has been a common evaluation, not followed by the author, has become difficult to honour because of procedural matters and that there is no such “gold rush” in the jungle.¹⁶⁰

However, this is Law, an extremely complex social institution in which the best effort to rule an object of law will be always under the threat of the abuse of law and abuse of rights. This only reason makes necessary an explanation of any law. The interpretation of something, in this case an article of

¹⁵⁵ Devi, S., *op. cit.*, note 152.

¹⁵⁶ Agarwal, Anuradha, “The Bill of Contention”, New Delhi, Centre for Science and Environment, 2003. <http://www.cseindia.org/html/dte/dte20020115/dte edit.htm>.

¹⁵⁷ Agarwal, Anuradha, *op. cit.*, note 156.

¹⁵⁸ Goodhealthyou.com, *op. cit.*, note 45.

¹⁵⁹ Agarwal, Anuradha, *op. cit.*, note 156.

¹⁶⁰ *Idem*.

an international treaty, is “an explanation of its meaning” using the words of Raz.¹⁶¹ Unfortunately, not too many has been able to understand this. The explanation of the meaning of Justice and Equity when sharing benefits, in this case, of genetic resources, is different in the legal system of India vis a vis other countries due to the particularities of the Indian legal system and the influences of cases like those depicted here.

8. *Rules on equitably sharing benefits in India*

After the Biodiversity Act was enacted in 2002, draft rules on the National Biodiversity Authority and the procedure for the equitable sharing of benefits were discussed in India. Number 21 of the Biological Diversity Rules 2003 developed the mechanisms for an Equitable Sharing of Benefits. The National Biodiversity Authority is charged with establishing specific rules on Equitable Sharing of arising Benefits and the “formula for benefit sharing shall be on a case-by case basis”. The quantum of the benefits is subject to mutual agreement, but the National Biodiversity Authority, in consultation with local bodies and benefit claimers may decide all the various aspects related to the benefits (Article 21 paragraph 3).¹⁶²

At the same time, the rules establish that in case that the biological resources are accessed from “specific individuals, groups of individuals, or organizations, the agreed amount will be paid directly to those individuals or groups. In case that the identification of individuals or groups is not possible”,¹⁶³ the amount will be paid to the National Biodiversity Fund (Article 21 paragraph 6).¹⁶⁴

9. *The Nagoya Protocol and the new regulation of 2014*

Further, in 2010 the Secretariat of the Convention on Biological Diversity promoted another international treaty derived from the Convention

¹⁶¹ Raz, Joseph, “Two views of the Nature of the Theory of Law: A partial comparison”, in Coleman, Jules, *Hart’s Postscript*, Oxford, Oxford University Press, 2001, p. 1.

¹⁶² Republic of India, *op. cit.*, note 106.

¹⁶³ *Idem.*

¹⁶⁴ *Idem.*

on Biological Diversity, a Protocol entitled “The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity”¹⁶⁵ and entered into force for India on September 10, 2012 generating new views on the interpretation and application, implementation, of an international legal rules *vis a vis* other international and national legal rules. India enacted a system of sharing benefits established as international obligation in article 5 of the Protocol by enacting new Biodiversity rules on Access and Equitable sharing of benefits to biological resources and traditional knowledge to honour the Protocol. The regulation expresses the following: “...and in pursuance of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity dated on 29th October, 2010, the National Biodiversity Authority hereby makes the following regulations, namely”.¹⁶⁶

These rules are “regulations”, this means, should be applied by legal force¹⁶⁷ to all subjects in India. The regulation has included biological resources and traditional knowledge when the object of these subjects is “research or bio-survey and bio-utilization for research” of “biological resources and/or associated traditional knowledge”,¹⁶⁸ “access to biological resources, for commercial utilization or for bio-survey or bio-utilization for commercial utilization”.¹⁶⁹ The regulation established a procedure for the subjects of the Act by using different forms in accordance to their objective (research, bio-survey and bio-utilization).¹⁷⁰ In case that the National

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¹⁶⁵ United Nations, *op. cit.*, note 2.

¹⁶⁶ Republic of India, Ministry of Environment, Forests and Climate Change (National Biodiversity Authority), *Regulation on Access to Biological Resources and Associated Knowledge and Benefits Sharing*, New Delhi, The Gazette of India, 2014, p. 11. The same regulation accepts that it may be called “Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014” but considering the official purpose and the possibility misunderstanding of the word “guidelines” this research will focus on its nature, regulation and its mandatory nature.

¹⁶⁷ Green, Leslie, “The forces of Law: Duty, Coercion and Power”, *Ratio Juris*, Vol. 29, No. 2, June 2016, pp. 164-181.

¹⁶⁸ Republic of India, Ministry of Environment, Forests and Climate Change (National Biodiversity Authority), *op. cit.*, note 166, p. 11, article 1 paragraph 1.

¹⁶⁹ *Ibidem*, article 2.

¹⁷⁰ *Ibidem*, p. 12, article 1, paragraph 2 first paragraph.

Biodiversity Authority (Authority) of India might be satisfied, it has to enter into negotiations of a “benefit sharing agreement” in which certain “upfront payment” has to be established in case of biological resources with “high economic value”.¹⁷¹ About sharing of benefits, the part of India is defined by consideration to the subjects as well as object of the access and it is possible to explain sharing by the following list of objects that has to pay such benefits and amounts:

- a) Direct purchase, up to 3 percent for the trader and 3 to 5 per cent for the manufacturer (purchase price of the biological resource).
- b) Trading, up to 3 per cent for the trader who buys, 3 to 5 per cent for the manufacturer who buy.
- c) Benefit sharing for the seller in the supply chain (percentage base on the part of the purchase price without sharing).
- d) The same percentages in case of a “prior benefit sharing negotiations”.¹⁷²

In case of biological resources of “high economic value” benefit sharing includes upfront payment no less than 5 per cent, and other possible objects and percentages are applicable.¹⁷³

As well, other options have been established by the regulation: benefit sharing on sale prices,¹⁷⁴ transfer of results of research,¹⁷⁵ transfer of accessed biological resources and/or associated knowledge to third party.¹⁷⁶

Inventions not only are related to biological resources but to traditional knowledge too and a regulation on the benefit sharing of intellectual property rights is included as well.¹⁷⁷ In this case should be used the application included in the 2004 Rules on intellectual property rights on invention based on research or information on any biological resources obtained from India.¹⁷⁸

¹⁷¹ *Ibidem*, p. 12, article 1, paragraph 2 second paragraph.

¹⁷² *Ibidem*, p. 12, articles 1, 2, 3, 4.

¹⁷³ *Ibidem*, p. 12, article 3, paragraph 3.

¹⁷⁴ *Ibidem*, p. 12, article 4.

¹⁷⁵ *Ibidem*, p. 12, article 6.

¹⁷⁶ *Ibidem*, p. 12, article 11.

¹⁷⁷ *Ibidem*, p. 12, article 8 paragraph 1.

¹⁷⁸ *Ibidem*, p. 12, article 8.

The determination of the benefits sharing is developed on one hand on the specific object of the access, the minimum of percentages to comply with, and the requirements of the NBA/SBB/BMC discussed with the applicant.¹⁷⁹

Therefore, a final agreement will be reached with the applicant.¹⁸⁰ A general principle has been developed on this subject, “[t]he amount of benefit sharing shall remain the same whether the end product contains one or more biological resources”.¹⁸¹

IV. CONCLUSION

India has implemented Article 15 of the 1992 Convention by enacting regulation on the issue of Equitable Sharing of Benefits, Sovereignty over Natural Genetic Resources, Prior Informed Consent as well as Mutually Agreed Terms in the national legal system. Equitable Sharing of Benefits is in place. Institutions seeking equitableness in the Biodiversity Act and Rules are: 1.-National Biodiversity Authority. 2. - Permission for foreigners asking for bioprospection activities. 3.-Enforcement of an Equitable Sharing of Benefits. 4.-Permission in case of any claim over any form of intellectual property rights related to Indian Biologic and Genetic Resources. 5.-Duty for opposition of the National Biodiversity Authority in case of intellectual property on Indian genetic resources granted by other countries without permission of the Indian Authority.

Incorporation of international legal rules into national legal system and fulfilment of an international obligation might be through one methodological approach: interpretation and application of an international legal rule into national legal system but with own interpretation and application. The question posed in the beginning has been answered supporting the claims

¹⁷⁹ *Ibidem*, p. 12, article 14. paragraph 1.

¹⁸⁰ The elements to be considered for the final decision on benefits sharing in an equitable way, the minimum standards, are commercial utilization of the biological resources, stages of research and development, potential market for the outcome of research, amount of investment already made for research and development of the product and risks involved in the commercialization of the product and others. *Ibidem*, p. 14, article 14 paragraph 2.

¹⁸¹ *Ibidem*, p. 14, article 14 paragraph 3.

of own interpretation and application, in this case, in a distributive, retributive and procedural way. Further, the forms are: an act, two sets of rules, regulations, in general. Based on regulations the interpretation of “sharing benefits fair and equitable” has been defined in legal institutions. These legal institutions, mainly compulsory, expresses different forms of fairness giving security to the applicant. However, in India lessons based on cases of misappropriation, abuse of intellectual property rights and violations of international obligations based on the Convention on Biological Diversity has played a role in the draft of national legal rules.

On the forms is to enact legal rules or administrative rules, both as a part of the process of incorporation however, the incorporation by administrative rules is a new type of incorporation because generally is accepted by a law, these are the form but the content is an interpretation of the international legal rule. About methodological approaches India as a country has considered incorporation by an interpretation first and application later of the Convention and the Protocol. Interpretation of benefits and equitableness and application to the national legislation of a variety of legal rules. Application here is the process of incorporation into national legal system and the generation of new rules as well as the process of application to subjects fulfilling requirements of the law.

These rules, the 2002 Act and the Rules in 2004 and 2014, represent the main elements that can determine and evaluate the existence of commutative, distributive and procedural Equity in a biodiversity law and they have been enacted into national legal system with the idea that the international obligation has been fulfilled. Through all these institutions, Equity seems to be protected and India may contribute via these institutions to the general goal of Article 15: an Equitable Sharing of Benefits at the national level.

However, criticism to the process might be voiced. India ruled on “biological resources” instead of “genetic resources” (a difference with article 15 of the Convention) and “traditional knowledge” related to intellectual property vis a vis traditional knowledge related to genetic resources. The first legal figure broad the scope of the regulation and the second legal figure is a product of the intellect. Further, traditional knowledge is not clear developed, particularly on the equitableness and fairness of the benefits for subjects of traditional knowledge.

Moreover, the Indian case shows certain failures on the explicit recognition of the protection of the benefits equitably by establishing certain kind

of penalties for those violating such rules, at the national level. Further, traditional knowledge as part of the concept of distributive and procedural Equity needs to be found and a larger and more detailed clarification on contract issues can also be of importance. Further elaboration on the application of these legal rules in the national legal system is needed, however, it is possible to explain the process of definition of just and equitable in the national legal system as a consequence of the legal rules containing rights and obligations from international legal system

Is it important for international law this conclusions, considering that international law governs above legal system of States the way in which legal systems formally and essentially define by interpretation and application in the national and subnational legal system of this international legal rule and different cases is remarkable. Cases has changed the primary direct application but without the rule national interpretation and application by enacting the law would not be possible. This is a new insight on the international legal system (influence) and the interpretation and application not only in the international legal systems as such by an international treaty but on the national interpretation and application of international legal rules in which countries further developed the general and abstract rules. What is remarkable for international law, as well, is the possibility of further development of interpretation of international legal rules, a topic that deserves a study that this research article has faced.

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