THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PATENTS IN BRAZIL: AN "INEFFECTIVE" LEGAL FRAMEWORK TO PROTECT THE TRADITIONAL KNOWLEDGE (TK) RESOURCES IN THE LIGHT OF THE NAGOYA PROTOCOL

O SISTEMA REGULATÓRIO DE PATENTES DE BIOTECNOLOGIA NO BRASIL: UM QUADRO LEGAL "INEFETIVO" PARA PROTEGER OS RECURSOS DO CONHECIMENTO TRADICIONAL (CT) À LUZ DO PROTOCOLO DE NAGOIA

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Abstract: In the light of the application of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABP), which is intended to the protection of rights arising from profitable use of resources from Traditional Knowledge (TK) mainly through Benefit-Sharing agreements, this paper analyses the main features of the Brazilian legislative framework on Patents and other IP rights. Brazil, which holds 70% of the "World's cataloged animal and plant species (see Convention of Biological Diversity (CBD)- Country profile), has not still ratified the ABP. Since the implementation of an effective patent granting regime (IP) and other equivalent rights could be a useful tool for combating biopiracy (and illicit trade), the regulatory options adopted by Brazilian legislation could be deemed a mix of systems (USPTO- Patent and Trademark Office, OMC/ TRIPS system, with European Patent Convention aspects) Also, with an

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unclear division between “sui generis” systems for plants (UPOV convention, which in charge of SNPC) and other IP rights linked with Genetically Modified Organism derived from autochthonous species plants, it would be a priority to define what exactly are the legislative options from the Brazilian system to protect nationwide rights in cases of technology transfer since that Brazil is also one of the worldwide markets from transgenic crops. Lastly, when this eventual transfer comprises active principles with potential medicinal use, which can be protected with IP rights under WTO-TRIPS rules, the regulatory options should consider all the interests at stake.

Keywords: ABS Protocol. Benefit Sharing, Bioprospecting, Traditional Knowledge, Commodification.

Resumo: À luz da aplicação do Protocolo de Nagoya sobre Acesso a Recursos Genéticos e Repartição Justa e Equitativa dos Benefícios Decorrentes de sua Utilização (ABP), que se destina à proteção dos direitos decorrentes do uso lucrativo dos recursos do Conhecimento Tradicional (TK) principalmente por meio de acordos de repartição de benefícios, este artigo analisa as principais características do arcabouço legislativo brasileiro sobre patentes e outros direitos de PI. O Brasil, que detém 70% das “espécies animais e vegetais catalogadas no mundo (ver Convenção da Diversidade Biológica (CDB) – Perfil do País), ainda não ratificou a ABP. Como a implementação de um regime efetivo de concessão de patentes (PI) e outros direitos equivalentes poderia ser uma ferramenta útil para combater a biopirataria (e o comércio ilícito), as opções regulatórias adotadas pela legislação brasileira poderiam ser consideradas um misto de sistemas (USPTO- Patent and Trademark Office, sistema OMC/TRIPS, com aspectos da Convenção Europeia de Patentes) Também, com uma divisão pouco clara entre sistemas “sui generis” para plantas (convenção UPOV, que está a cargo do SNPC) e outros direitos de PI vinculados a Organismos Geneticamente Modificados derivados de espécies autóctones plantas, seria prioritário definir quais são exatamente as opções legislativas do sistema brasileiro para proteger direitos nacionais em casos de transferência de tecnologia, já que o Brasil também é um dos mercados mundiais de transgênicos. Por fim, quando essa eventual transferência compreende princípios ativos com potencial uso medicinal, que podem ser protegidos com direitos de PI sob as regras da OMC-TRIPS, as opções regulatórias devem considerar todos os interesses em jogo.

Palavras-chave: Protocolo ABS. Repartição de Benefícios, Bioprospecção, Conhecimento Tradicional, “Comodificação”.

INTRODUCTION

The process of globalization, which has intensified international trade relations, has placed into the market new profitable practices through the

so-called Key Enabling Technologies.

The question of the commodification, in the post-genomic era, of the global genetic heritage, the human body organs, or the resources covered by the Traditional Knowledge umbrella and its subsequent treatment as saleable commodities-has increasingly brought to the attention of the relevant research areas (Sociology, Ethics, Law) on the role of innovative technology leading sectors on the grounds of the profitable bioprospecting of this heritage.

Culminating with applying the Convention on Biological Diversity (CBD) and, in particular, its Nagoya Protocol on Access to Genetic Resources. Nevertheless, Brazil has still not signed the ABP (Benefit sharing) Protocol. The European Union approved the Nagoya Protocol, by Council Decision 2014/283/EC and by Regulation (EU) 511/2014, to safeguard the legitimate rights of traditional societies of origin through the obligation to guarantee their fair use, proven by internationally recognized certificates of conformity or credible equivalent evidence.

1 BIOPROSPECTING, BIOPIRACY, AND COMMODIFICATION OF GLOBAL COMMON

According to professor A. Fontes, Bioprospecting, in the framework of the link between the Biology and Law, is a definition euphemistic to use instead of biopiracy, the meaning of exploitation of biodiversity, and have a specific target: protection with patents of the biodiversity resources, taking advantage that the legitimate holders (ethnic groups or communities which have not access to the legal mechanisms for the protection of their legal interests). In the case of Amazon area resources, the bioprospection supposes a sort of immunity since, in many instances, it is not possible to know the natural origin of the technology, which incorporates resources of traditional knowledge, making it impossible to claim or challenge the molecular behind the finally marketed.

One of the earlier successful examples of bioprospecting carried out in the modern era (and a significant milestone in the expansion of the pharmaceutical industry in the 20th century) came from the exploitation/ prospection of salicylic acid derivatives and ultimately of aspirin[2]. Salicylic acid, or salicylate, was discovered in willow bark extracts. The willow tree

2 Mahdi, J. G.: Medicinal potential of willow: A chemical perspective of aspirin discovery. Journal of Saudi Chemical Society, 2010.

belongs to the Salicaceae family, which includes three species: Salix alba L., Salix pentandra L., and Salix purpurea. Its use as a medicinal plant has been known by Assyrians (4000 BC) and Sumerians (3500 BC). In 1838, the main pharmacologically active ingredient of willow bark was isolated, the salicylic acid or salicylic. Sixty years later, a lesser irritating derivative was developed, the acetylsalicylic acid or aspirin.

The Traditional Knowledge (TK) resources have, in addition, great potential for profitable use by identifying and purifying their active principles with relevant biological activity and, therefore, for regulated or unregulated bioprospecting[3].

In this respect, ethnobotany[4] and ethnopharmacology[5], prima facie connected topics, differ in practical terms; ethno-pharmacists, in charge of conducting scientifically regulated bioprospecting of "phytochemicals entities," are far from being identified with any cultural, subjective or unscientific aspect intuitively connected with ethnobotanicals[6].

Despite Brazil's large numbers and position as one of the world's ten largest economies, its exports are mainly composed of non-industrial or low-technological goods. It results in a trade deficit and technological dependence that affects several sectors, including biotechnology. The major problem seems to be that the increase in the number of scientists is not accompanied by a proportional rise in effective development policies[7].

"Any unauthorized appropriation of biological material for any type of use" is restricted to "unauthorized appropriation and use of biological material and associated traditional knowledge for product development

3 Dedeurwaerdere, T.: *From bioprospecting to reflexive governance*. Ecological Economics 53 (2005) 473–491. According to Convention on Biological Diversity (CBD), agreed at the 1992 Earth Summit in Rio de Janeiro, bioprospecting is regulated through Access and Benefit- Sharing Agreements which are bilateral contractual arrangements between ecologically-rich states or communities and private corporations and are based on the principles of "prior informed consent" and "equitable sharing of benefits".

4 Ethnobotany refers to "the study of how plants are used in a particular culture" (Webster's New World College Dictionary, 2010) and also to "the branch of botany concerned with the use of plants in folklore, religion, etc."(Collins English Dictionary, Complete & Unabridged 10th Edition, 2009)

5 Ethnopharmacology is "a multi-disciplinary area of research, concerned with the observation, description, and experimental investigation of indigenous drugs and their biological activities". (Rivier and Bruhn 1979)

6 See Gertsch, J.: *Cross- cultural comparisons of medicinal floras- What are the implications for bioprospecting?* Journal of Ethnopharmacology 139 (2012) 685- 687 Referring to the "lack of understanding between these disciplines", the author states: "the application of chemioinformatics [= omic techniques, see note 27 below] seem to be more promising for bioprospecting and closer to pharmacological mechanisms than the obscure anecdotal evidence commonly found in ethnomedical systems."

7 Daiha K Coelho Brêda, Larentis *Enzyme technology in Brazil: trade balance and research community*. Braz J Sci Technol (2016) 3:17. "Despite Brazil's large numbers and its position as one of the world's ten largest economies, its exports are mainly composed of non-industrial or low-technological goods. It results in a trade deficit and technological dependence that affects several sectors, including biotechnology"

and commercialization, whether it involves obtaining intellectual property rights." (J.P. RIBEIRO CAPOBIANCO, Secretary of Biodiversity and Forests of the Ministry of Environment - MMA 2005)

2 THE COMMODIFICATION OF GLOBAL COMMON

In this regard, the authors define this shifting from the live sciences traditional areas to the new overarching concept of "Big Pharma" as a transliteration of the "Big Data"-like trends that have ultimately transformed the life sciences into a "gigantic biotechnosciences leading sector" (Rose 2012)

As with Big Data, the analysis of the impact of those commodification trends in Big Pharma can use predictive and user behavior analytics to extract the main drivers of this appropriation process and the subsequent dissemination of knowledge among the biopharmaceutical industry as a leader in innovation-led development.

This perception impacts the role of legitimate factors in the discussions on global acceptance of some resources of Traditional Knowledge with a long tradition of medicinal remedies. Here, nevertheless, the same rationale used against the authorization of genetically modified crops can be applied mutatis mutandis to the acceptance of those resources in developed societies, sometimes deemed as a "battle over science and precaution"[8] where conventional risk analysis overlaps with the "emotion dimension" of the issue[9]. Another influential element in its acceptance is the role of feelings, as long as those feelings "stimulate strong emotional responses, such as fear and anxiety"[10]: "(…) Fearsome risks are those that stimulate strong emotional responses. Such risks, which usually involve high consequences, tend to have low probabilities since life today is no longer nasty, brutish, and short In the

8 See Spanggaardt, T.: The marketing of GMOs A supra-national battle over Science and precaution Yearbook of European Environmental Law. (3) 2004

9 Lange, B.: The Emotional Dimension in Legal Regulation Journal of Law and Society, Vol. 29, 2002, pg. 211: "Law-making and enforcement organizations, as well as the organizations of the regulated, in turn, are crucial for constructing the meaning of regulatory law. Some aspects of regulating through law may more strongly than others involve interaction with the 'laws of emotions.' Rules for behavior guidance, such as emotion rules, become particularly relevant when various, mutually exclusive opportunities for action exist, such as in the case of conflict. Conflicts of interest can arise between regulated and regulators. They can also arise between different parts of a regulated organization, such as health and safety, environmental management or compliance departments on the one hand, and commercial and operational sections on the other hand."

10 Sunstein, C.R. Zeckhauser, R.: Overreaction to Fearsome Risks. Harvard University. 2008. Harvard Law School Program on Risk Regulation Research Paper No. 08-17. The study also cited the "risk as feelings" hypothesis, which highlights the "role of effect experienced at the moment of decision making" (Loewenstein et al., 2001, p. 267), as opposed to a cognitive assessment of risk.

face of a low-probability fearsome risk, people often exaggerate the benefits of preventive, risk-reducing, or ameliorative measures. In both personal life and politics, the result is damaging overreactions to risks. We offer evidence for probability neglect, failing to distinguish between high and low-probability risks. Action bias is a likely result."

A similar emotional process involved the scientific analysis in other ethically sensitive areas such as bioethics or biotechnology[11], including the commodification of certain public services and inequalities of access to political power. It should be emphasized that, among the advanced technology industries, the biopharmaceutical sector has the highest R&D spending per worker, far exceeding the average cutting-edge area spending by more than 57 percent (Brooking Institution).

According to Mark Schweizer, the human being is hopelessly incompetent when making choices that may affect his interests. Therefore, it is from the government's competence to redirect its intentions to the most appropriate ones in the absence of an optimal individual decision, looking for a balance in terms of the Pareto optimum (the benefit of one party cannot be increased without penalizing the expectancies of the others)

Therefore, it is not a chance that concepts such as morality and public order are also the common grounds to impose limits to the commodification in the systems of protecting, under intellectual property rights, the patenting life in general, and the human body in particular. For example, solving the organ and tissue shortage is the policy-makers primary challenge. Irrespective of the ban on making the human body or its parts "a source of financial gain" embodied in the central Constitutional legal systems, these borderline questions amalgamated policy options and public morals.

It is not a chance that both concepts of morality and public order are also the common grounds to impose limits to the commodification in the systems of protection under intellectual property rights in the framework of the patenting life in general and the human body in particular. After the Oliver Brustle v Greenpeace e.V. ruling, the exclusions of patentability of the human body, parts, cells, or genes also covers the human beings' cloning and the essential organic processes. Noted the position on this line of case law

11 For example, in the field of protection of human rights through the legal guardian of the human genome beyond scientific interests, such as the recent ruling of the European Court of Justice of 18 October 2011 concerning non-patentability of human embryonic cells. See Blance, S.: *Brüstle v Greenpeace(C-34/10): The end for Patents Relating to Human Embryonic Stem Cells in Europe?* Biotechnology Law Report 1, 2012, pg 33-38.

established, among other things, by the judgment of the Court of Justice in the case, on the patentability of human embryonic stem cells is built around the principle that the use of human embryos for therapeutic or diagnostic purposes applicable in the is patentable, but not their use in scientific research.

Whereas the Directive 98/44/EC states that there is a consensus within the Community that interventions in the human germ line and the cloning of human beings are against the order, public, and morality, this position shall be confronted by those of the United States Patent and Trademark Office (USPTO), the US Federal Legislation and the strongfirmotections policy again by the USTR, the TRIPS enforcement, etc., through the review of relevant cases and public policy doctrines: Parke- Davis & Co. v. H.K. Mulford & Co (1912), Diamond v. Chakrabarty (1980), Plant Genetic Systems, N.V. & Biogen, Inc v. Dekalb Genetics Corp (2001) and others.

Biotechnological inventions also refer to products that could be developed from genetic material from TK that has been genetically modified or processed with other types of gene manipulation.

At the EU level, are regulated by Directive 98/44/EC also establishes limits and requirements for utilization that have been additionally interpreted through the rulings of the UE Court of Justice (i.e., case C-34/10, Oliver Brustle vs. Greenpeace e.V., on the extraction of cells of embryonic stem cells precursors) the use of human embryos for therapeutic or diagnostic purposes which is applied to the human source is patentable, but do not use animals in scientific research. Interventions in the human germ line and the cloning of human beings are contrary to public order and morality.

Many Sustainable Development Goals and associated targets are relevant for indigenous peoples. The agenda 2030 for Sustainable Development[12] covers several issues that directly affect the lives of those that apply for the

3 PATENTS, GMO AND CBD

About the protection of Biodiversity, Art. 27.3b of TRIPS deals with patentability or non-patentability of plant and animal inventions and the protection of plant varieties in line with Paragraph 19 of the 2001 Doha Declaration.

The relationship between the TRIPS Agreement and the UN Convention on

12 Available at: <https://sustainabledevelopment.un.org/>. Last access is March 3rd, 2019.

Biological Diversity, the protection of traditional knowledge and folklore (CBD) has been a topic of discussion guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8).

In May 2008, Brazil, China, Colombia, and other countries submitted a declaration to the Members to include in the TRIPS Agreement a mandatory requirement for the disclosure of the origin of biological resounded/or associated traditional knowledge in patent applications by the proposal of a new Art. 29bis - Disclosure of Origin of Genetic Resources and Associated Traditional Knowledge

The evidence of "prior art" has become a solid basis for further enhancing the oversight of natural heritage and challenging previous patents.

Reactions to the risk of unfair use of TK resources from not regulated bioprospecting have led developing countries to deepen the research on botanicals by allocating funds for research addressed to verify the "prior art" or proof of previous knowledge, which is opposite to "novelty" requirements. The other conditions are related to "human invention" and "applicability."

In this context, some interesting parts have patents on active substances from botanicals growing in natural forests (such as the Amazon Rainforest), which have long been used by indigenous people and subsequently marketed.

The Nagoya Protocol sets out core obligations for its contracting Parties to take measures about access to genetic resources, benefit-sharing, and compliance Access obligations: Domestic-level access measures are to Create legal certainty, clarity, and transparency, Provide fair and non-arbitrary rules and procedures, Provide for issuance of a permit or equivalent when access is granted, Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use. Pay due regard to cases of present or imminent emergencies that threaten human, animal, or plant health. Consider the importance of genetic resources for food and agriculture for food security.

3.1 PATENTS' CASES RELATE TO ABP

In the case of the patent on Turmeric (Curcuma longa), the US patent 540,1504 was awarded to the University of Mississippi Medical Centre in March 1995 for using powdered turmeric as an agent for wound healing. The patent was revoked successfully since the features of Curcuma (C. longa) in India have been known for centuries, as revealed by the Indian Council for

Scientific and Industrial Research (CSIR). The use of powdered Curcuma is registered among the indications of the pharmacopeia Hindu and thus did not have the alleged novelty.

The patent Neem tree oil was solved with the revocation, promoted before the European Patent Office (EPO) granted a patent to the US institutions (pat. EPO 436257) for implementing the fungicide of the oil obtained from Azadirachta Indica A. Juss. (Neem tree). Another case study is ayahuasca (Banisteriopsis caapi), a woody vine from the Amazonian rainforest traditionally used to create a hallucinogenic drink. In 1986, was granted a patent by the United States government to Loren Miller for "Da Vine," a new variety of the ayahuasca plant which he had been cultivating (Tupper, 2009). The Coalition for Amazonian Peoples and their Environment (Amazon Coalition) and others challenged the patent asking for a re-examination on the basis that "Da Vine" had been previously cultivated and that the patent violates the United States' morality and public policy. Lately, in 2001, Miller submitted new evidence U.S. government's decision, and a reinstatement of the "Da Vine" patent was granted.

4 THE OMICS TECHNOLOGIES ON THE SHAPE OF BIOPROSPECTING

Modern molecular biotech is dependent on information technology development. The worldwide proliferation of DNA biobanks depends on the processing and managing of a vast amount of data and, finally, the global spread of biomedical information[13]. Regarding biodiversity, the development of so-called post-genomic techniques has shed light on the rationale behind most empirical knowledge on the mechanisms of action of principles actives and organic molecules synthesized by the plants as natural resources forming part of the Traditional Knowledge of indigenous societies. Taking into account that an overwhelming majority of biopiracy intellectual property cases are directly connected with the long-scale resource utilization from the plant kingdom.

Current trends in research of those resources stress the fact that traditional utilization of those resources has developed historically through an empirical "trial and error" approach, whose reliability can be confirmed today with the most recent analytical tools applicable, for instance, to medicinal herbs: the

13 Rose, H., Rose, S. Genes, Cells, and Brains: The Promethean Promises of the New Biology. Verso, 2014 - ISBN-13: 978-1781683149

"omic" or molecular techniques[14]. That "reverse" risk assessment process (relying first on the "clinical" experience instead of a proper scientific analysis) was also at the very origin of modern Western pharmacology[15]. However, criticism about "the use of polyhedral drug formulations [phytocomplexes] hampering the risk assessment by the complexity of the molecular mixtures with many different molecules participating to the overall effect, either positively or negatively."[16]

Counterbalancing the fact that Western science has "grudgingly accepted" those traditional practices, many authors point out that the argument that Eastern medicine is not based on scientific evidence "may well ignore the centuries of trial and error, which has gone into making a particular medicine or remedy appropriate to a given community." Furthermore, "while for many traditional medicinal products scientific, documented evidence of safety and efficacy is scarce, these products have been 'field-tested' for centuries; much empirical knowledge has thus been accumulated in communities and passed on by generations of healers."

4.1 SOME EXAMPLES FROM TRADITIONAL MEDICINE RESOURCES

These new approaches are also partially a result of improved knowledge of the molecular profiles of herbal substances in the so-called "post-genomic era." In addition, Western medicine's emerging tendencies toward personalized attention to patients (or allostasis), which requires "in-depth knowledge of mechanisms of action of the active compounds," are also helpful for a better understanding of the physiological effects of the herbal substances.

It is a well-known fact that consumers have increasingly turned to plant-derived remedies believing that alternative herbal medicines are safer[17]. Research carried out in the United Kingdom by the Medicine and Healthcare

14 Brierley, S. M, Kelber, O. *Use of natural products in gastrointestinal therapies*. Current Opinion in Pharmacology, 2011, Vol. 11(6), pp.604-611: "In particular, the alternative medicines have traditionally been looked at by mainstream medicine with cynicism. However, new evidence demonstrates that the active components in natural products have actions on specific ion channels"

15 See Mahdi, note 23 *supra*: Salicylic acid was first tested with adverse effects: the father of the discoverer, Felix Hoffman, became very sensitive to acid salicylic used as remedy for his arthritis since it acted as an irritant to the upper gastrointestinal tract. Hoffman, a chemist of Bayer Industry, managed to synthetize acetylsalicylic acid from salicylic acid to reduce this side effect. Acetylsalicylic acid was then marketed in 1899 under the trademark name aspirin. From a practical point of view, aspirin was developed after a factual "trial and error "process.

16 Buriania, A., et al.: *Omic techniques in systems biology approaches to traditional Chinese medicine research: Present and futur*. Op.cit.

17 Raynor D., Dickinson, R., Knapp, P., Long., A, Nicolson,D.J..: *Buyer beware? Does the information provided with herbal products available over the counter enable safe use*. BMC Medicine 2011, 9:94

Products Regulatory Agency (MHRA) also found that most people believe herbal products are safer because they are natural. The research also found that patients refrain from telling their physicians when using herbal products[18].

However, the words "natural herbal substance" and "plant-derived substance" can be misleading, and the public needs to be reminded that herbal remedies "are medicines in their own right,"[19] which therefore have to be used according to the instructions. A similar tendency towards using "natural" medicinal products has also been shown in patients with chronic diseases[20]. The term natural refers to any use of traditional therapeutic resources even when herbal substances are primarily incorporated if extracts, essential oils, or other preparations; therefore, these forms are far from the mere original use of plants and their parts. In any case, new purification processes provide greater biochemical purity (in the sense of quality) and, subsequently, safer use.

Parallels between the new acceptance of THM and reactions in Europe against genetically modified organisms mainly used in crop production (GMO) can be found in the meta-scientific discourse on acceptance of THMP as natural products, as it revolves around the public perception of the concept of "natural." Hence, the analysis of the rationality arising from such a concept, where science and socio-legal concerns are closely connected, deepens in an "emotion discourse"[21] similar to the ongoing debate on the authorization of GMO varieties as a threat to "natural" plants.

Cultural attitudes influence the debate on the safety of "natural" herbal

18 MHRA- IPSOS Mori Report: *Public Perceptions of Herbal Medicines. General Public Qualitative & Quantitative Research* . http://www.mhra.gov.uk/home/groups/comms-po/documents/news/con036073.pdf

19 Fan, T. ; Deal, G. ; Koo, H. ; Rees, D. ; Sun, H. ; Chen, S. ; Dou, J. ; Makarov, V. G. ; Paritskaya, O. N.; Shikov, A. N. ; Kim, Y. ; Huang, Y. ; Chang, Y. S.; Jia, W. ; Dias, A. ; Wong, V. C. ; Chan, K.: *Future development of global regulations of Chinese herbal products*. Journal of Ethnopharmacology, 2012, Vol.140(3), pp.568-86

20 The "returning to natural" choice has an increasing role in the treatment of chronic, fatal diseases and for "natural" slimming products. See Brierley, S. M., Kelber, O.: *Use of natural products in gastrointestinal therapies*. Current Opinion in Pharmacology, 2011, Vol.11(6), pp.604-611

21 See Lange, Bettina: *'Getting to Yes: Structuring and disciplining arguments for and against transgenic agricultural products in European Union (EU) authorisations'*, 2012, in Brad Jessup and Kim Rubinstein (eds) Environmental Discourses, Cambridge, Cambridge University Press, pp 143-168. "The Distinctions – on a rhetorical level – not just between scientific and political knowledge, between 'facts' and 'interests', but also between emotive public policy debates and rational deliberation in administrative authorisations are central to EU GMO authorisations. But maintaining such boundaries is precarious. 'Boundary work' at the science/politics interface is unstable because scientific knowledge becomes embedded in political governance structures and economic contexts during EU GMO authorisations. Similarly, emotion discourses are not excluded from EU authorisations but are also mobilised through appeals to trust data, science and experts in the light of highly contested scientific claims about the safety of transgenic agricultural products. The first debate is concerned with the limits and possibilities of a 'rationality project' in risk regulation, which seeks to distinguish between scientific knowledge and politics".

substances, ranging from beliefs and desires to emotions and feelings. About those beliefs and desires, the knowledge of ethnobotanicals in primitive societies has traditionally been restricted to individuals who typically acquired it by oral tradition[22]. Most of the substances used for ceremonial purposes, as they are now known, either have significant effects on the central nervous system, including hallucinations or improve the general welfare, contributing to the individual's endurance and better adaptation to the environment[23]. Ancient beliefs were, in some cases, reinforced through the ritual use of ethnobotanicals[24].

Although, from a sociological point of view, the acceptance of traditional medicine depends on the beliefs of potential consumers[25], evaluation of modern THM is based on real-case assessments of safety and efficacy, including a historical trial and error approach. That approach is currently considered in the initiatives of the World Health Organization through the WHO Strategy for Traditional Medicine. According to the WHO, more than three-quarters of the world's population relies on traditional medicine for health care, mainly through herbs (medicinal plants). The diversity of factors affecting the acceptance of THMP also stresses the relevance of the social and cultural dimension: ethnobotanical remedies are, by nature, resources of native cultural groups which tend to, as a first option, use remedies that they are familiar with. When individuals migrate abroad for a better standard of living, they tend to bring their natural remedies (for instance, the Chinese immigrant population)[26]. Ensuring the availability of traditional herbal products would be essential for the safe supply to a population demanding

22 Some of the ethnobotanicals used in primitive societies were purposely in the hands of the few who heavily influenced the lives of their peers.

23 Many examples are: *Hyoscyamus niger,* (henbane) which contains pschicoactive and hallucinogen agents hyoscyamine and scopolamine, *Whitania somnifera* (ashwaganda) adaptogenic tonic which increases endurance, *Centella asiatica* and *Bacopa monnieri*, ayurvedic plants which improve intelligence and memory. Passion flower (Passiflora spp) which is reported to reduce insomnia and hysteria. Skullcap (*Scutellaria spp*), lemon balm (*Melissa officinalis*) and valerian (*Valeriana officinalis*) are anxiolytic agents and mild sedatives.

24 See Gertsch, J.: Op. Cit. "Anyone doing ethnobotanical field work will sooner or later realize that ethnomedical knowledge systems are belief systems. We should not forget that just because many people believe the same thing over many generations at different locations (as in religion) it is necessarily true"

25 Recent scientific studies focus on the belief components of therapies. See Kemppainen, J., Bormann, J. Shively, M., Kelly, A., Becker, S. Bone, P. Belding, W. Gifford, A. *Living with HIV: Responses to a Mantram Intervention Using the Critical Incident Research Method*. The Journal of Alternative and Complementary Medicine Volume 18, Number 1, 2012, pp. 76–82

26 Efferth, T. Greten H.J.: *The European directive on traditional herbal medicinal products: friend or foe for plant-based therapies*? Journal of Chinese Integrative Medicine, 2012, Vol.10(4), pp.357-361. Increasing fear of herbal products from non EU traditional medicines have been restricted or prohibited as well as novel combinations of traditional herbal products since this legal framework is not suitable for complex herbal mixtures.

those conventional products[27].

The dominant feature of they has widely used vegetable resources in healthcare. However, its principles have been poorly assets, including in the European Pharmacopoeia or the nationals of EU Member States.[28] Until very recently, clinical studies have not been carried out on a large scale by validated methodology.[29]

As recognized by the WHO (2013), Eastern countries where they originate or have a long tradition of the traditional herbal resources taking into account that "Traditional medicine is the knowledge, skills, and practices of holistic healthcare, recognized and accepted for its role in the maintenance of health and the treatment of diseases. It is based on indigenous theories, beliefs, and experiences passed on from generation to generation"[30]. The growing awareness that by protecting THM, we also protect TK, indigenous traditions & culture, and biodiversity is another essential analysis element. [31]

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