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HOW TO PROTECT THE RIGHTS OF INDIGENOUS PEOPLES TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN RESPECT OF MEDICAL INTERVENTIONS OR SCIENTIFIC RESEARCH IN THE 'GLOBAL BIOMEDICAL CONVENTION': LESSONS FROM INTERNATIONAL BIODIVERSITY LAW AND BIOPIRACY CASE[1]

CÓMO PROTEGER LOS DERECHOS DE LOS PUEBLOS INDÍGENAS ANTE EL CONSENTIMIENTO INFORMADO PREVIO Y LA DISTRIBUCIÓN DE BENEFICIOS EN RELACIÓN CON LAS INTERVENCIONES MÉDICAS O LA INVESTIGACIÓN CIENTÍFICA EN LA "CONVENCIÓN BIOMÉDICA MUNDIAL": LECCIONES DESDE EL DERECHO INTERNACIONAL DE LA BIODIVERSIDAD Y EL CASO "BIOPIRATERÍA".

Jinyup KIM

ABSTRACT

Biological resources and associated traditional knowledge of indigenous peoples have long been exploited by multinational corporations for their profits with little or no acknowledgement of and compensation for them and it is called '*biopiracy*'. Not just their natural resources and associated knowledge but their own genetic information or genes in their bodies have also been the target of the scientists who are seeking to trace human history or cure disease by investigating human genes.

Thus, to combat biopiracy, a number of international agreements such as the Convention on Biological Diversity (CBD) have been adopted and benefit sharing agreements between users and providers of the resources including indigenous peoples in some biopiracy cases have shown how benefits can be shared with indigenous peoples. However, in biomedical field while plenty of piracies of genetic information of indigenous peoples have happened, no international legal binding convention has been adopted and few benefit sharing agreements have been reported, which makes it difficult to protect their rights in a coherent manner.

Thus, this paper would like to argue that *a global convention in the biomedical field or the 'Global Biomedical Convention' which contains some provisions for the protection of the rights of indigenous peoples to their genetic information* should be adopted and international biodiversity laws such as the CBD could provide some lessons in this regard. For instance,

[1] Conference Paper presented at the International Workshop 'INTERNATIONAL BIOLAW AND INTERACTIONS WITH ENVIRONMENTAL, HUMAN RIGHTS AND HEALTH LAW', the European Society of International Law Interest Group on International Bio Law, Malaga, Spain, October 27th 2017.

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while the CBD (and Nagoya Protocol adopted under the Convention) ensures the rights of indigenous peoples to benefit sharing, few benefit sharing provisions have been provided in international biomedical laws.[2] In addition, as some biopiracy cases such as *Hoodia* case provide a good benefit sharing experience, such biopiracy cases could provide useful *practical* lessons for the protection of the rights of indigenous peoples to their genetic information. Therefore, this paper would like to suggest some key components of the provisions of the 'Global Biomedical Convention' regarding the protection of the rights of indigenous peoples to their genes especially focusing on their rights to prior informed consent and benefit sharing in respect of medical interventions or scientific research based on the analysis of some international biodiversity laws as well as some existing international biomedical laws. At the same time, an important biopiracy case, *Hoodia* case, will also be analyzed to show how indigenous peoples successfully fought against the exploitation of their natural resources because it could provide some practical lessons for the protection of the rights of indigenous peoples to their genetic information.

KEYWORDS: Indigenous people, Biopiracy, Prior Informed Consent, Benefit sharing, Right to genetic information.

RESUMEN

Los recursos biológicos y el conocimiento tradicional asociado a los pueblos indígenas han sido explotados por corporaciones multinacionales en su propio beneficio, con poco o ningún reconocimiento y compensación para los pueblos indígenas, y esto se llama *biopiratería*. No solo sus recursos naturales y el conocimiento asociado, sino que también su propia información genética o genes de sus cuerpos han sido objetivo de científicos que persiguen rastrear la historia humana o curar enfermedades mediante la investigación de genes humanos. Por lo tanto, para combatir la biopiratería se han adoptado varios acuerdos internacionales, como el Convenio sobre la Diversidad Biológica (CDB) y los acuerdos de distribución de beneficios entre usuarios y proveedores de recursos, incluidos los pueblos

[2] In this paper, although there are some international biodiversity and biomedical laws, this paper would like to focus on the *CBD* and its *Nagoya Protocol* for international biodiversity law and the *Universal Declaration on Bioethics and Human Rights*, the *Universal Declaration on the Human Genome and Human Rights* and, the *Convention on Human Rights and Biomedicine* for international biomedical law because they are the most comprehensive (and representative) international laws in each field.

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indígenas; en ciertos casos de biopiratería se ha demostrado cómo se pueden compartir los beneficios con los pueblos indígenas. Sin embargo, en el campo biomédico, pese a haberse producido una gran cantidad de actos de piratería de la información genética de los pueblos indígenas, no se ha adoptado ninguna convención legal internacional vinculante y son pocos los acuerdos de distribución de beneficios de los que se tiene noticia, lo que dificulta la protección de los derechos de forma consistente. Por esta razón, este artículo pretende argumentar que *una convención universal en el campo biomédico que contenga algunas disposiciones para la protección de los derechos de los pueblos indígenas con respecto a su información genética* debería adoptarse, y las leyes internacionales de biodiversidad, como el CDB, pueden proporcionar algunas lecciones al respecto. Por ejemplo, si bien el CDB y su Protocolo de Nagoya garantizan los derechos de los pueblos indígenas a la distribución de beneficios, la normativa biomédica internacional contiene pocas disposiciones sobre la distribución de beneficios.[3] Además, algunos casos de biopiratería como el caso Hoodia proporcionan una buena experiencia en la distribución de beneficios; estos casos de biopiratería podrían suponer una útil lección *práctica* sobre protección de los derechos de los pueblos indígenas sobre su información genética.

De este modo, el presente artículo pretende sugerir algunos elementos centrales de las disposiciones de la convención universal biomédica en relación con la protección de los derechos de los pueblos indígenas sobre sus genes, centrándose especialmente en su derecho al consentimiento fundamentado previo y la distribución de beneficios con respecto a intervenciones médicas o investigación científica a partir del análisis de algunas leyes internacionales sobre biodiversidad, así como algunas leyes internacionales existentes sobre biomedicina. Al mismo tiempo, se analizará un importante caso de biopiratería, el caso Hoodia, a fin de mostrar cómo lucharon con éxito los pueblos indígenas contra la explotación de sus recursos naturales, dado que podría proporcionar lecciones prácticas para la protección de los derechos de los pueblos indígenas sobre su información genética.

[3] El presente artículo, pese a la existencia de múltiples leyes internacionales sobre biomedicina y biodiversidad, se centra en el CDB y su Protocolo de Nagoya para la legislación internacional sobre biodiversidad y la Declaración Universal sobre Bioética y Derechos Humanos, la Declaración Universal sobre el Genoma Humano y Derechos Humanos, y el Convenio sobre Derechos Humanos y Biomedicina para el derecho internacional sobre biomedicina, siendo estas las leyes internacionales más importantes y completas en cada campo.

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PALABRAS CLAVE: Pueblos Indígenas, Bipiracy, Consentimiento Informado Previo, Participación en los beneficios, Derecho a la información genética

I. INTRODUCTION

The rights of indigenous people have long been violated in almost all aspects of their lives by other entities such as governments and multinational companies ranging from their rights to land, natural resources and traditional knowledge to their own genes in their bodies.

Of these rights, as biotechnology has advanced and multinational companies such as pharmaceutical companies have realized the importance of biogenetic resources as a potential component of drugs or dietary supplements, natural resources that they have conserved and used for centuries and associated traditional knowledge have been subject to the exploitation and subsequently, the rights of indigenous peoples who have lived in the areas rich in biodiversity for a very long time to biological resources and associated traditional knowledge have been violated at an alarming rate. In order to tackle such misappropriation of biological resources or 'biopiracy', countries have adopted some international agreements, one of which is the Convention on Biological Diversity (CBD) adopted in 1993 whose objectives include the conservation and sustainable use of biological resources and fair and equitable sharing of the benefits arising from the utilization of the resources and associated traditional knowledge.[4] In particular, the Nagoya Protocol to the CBD adopted in 2010 focuses on the third objective of the Convention, namely fair and equitable sharing of the benefits and contains several provisions for the protection of the rights of indigenous peoples to biological resources and associated traditional knowledge including their rights to prior informed consent and benefit sharing.

In the meantime, when it comes to the rights of indigenous peoples to their genetic information or genes, although a number of violations of their rights to genes have been found, only declarations such as UNESCO Declarations which do not have a binding force have been adopted and the only binding agreement is the Convention on Human Rights and Biomedicine which is a European Convention, not a global agreement.

Therefore, this paper argues that *a global convention in biomedical field or the 'Global Biomedical Convention'* should be adopted and particularly, provisions dedicated to the

[4] Article 1, Convention on Biological Diversity (CBD)

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protection of the rights of indigenous people to their genes should be contained in the Convention for more effective protection of their rights to their genes. Although a variety of rights should be protected in the Convention, this paper would like to focus on their *rights to prior informed consent and benefit sharing*, two most important rights to prevent piracy of their genetic information and suggest how such rights should be stipulated if such a global convention were to be adopted.

In order to do so, this paper would like to argue that international biodiversity laws, namely the CBD and Nagoya protocol can provide useful lessons because as mentioned above, they already contain some provisions requiring its parties to take measures to protect the rights of indigenous peoples to prior informed consent and benefit sharing. Thus, based on the CBD and Nagoya Protocol as well as some existing international biomedical laws, namely two UNESCO Declarations and the Convention on Human Rights and Biomedicine, this paper would like to suggest key elements of the provisions regarding the protection of the rights of indigenous people to prior informed consent and benefit sharing in the Global Biomedical Convention.

In addition, *Hoodia* case, one of the most important biopiracy cases will also be analyzed to show how indigenous peoples successfully fought against the exploitation of their natural resources because it could provide practical lessons to protect the rights of indigenous peoples to their genetic information.

Therefore, this paper aims to suggest how to protect the rights of indigenous peoples to prior informed consent and benefit sharing in relation to genetic information in their bodies in the 'Global Biomedical Convention' and show how the peoples protect their rights to their genes based on the international biodiversity laws and cases.

II. RIGHTS OF INDIGENOUS PEOPLES TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN INTERNATIONAL BIOMEDICAL LAWS AND BIODIVERSITY LAWS

In this chapter, this paper will conduct analysis of the provisions regarding prior informed consent and benefit sharing in international biomedical laws and biodiversity laws to figure out their current status. In the case of biomedical laws, this paper will analyze the relevant provisions in two UNESCO Declarations, namely the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights as

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they are the most comprehensive international biomedical soft law instruments. In addition, the Council of Europe's Convention on Human Rights and Biomedicine or Biomedicine Convention will also be analyzed because although its scope is Europe, it is the first comprehensive multilateral treaty (i.e. a legally binding instrument) addressing issues at the intersection of human rights and biomedicine.[5] And then, some provisions that provide the protection of the rights of indigenous people to prior informed consent and benefit sharing in the CBD and its Nagoya Protocol will also be analyzed to suggest core elements in the next chapter.

2.1. ANALYSIS OF RIGHTS TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN INTERNATIONAL BIOMEDICAL LAWS

In the case of the two UNESCO declarations and the Biomedicine Convention, they have no provisions dedicated to the protection of the rights of indigenous people to prior informed consent and benefit sharing. Instead, they have some provisions regarding the rights to consent and benefit sharing (i.e. Only one of the two UNESCO declarations puts a benefit sharing provision in place.) for all the individuals of the parties to the instruments which of course apply to indigenous peoples as well if they live within the jurisdiction of one of the parties. Thus, in this section, this paper will analyze and discuss the provisions regarding the rights to consent and benefit sharing in the three biomedical instruments.

2.1.1. RIGHTS TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE (BIOMEDICINE CONVENTION)

The Convention on Human Rights and Biomedicine (hereinafter Biomedicine Convention) adopted in 1998 by the member countries of the Council of Europe is a transnational binding instrument aimed at the protection of human rights in the specific field of biomedical research, genetics, and health care.[6] It contains some provisions to protect the rights of the

[5] Roberto Andorno, *Principle of International biolaw: Seeking common ground at the intersection of bioethics and human rights* (Bruxelles: Bruylant, 2013) : p.

[6] Vera Lu´cia Raposo and Eduardo Osuna, "European Convention of Human Rights and Biomedicine" in *Legal and Forensic Medicine,* ed. R.G. Beran (Berlin: Springer-Verlag, 2013) : p.1405

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person concerned to consent with regard to a medical intervention.

At first, Chapter II of the Convention is devoted to the right of the person concerned to consent. Article 5 in the Chapter stipulates a free and informed consent of the person concerned as a precondition of an intervention in the health field, requiring appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks to be given to the person concerned.[7] In this article, the 'intervention' should be understood in its wildest sense, covering all medical acts including interventions performed for the purpose of preventive care, treatment and research.[8] In particular, although the second paragraph of the article mentions some important aspects of the information such as nature and risk of the intervention, the list is not exhaustive and additional elements could be added.[9] In addition, the information should be clear and understandable enough for the patient to be able to understand and the form of the consent can be express or implied and verbal or written.[10] The consent can be withdrawn at any time.[11] One thing to note is that this principle of free and informed consent is already stipulated in the International Covenant on Civil and Political Rights (ICCPR) in its article 7[12] although its scope is narrower because it requires informed consent only for medical research, not for all biomedical intervention.[13] And, article 6 of the Convention deals with the people who cannot give or refuse to consent to an intervention, specifically mentioning a minor and an adult with mental disability or some similar reasons.[14] For them, the authorization of his or her representative or an authority or a person or body provided for by law is required for the invention to be carried out

[7] Article 5 of the Convention on Human Rights and Biomedicine

[8] Council of Europe, *Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (1997) : p.6

[9] *Ibid*. p.7

[10] Ibid.

[11] Article 5 of the Convention on Human Rights and Biomedicine

[12] No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation. (Article 7 of the ICCPR)

[13] Roberto Andorno, *Principles of International Biolaw: Seeking Common Ground at the Intersection of Bioethics and Human Rights* (Bruxelles: Bruylant, 2013) : p.

[14] Article 6 of the Convention on Human Rights and Biomedicine

although their opinions and participation should also be taken into account.[15]

In addition to the Chapter II of the Convention, some provisions contain important elements with regard to the rights to consent, one of which is article 16. Particularly, paragraph 5 of the article requires that not only the person's free and informed consent but also their express, specific and written consent be undertaken for research on a person.[16] Moreover, article 17 provides that research on a person without the capacity to consent should be allowed only when the research benefits his or her health potentially, there should be no alternative subject with full capacity, and the necessary authorization as provided for under Article 6 is given specifically and in writing.[17] And article 19 of the Convention setting up the conditions for organ and tissue donation by living donors for the purpose of transplantation requires the express, specific and written consent before an official body which is more stringent than article 5 of the Convention.[18]

Although the Convention contains many provisions regarding the rights to consent, it does not specially mention the rights of the person concerned to share the benefits arising from the medical intervention or research.

2.1.2. RIGHTS TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMA RIGHTS (UDHG)

The UDHG is a universal declaration adopted by the UNESCO member countries in 1997 whose main objectives include the prevention of abuse of human genome and protection of human rights and human dignity.

With regard to the right to prior informed consent, as is the case with the Biomedicine Convention, in its article 5, this Declaration stipulates that if research, treatment or diagnosis affects an individual's genome, it shall be undertaken only after rigorous and prior

[15] Ibid.

[16] Council of Europe, Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997) : p.16

[17] Ibid.

[18] *Ibid*. p.19

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assessment of the potential risks and benefits.[19] As discussed above, this provision is line with the article 7 of the ICCPR which provides this right in a more broad manner.[20] In this Declaration, the scope of the right to free and informed consent is extended to all forms of intervention, for medical or scientific purposes on an individual's genome.[21] Although the patient should be considered to be competent to make the decision for an informed consent to be valid, if the person concerned is not capable of giving or refusing consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law.[22] In addition, when research does not have an expected direct benefit, the research shall be taken only when the person concerned is exposed to a minimal risk and burden and the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, which were also mentioned in the Biomedicine Convention.[23] Although the Declaration does not specifically mention who the person who does not have the capacity to consent is, minors and adults with mental disability or vulnerable people could be included in the light of the Biomedicine Convention. However, unlike the Biomedicine Convention, the Declaration mentions the need of the submission of protocols in accordance with relevant national and international research standards or guidelines when research affecting an individual's genome is undertaken.[24]

As regards benefit sharing, although no direct provision is contained in the Declaration, article 8 stipulates the right to just reparation. This makes it clear that the person concerned has the right to receive compensation if certain damage occurs as a result of the intervention affecting his or her genome although it does not provide for the right to share the benefits

[19] Article 5(a) and (b) of the Universal Declaration on the Human Genome and Human Rights (UDHG)

[20] Noalle Lenoir, "Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level" *Columbia Human Rights Law Review* 30:537 (1999) : p.563

[21] Ibid.

[22] Article 5(e) of the Universal Declaration on the Human Genome and Human Rights (UDHG)

[23] Article 17.2.i of the Biomedicine Convention provides additional conditions for the research without the potential to produce results of direct benefit to the health of the person concerned to be carried out, one of which is that *the research should have the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.*

[24] Ariticle 5(d) of the Universal Declaration on the Human Genome and Human Rights (UDHG)

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arising from the research.

2.1.3. RIGHTS TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN THE UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS (UDBHR)

The UDBHR is another universal declaration adopted by the UNESCO in 2005 to address ethical issues related to medicine, life sciences, and associated technologies as applied to human being. Its aim is to provide a universal framework of principles and procedures to guide states in the formulation of their legislation, polices or other instruments in the field of bioethics.[25]

Among the 28 articles in the Declaration article 6 and 7 address consent and persons without the capacity to consent. Unlike the relevant provisions in the Biomedicine Convention and the UDHG, article 6 of the UDBHR deals with the consent in medical intervention and scientific research separately. In the case of a medical intervention, the prior, free and informed consent of the person concerned is required for any preventive, diagnostic and therapeutic medical intervention.[26] Although the article states that the consent should be express, there is no mention that written consent is required. It also provides that such consent should be based on 'adequate information' and the 'adequate information' could be interpreted to include the information as to the purpose and nature of the intervention as well as on its consequences and risks in the light of the article 5 of the Biomedicine Convention. In the case of scientific research, the prior, free and informed consent of the person concerned is also required and the 'adequate information' should include modalities for withdrawal of consent. This article makes clear that ethical and lawful human experimentation requires the voluntary, competent, informed and understanding consent of the subjects to protect research subject's rights.[27] Limitation on this principle is left to the ethical and legal standards adopted by states.[28] What makes this Declaration different from the other UNESCO Declaration and

[25] Article 2(a) of the Universal Declaration on Bioethics and Human Rights (UDBHR)

[26] Article 6.1 of the UDBHR

[27] Violeta Begirevi, "Basic norms of Bioethics: Informed Consent in UNESCO Bioethics Declarations", *Annals - Belgrade Law Review* 3 (2008) : p.262

[28] Article 6.2 of the UDBHR

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the Biomedicine Convention is the requirement of 'group consent'.[29] According to article 6.3, when research is conducted on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned is required. However, in the article, the UDBHR makes clear that an individual's consent should get priority by providing that a collective community agreement or the consent of the community leader should not substitute for an individual's informed consent. Despite this qualification, this requirement is of great significance for the protection of the rights of indigenous peoples to their genes mainly because in most of the indigenous communities, group rights are regarded as critical as their resources including genes of each individual of the community are regarded as 'collective assets' and culturally sacred.[30] In its article 7, the UDBHR addresses persons without the capacity to consent, requiring authorization for research and medical practice to be obtained in accordance with the best interest of the person concerned. And by stating 'in accordance with domestic law', the Declaration places a main responsibility for protecting the rights of the persons without the capacity to consent on national states.[31] Although authorization is required, the Declaration still requires the person concerned to be involved to the greatest extent possible in the decision making process of consent as well as that of withdrawal process. In addition, in its second paragraph (b), the article adds more conditions for research and medical practice on the person without the capacity to consent such as direct health benefit for the person concerned and no research alternative of comparable effectiveness with research participants able to consent. Finally, the article stipulates that when there is no potential direct health benefit for the person concerned without the capacity to consent in the research, if the research is expected to contribute to the health benefit of 'other persons in the same category', the research is allowed to be undertaken exceptionally.

With regard to the sharing of benefits, unlike the two previous instruments, the UDBHR explicitly requires the benefits resulting from any scientific research and its applications to be shared. However, this article does not mention 'the person concerned'. In other words, this article does not mean sharing of the benefits with the provider(s) of, for instance, blood

[29] Article 6.3 of the UDBHR

[30] Group consent is somewhat controversial. However, many experts advocate the group rights of indigenous peoples to the genes of each member of the community for many reasons which will be discussed later in this paper.

[31] Violeta Begirevi, "Basic norms of Bioethics: Informed Consent in UNESCO Bioethics Declarations", *Annals - Belgrade Law Review* 3 (2008) : p.263

samples or research subject(s) for their own benefit. Instead, this article emphasizes that such benefits be used for the benefits of human as a whole. Thus, the meaning behind this provision is slightly different from the provision of the Global Biomedical Convention for sharing of benefits with indigenous people. And the article provides a list of benefits but, this is not exhaustive and it is emphasized that benefits should not be used as an improper means to induce the person concerned to participate in research.

2.2. ANALYSIS OF RIGHTS OF INDIGENOUS PEOPLES TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN INTERNATIONAL BIODIVERSITY LAWS

As mentioned above, international biodiversity laws, namely the CBD and its Nagoya Protocol have some provisions devoted to the protection of the rights of indigenous people to biological resources and associated traditional knowledge including their rights to prior informed consent and benefit sharing. Thus, in this section, this paper would like to analyze these articles to show how their rights to prior informed consent and benefit sharing are protected in these agreements.

2.2.1. RIGHTS OF INDIGENOUS PEOPLES TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The CBD is one of the few international environmental agreements that explicitly requires the rights of indigenous peoples to biological resources and associated traditional knowledge to be protected.[32] In particular, in its article 8(j), the Convention addresses the rights of indigenous people by stating that '*Each Contracting Party shall, as far as possible and as appropriate, subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such*

[32] Konstantia Koutouki et al, "The Nagoya Protocol : Sustainable Access and Benefit Sharing for Indigenous and local communities", *Vermont Journal of Environmental Law*, Vol.13 (2012) : p.514

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knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.'[33]

With regard to the right to prior informed consent, although this article stipulates their rights to participation, it does not explicitly mention '*prior informed consent*' and instead, uses '*the approval and involvement* of the holders of ...'. This shows the reluctance of the CBD parties to fully endorse the rights of indigenous people to prior informed consent, allowing them a greater degree of flexibility in implementation at the national level.[34]

And, as regards the right to benefit sharing, this article requires the state parties to encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Even though this article provides for the right of indigenous people to prior informed consent and benefit sharing, it contains several qualifications. First, the phrase 'as far as possible and as appropriate' allows state parties more discretion in implementing the article. Second, by adding the phrase 'subject to its national legislation', this article makes the obligations governed by national legislations. Finally, the article merely 'encourages' the equitable sharing of the benefits arising from the utilization of traditional knowledge, not 'ensure' it.

2.2.2. RIGHTS OF INDIGENOUS PEOPLES TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN 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 (NAGOYA PROTOCOL)

In an effort to enhance the third objective of the CBD, namely sharing the benefits arising from the utilization of genetic resources and associated traditional knowledge in a fair and equitable way, the Nagoya Protocol was adopted in 2010 and entered into force in 2014.

The Protocol contains some provisions related to the protection of the rights of indigenous peoples[35] to genetic resources and associated traditional knowledge including the rights to

[33] Article 8(j) of the Convention on Biological Diversity (CBD)

[34] Elisa Morgera et al, *Legal Studies on Access and Benefit-sharing* (Leiden: Brill, 2014) : p.152

[35] Although the Nagoya Protocol uses the term 'indigenous and local communities' instead of indigenous

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prior informed consent and benefit sharing. As the focus of this paper is their right to prior informed consent and benefit sharing, this paper would like to focus on the relevant provisions, namely article 5, 6 and 7 of the Protocol. In addition to them, this paper will further discuss article 12, especially its first, third and fourth paragraphs because the article addressing the rights of indigenous people to 'customary laws and community protocols' is also important for the protection of the rights of indigenous peoples to their genes as well as their genetic resources.

Article 5 of the Protocol provides for a fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge and in particular, its second and fifth paragraphs address states' obligations regarding the sharing of benefits with indigenous peoples. In its second paragraph, article 5 requires each Party to take measures to ensure that benefits arising from the utilization of genetic resources that are held by indigenous and local communities are shared in a fair and equitable way with the communities concerned.[36] However, this article is qualified by the phrase '*in accordance with domestic legislation regarding the established rights of these indigenous and local communities*', which leaves much of a discretion to Parties with respect to the implementation of the obligation[37] and link this obligation to domestic legislation and states' recognition of their rights.[38] In addition, this article is also qualified by the phrase '*as appropriate*' allowing states more discretion as is the case with article 8(j) of the CBD. As regards the phrase '*in accordance with domestic legislation regarding the established rights of these indigenous and local communities*', although it is quite controversial about how this obligation, particularly '*established right*', should be interpreted, this paper would like to argue that the 'established rights' should not be interpreted in a way that only when such rights are affirmed in domestic laws, they can claim their '*established rights*' but should be interpreted in a broad manner that such 'established rights' can also include community

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peoples, since the COP 12 of the CBD, the Parties have adopted the use of the terminology 'indigenous peoples and local communities' and continued to use the terminology in their Decisions and documents.

[36] Article 5(2) of the Nagoya Protocol

[37] Ricardo Pepeira and Orla Gough, "Permanent Sovereignty over natural resources in the 21st century : Natural Resources Governance and the Right to Self-Determination of Indigenous Peoples under International Law", *Melbourne Journal of International Law* Vol.14 (2013) : p.482

[38] Thomas Greiber et al, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing", *IUCN Environmental Policy and Law Paper* No. 83 (2012) : p.87

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customary rights because such restrictive interpretation could deprive the peoples of the benefits arising from the utilization of genetic resources held by them.[39] In its fifth paragraph, article 5 requires Parties to take measures to ensure sharing of the benefits arising from the utilization of traditional knowledge associated with genetic resources held by indigenous peoples.[40] Interestingly, this paragraph does not include the phrase 'in accordance with domestic legislation', which makes this obligation more mandatory.[41] However, the paragraph is still qualified by the phrase '*as appropriate*'.

In addition to these two paragraphs, its fourth paragraph indicates that benefits may include monetary and non-monetary benefits, emphasizing that there is a list of benefits in the Annex but, the list is not exhaustive.[42]

Article 6 and 7 of the Nagoya Protocol address access to genetic resources and associated traditional knowledge, requiring each party to obtain the prior informed consent or approval and involvement of indigenous peoples. In the case of article 6, particularly its second paragraph stipulates this obligation but, as in the case of article 5 of the Protocol, this obligation is also qualified by the phrases namely, '*in accordance with domestic law*' and '*as appropriate*'. However, such qualifications should be interpreted to mean that parties can decide *the form of measures for the implementation* of this obligation rather than whether to take measures or not.[43] In addition to the phrases, this article also states another condition, namely '*established right*' to grant access to such resources. As discussed above, the '*established right*' should be interpreted broadly in the light of community customary rights. And, the third paragraph of article 6, particularly its subparagraph (f) requires parties in which indigenous peoples hold genetic resources to set out criteria and processes for obtaining prior informed consent or approval and involvement of indigenous peoples for access to genetic resources.[44] This is part of an effort to create a certain level of legal certainty in the access process for users of the resources.[45] However, the subparagraph is

[39] Elisa Morgera, Unraveling the Nagoya Protocol, (the Netherlands : Koninklijke Brill, 2014) : p.124

[40] Article 5(5) of the Nagoya Protocol

[41] Elisa Morgera, Unraveling the Nagoya Protocol, (the Netherlands : Koninklijke Brill, 2014) : p.127

[42] Article 5(4) of the Nagoya Protocol

[43] Thomas Greiber et al, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing", *IUCN Environmental Policy and Law Paper* No. 83 (2012) : p.100

[44] Article 6(3)(f) of the Nagoya Protocol

[45] Thomas Greiber et al, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing", *IUCN Environmental Policy and Law Pap*er No. 83 (2012) : p.101

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qualified by the phrase, namely '*Where applicable and subject to domestic legislation*', which means that parties have discretion to implement or not with regard to the article 6(3)(f).[46] In the case of article 7 of the Protocol which deals with the access to traditional knowledge to traditional knowledge associated with genetic resources, as is the case with the article 6, the article also requires the prior and informed consent or approval and involvement of the indigenous peoples to be obtained and it is also qualified by some phrases such as "*in accordance with domestic law*" and "*as appropriate*" and as discussed above, they should be interpreted in a way to offer parties flexibility when deciding the forms of measures to take to implement the provision, not whether parties take measures or not.[47] Interestingly, this article only covers traditional knowledge *held by the communities*, and ex situ traditional knowledge cannot be covered by this article if it is no longer held by them.[48]

Finally, this paper would like to analyze the article 12 of the Protocol which addresses customary laws and community protocols. Even though this article is not directly related to the rights to prior informed consent and benefit sharing, the recognition, protection and realization of their rights to customary laws and community protocols is critical for the protection of their rights to their genetic information as well as biogenetic resources and associated traditional knowledge. The first paragraph of this article requires parties to take into consideration their own instruments or mechanisms when implementing their obligation, paving the way for the interaction between international and domestic laws and communities' rules.[49] However, this article is also qualified by some phrases such as '*in accordance with domestic law*' and '*as applicable*'. Moreover, this article goes beyond just considering their rules and requires parties to endeavor to support the peoples in developing tools helping them to better deal with access to traditional knowledge and ensure the fair and equitable sharing of benefits.[50] But, this provision is also qualified in that parties are merely required to '*endeavor*' to '*support*' the peoples to develop the tools '*as appropriate*'.[51] The last

[46] Elisa Morgera, Unraveling the Nagoya Protocol, (the Netherlands : Koninklijke Brill, 2014) : pp.157-158

[47] Thomas Greiber et al, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing", *IUCN Environmental Policy and Law Paper* No. 83 (2012) : pp.111-112

[48] Elisa Morgera, Unraveling the Nagoya Protocol, (the Netherlands : Koninklijke Brill, 2014) : p.175

[49] *Ibid*. p.218

[50] Article 12(3) of the Nagoya Protocol

[51] Thomas Greiber et al, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing", *IUCN Environmental Policy and Law Paper* No. 83 (2012) : p. 141

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paragraph calls on parties not to restrict the customary use and exchange of genetic resources and associated traditional knowledge within and among the communities and it is also qualified by the phrase '*as far as possible*'.[52]

III. RIGHTS OF INDIGENOUS PEOPLES TO PRIOR INFORMED CONSENT AND BENEFIT SHARING IN THE GLOBAL BIOMEDICAL CONVENTION

So far, this paper has carried out an analysis of the articles related to the right to prior informed consent and benefit sharing in international biomedical laws and biodiversity laws by focusing on five hard and soft law instruments. On the basis of this analysis, in this chapter, this paper would like to suggest some core elements of the provisions regarding the protection of the rights of indigenous peoples to prior informed consent and benefit sharing with respect to a medical intervention or scientific research under the Global Biomedical Convention.

3.1. RIGHT OF INDIGENOUS PEOPLE TO PRIOR INFORMED CONSENT IN THE CONVENTION

With regard to the rights of indigenous people to prior informed consent, on the basis of the above analysis of the provisions in the two fields of international laws, this paper found that most of the *substantial and specific elements* can derive from the consent provisions in international biomedical laws because although they are not dedicated to the protection of the rights of indigenous peoples, they stipulate various rights or points for the protection of the rights to consent with respect to a medical intervention or scientific research and these rights should and can apply to the protection of the rights of indigenous peoples to their genetic information.

Thus, at first, as a general provision, the Convention should provide for the requirement of obtaining prior informed consent from indigenous people before undertaking any intervention or scientific research and in particular, it should be highlighted that such consent should be express. As mentioned in the Biomedicine Convention, the 'intervention' in this context

[52] Article 12(4) of the Nagoya Protocol

should be interpreted in its wildest sense so as to cover all medical acts including intervention performed for the purpose of treatment and research. In addition, in order to be 'informed' consent, appropriate information should be given to the indigenous people and such information could include the purpose and nature of the intervention or research and its consequences and risks. In particular, given that most of the indigenous peoples are not well educated and they have their own languages, it should be emphasized that such information is given 'in their own languages'. In addition to the information, as stated in the UDHG, in the case of research, protocols should be submitted for prior review in accordance with relevant national and international research standards or guidelines and such protocols should also be submitted in their own languages as well as the local language. The right to withdraw consent should also be stipulated and such withdrawal should be able to be done at any time and for any reason without disadvantage or prejudice. Last but not least, for more appropriate protection of the rights of indigenous peoples to prior informed consent with respect to medical interventions or scientific research, their right to *group consent* should also be provided in the Convention. As discussed above, there is only one provision regarding the group agreement or consent among the three biomedical instruments discussed in this paper. According to the provision, '*In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought*.' However, this article limits the group consent by providing that '*In no cases should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent*.' Although the right of the individual to consent is important, this paper argues, for indigenous peoples, group rights or group consent should be treated more importantly because in most of the cases, their culture is collective and they share every asset they have including genes of each member. And, since many indigenous groups have communal decision-making processes, the most ethical approach is through the culturally appropriate authorities.[53] Moreover, many indigenous people are concerned that genetic research could cause harm to them. For instance, if a genetic study is conducted without the group consent and the outcome of the research is contrary to their traditional belief, such inconsistency is generally determined in favor of Western science, which could constitute a cultural harm to the

[53] Jason Grant Allen, "Group Consent and the Nature of Group Belonging: Genomics, Race and Indigenous Rights", *Journal of Law, Information and Science* 20 (2010) : p.36

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people.[54] Thus, although the provision in the Convention should strike a balance between the right of the individual and that of the group with respect to an intervention or research, this paper argues, a group agreement or consent *should be sought* under the Convention. In other words, when members of an indigenous group are subject to a medical intervention or scientific research, the group consent or group rights *should at least be carefully taken into consideration* to determine whether to conduct research and how research should be carried out. In the case of indigenous persons who do not have capacity to consent, the authorization of the members' representative or an authority or a person or body provided for by law should also be obtained as is the case with such persons who are not indigenous. When determining the representative or authority or person or body, even if such authority is stipulated by the domestic law, considering the culture and decision making process of many indigenous groups as discussed above, decision making bodies of indigenous peoples such as chief of the tribe or a community board must be at least one of the representatives whose authorization should be obtained. As regards other conditions such as direct benefits, minimal risk, and contribution to the health benefit of other persons in the same age category or with the same genetic condition, this paper argues that indigenous peoples' customary laws or community protocols should be respected to determine whether these conditions will be applied and if so, what forms they should take. However, the person(s) concerned should also be involved to the greatest extent possible.

While the *substantial and specific elements* of the provisions regarding the protection of the rights of indigenous peoples to prior informed consent under the Global Biomedical Convention can derive from the international biomedical laws, this paper argues, international biodiversity laws particularly, the Nagoya Protocol could provide some *procedural elements* to protect their rights under the convention. Nowadays the most important and basic actor in international law is a nation state and the world is largely composed of nation states. Thus, almost all indigenous peoples are living within the jurisdiction of each nation state although some of them argue their rights to self-determination. And, in view of many of the cases of piracy of genes or genetic information of indigenous people, governments, multinational corporations, or researchers in developed countries approach indigenous peoples in developing countries and exploit their information without their acknowledgement and sharing of benefits. Moreover, most of the indigenous

[54] *Ibid*. p.33

peoples do not have enough capacity to require the users in developed countries to obtain their prior informed consent before such research or medical intervention is conducted. Considering this reality, this paper argues that when their right to prior informed consent is stipulated in national laws or at least supported by national governments, more effective protection could be possible. Therefore, as article 6(3) of the Nagoya Protocol provides, the Global Biomedical Convention should ensure that parties to the Convention in which indigenous peoples live take measures to require users to obtain prior informed consent of indigenous peoples including setting out criteria and/or processes. This obligation could enhance the bargaining power of indigenous peoples when they are approached by those who seek to obtain their genetic information and at the same time, legal certainty could also be secured.

3.2. RIGHT OF INDIGENOUS PEOPLE TO BENEFIT SHARING IN THE CONVENTION

With regard to benefit sharing, the relevant provisions in both of the international laws, namely benefit sharing provisions in the UDBHR and CBD and Nagoya Protocol require that benefits should be shared (or encouraged for the CBD) and list various forms of benefits. The difference is that in the case of UDBHR, its article 15(2) requires that benefits not be used as improper inducements to participate in research while the Protocol requires benefit sharing to be upon mutually agreed terms.

On this basis, at first, the Global Biomedical Convention should ensure that benefits resulting from any scientific research and its applications on genetic information from indigenous people should be shared in a fair and equitable way with the indigenous people who are subject to the research. In addition, as stated in the Protocol, it should be stipulated that such benefit sharing should be upon mutually agreed terms between the indigenous people and the recipient or user of their genetic information. In this case, as is the case of prior informed consent, not just the decisions of the indigenous persons concerned but decisions of the indigenous people or their leader should be at least taken into consideration. In other words, when terms of the benefit sharing such as how to distribute benefits or who should receive the benefits are negotiated between the two sides, their customary laws or community protocols should be respected. Moreover, for the same reasons mentioned in the prior informed consent, the Global Biomedical Convention should ensure that parties to the

Convention in which indigenous peoples live take measures to require users to share the benefits with the indigenous people in a fair and equitable way.

When it comes to forms of benefits, this paper argues that as stipulated in the Nagoya Protocol, it would be better for the benefits to be divided into monetary and non-monetary benefits. Monetary benefits could include financial assistance to the indigenous people as well as the members of the people who have participated in the research, access fees per sample collected, and license fees in case of commercialization. On the other hand, non-monetary benefits could include access to quality health care, support for health services, and provision of new diagnostic and therapeutic modalities or products stemming from research. In addition to them, other forms of benefit should be possible as long as they are consistent with the principles set out in the Convention.

Last but not least, as stated in the UDBHR, it should be provided that benefits should not constitute improper inducements to participate in research because otherwise indigenous people could be involved in the research for benefits from the research against their will and this is particularly so, given that most of the indigenous people are impoverished.

3.3. RIGHT OF INDIGENOUS PEOPLE TO CUSTOMARY LAWS OR COMMUNITY PROTOCOLS

Finally, although it is not directly related to the right to prior informed consent and benefit sharing, this paper would like to argue that protecting the right of indigenous people to customary laws and community protocols with respect to medical interventions or scientific research is critical for a proper consent and equitable benefit sharing because if their culture, customs and rules are ignored, such consent and agreement could be a unilateral agreement rather than bilateral or multilateral ones and cannot be considered appropriate.

Therefore, as stipulated in the Nagoya Protocol, the Convention should ensure that indigenous peoples' customary laws or community protocols should be taken into consideration when the users of their genetic information seek to obtain prior informed consent, share benefits, and determine the way such information is utilized for their research.

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IV. ANALYSIS OF CASES OF PIRACY OF GENETIC INFORMATION AND BIOGENETIC RESOURCES OF INDIGENOUS PEOPLE AND PRACTICAL LESSONS

So far, based on the analysis of relevant provisions in international biodiversity legal instruments as well as existing international biomedical instruments, this paper has suggested some core elements of the provisions for the protection of the rights of indigenous peoples to prior informed consent and benefit sharing with respect to medical interventions and scientific research under the Global Biomedical Convention assuming that such a convention is adopted. On the basis of the analysis, this paper found that while specific and substantial elements could be drawn from international biomedical instruments, procedural elements can be provided from international biodiversity laws, particularly the Nagoya Protocol.

In addition to such legal dimension, this paper argues that cases relating biological resources or biopiracy cases could also provide some lessons for the protection of the rights of indigenous people to prior informed consent and benefit sharing because some biopiracy cases show that prior informed consent can be obtained from indigenous people in a proper manner and some benefits can also be shared with them. Therefore, this paper would like to analyze two important cases where biological resources and genetic information of indigenous people are pirated respectively to draw some practical lessons.

4.1. HAVASUPAI TRIBE CASE

The Havasupai tribe which numbered around 650 migrated north from Mexico around 300 BC and settled in the remote location in the Grand Canyon.[55] Such remoteness led to a restricted gene pool in which certain genetic diseases are at a higher incidence than other people or general population and in fact, they have one of the highest incidences of type-2 diabetes in the world.[56]

In 1989, some members of the tribe approached the Arizona State University (ASU) professor John Martin who the tribe had a trusting relationship with to ask for help to figure

[55] "Research without patient consent", Who owns your body?, accessed September 7th 2017, http://www.whoownsyourbody.org/havasupai.html

[56] Ibid.

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out why the incidence of diabetes within their community is high.[57] In the early 1990s, professor Marin and professor Markow obtained approval for the diabetes project from the member tribal council to conduct the research and the ASU's human subjects committee of the Institutional Review Board approved it.[58] Since then, the ASU researchers collected more than 400 blood samples and fingerprints from the members of the tribe.[59] It is important to note in the project that the consent document signed by the tribal members indicated that this project studies the causes of behavioral/medical disorders while prestudy communications with tribal leaders apparently focused on diabetes.[60] However, the tribe made it clear that the tribal council permitted the research project on the condition that the study focuses on diabetes[61] and most of the tribal members who had not completed high school and for whom English is a second language believed that they were donating their blood to look for a link between diabetes and their genes.[62]

By the late 1990s, no link was found between their genes and diabetes but, the researchers used the samples for other studies on schizophrenia, migration, and inbreeding, and published many papers using the samples without the consent of the tribe and sharing of findings with them.[63] In the meantime, the tribe believed that the research project was over as a freezer failure at ASU damaged the blood samples and Markow left the university.[64] However, the samples were recovered and even after leaving the university, Markow took the remaining samples and sent them to other researchers around the country including a doctoral

[57] Robyn L. Sterling, "Genetic Research among the Havasupai: A Cautionary Tale", *American Medical Association Journal of Ethics,* Volume 13, Number 2 (2011) : p.115

[58] Matthew Rimmer, "The Genographic Project: Traditional knowledge and Population Genetics", *Australian Indigenous Law Review* 11 (2007) : p.40

[59] Ibid.

[60] Michelle M. Mello, "The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples", *The New England Journal of Medicine* 363 (2010) : p.204

[61] Matthew Rimmer, "The Genographic Project: Traditional knowledge and Population Genetics", *Australian Indigenous Law Review* 11 (2007) : p.40

[62] Robyn L. Sterling, "Genetic Research among the Havasupai: A Cautionary Tale", *American Medical Association Journal of Ethics,* Volume 13, Number 2 (2011) : p.115

[63] 'Havasupai Tribe and the lawsuit settlement aftermath' American Indian and Alaska Native Genetics Resource Center, accessed September 8th 2017, http://genetics.ncai.org/case-study/havasupai-Tribe.cfm

[64] LorrieAnn Santos, "Genetic Research in Native Communities", *Prog Community Health Partnersh*. 2(4) (2008) : p.322

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candidate.[65]

In 2003, the doctoral candidate at ASU delivered a lecture on the markers in the Havasupai as part of his defense of his doctoral dissertation and it was at that time when Carletta Tilousi, a member of the Havasupai tribe and a participant in the Diabetes Project, who attended the lecture at ASU learned that the samples were used for the later studies without her consent or the consent of other tribal members.[66]

In response to such unauthorized exploitation of their genes, the tribe placed a moratorium on biomedical research and they were supported by many tribes and tribal organizations despite hostile reactions from the researchers.[67]

In 2004, some tribal members filed lawsuits against some institutions including ASU and researchers and they included six causes of action. : *'(1) breach of fiduciary duty and lack of informed consent (including not having appropriate procedures for vulnerable subjects such as children, people with mental illness, and people whose main language was the tribal language); (2) fraud and misrepresentation/fraudulent concealment; (3) intentional or negligent infliction of emotional distress; (4) conversion; (5) violation of civil rights; and (6) negligence, gross negligence and negligence per se*'[68]. After several years of legal battles including dismissal of the some causes and reinstatement of the lawsuits, in 2010, the two sides, the tribe and ASU finally came to an agreement and the terms of the settlement were '*a payment of $700,000, the return of the blood samples, and additional assistance including scholarships and help in obtaining federal funding for a health clinic for the impoverished tribe*'.[69]

Although the settlement sets no formal legal precedent, the university's public acknowledgment of wrongdoing is important symbolically and could affect prospective plaintiffs' and attorneys' views of litigation opportunities.[70]

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[65] Matthew Rimmer, "The Genographic Project: Traditional knowledge and Population Genetics", *Australian Indigenous Law Review* 11 (2007) : p.41

[66] 'Havasupai Tribe and the lawsuit settlement aftermath' American Indian and Alaska Native Genetics Resource Center, accessed September 8th 2017, http://genetics.ncai.org/case-study/havasupai-Tribe.cfm

[67] Debra Harry, "Indigenous peoples and Gene Disputes", *Chicago Kent Law Review* 84 (2010) : p.151

[68] "Research without patient consent", Who owns your body?, accessed September 7th 2017, http://www.whoownsyourbody.org/havasupai.html

[69] Robyn L. Sterling, "Genetic Research among the Havasupai: A Cautionary Tale", *American Medical Association Journal of Ethics,* Volume 13, Number 2 (2011) : p.115

[70] Michelle M. Mello, "The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic

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4.2. HOODIA CASE

4.2.1. WHAT IS HOODIA AND ITS TRADITIONAL USE BY INDIGENOUS PEOPLES?

Hoodia species are cactus-like and succulent plants and they are found throughout southern Africa including South Africa and Namibia.[71]

Many traditional medicinal applications of the plant have been reported and they are known for "reducing hunger and thirst, treating coughs and colds, and preventing aspirin induced gastric damage".[72]

The indigenous peoples of southern Africa have traditionally used Hoodia plants as a source of food and water and it was reported in the 19th Century that the plant was eaten by indigenous peoples to quench their thirst.[73]

One of the indigenous peoples who have traditionally used the plants is the San people who chew the stems of the plant to suppress hunger during long hunting trips in the Kalahari desert.[74] The San peoples who were nomadic hunter gatherers and the oldest inhabitants in southern Africa now live in rural areas or reserves and currently number around 100,000 and are scattered in some countries in southern Africa such as Botswana, Namibia, South Africa and Angola.

4.2.2. PATENT ON HOODIA AND SUBSEQUENT DEVELOPMENTS

As discussed above, the San people has traditionally used Hoodia plant for a long period of time as a source of food, water and particularly, a means to suppress hunger during hunting

Samples", *The New England Journal of Medicine* 363 (2010) : p.205

[71] Barry Lynch et al, "Genotoxicity of dried Hoodia parviflora aerial parts", *Food and Chemical Toxicology* 55 (2013) : p.272

[72] W.C. McClatchey et al, "Ethnobotany as a pharmacological research tool and recent developments in CNS-active natural products from ethnobotanical sources", *Pharmacology & Therapeutics* 123 (2009) : p.247

[73] T.L. Knight et al, "Cultivation practices and manufacturing processes to produce Hoodia gordonii extract for weight management products", *Food and Chemical Toxicology* 50 (2012) : p.2

[74] Barry Lynch et al, "Genotoxicity of dried Hoodia parviflora aerial parts", *Food and Chemical Toxicology* 55 (2013) : p.272

trips in the deserts and such traditional use of the Hoodia plant was documented in colonial botanical accounts. The botanical accounts inspired the Council for Scientific and Industrial Research (CSIR), a South African institution, to include Hoodia for investigation in a 1963 project on edible wild plants in the region.[75] Although due to some technological problems the research was stopped, after several years of research and development, the CSIR finally isolated the active compound in Hoodia plant and filed for a South African patent in 1995 on the use of the extracted compound, P57 which is responsible for suppressing appetite.[76]

In 1998, a licensing agreement between the CSIR and PhytoPharm, a small British company was concluded to further develop and commercialize the product and the licensing agreement gave the company an exclusive license to manufacture and market products containing Hoodia and exploit any other part of the CSIR's intellectual property rights (IPRs) relating to Hoodia species.[77] And at the same year, PhytoPharm sublicensed the rights to develop and market drugs based on P57 to Pfizer, a US pharmaceutical company.[78] However, in 2003 as Pfizer closed its Natureceutical group responsible for the development of P57, the company withdrew its involvement from Hoodia development.[79] In 2004, Unilever, a Dutch-British transnational consumer goods company, signed a new agreement with PhytoPharm, beginning to conduct final drug trials on the compound and expected to sell it as a food additive in Unilever products.[80] Under the agreement, the two companies agreed that "*Unilever would buy exclusive rights to the product for an initial £6.5 million, rising to £21 million once it had achieved certain milestones. Phytopharm would also receive an undisclosed royalty on sales of all products containing the extract*".[81] However, in 2008, Unilever also decided to abandon the development of Hoodia because there are some safety problems.[82] In 2011, even PhytoPharm decided to pull out of the development of Hoodia-

[75] Rachel Wynberg et al, *Indigenous Peoples, Consent and Benefit Sharing* (London: Springer, 2009) : p.95

[76] Ibid.

[77] Rachel Wynberg et al, *Indigenous Peoples, Consent and Benefit Sharing* (London: Springer, 2009) : p.95

[78] *Ibid*. p.96

[79] Daniel Robinson, *Confronting Biopiracy : Challenges, Cases and International Debates* (London : EarthScan, 2010), p.62

[80] Laura A. Foster, "Situating Feminism, Patent Law and the Public Domain", *Columbia Journal of Gender and Law* 20.1 (2011): p.268

[81] Rachel Wynberg et al, *Indigenous Peoples, Consent and Benefit Sharing* (London: Springer, 2009) : p.96

[82] Daniel Robinson, *Confronting Biopiracy : Challenges, Cases and International Debates* (London : EarthScan, 2010), p.62

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based products.[83] Currently, Hoodia is sold in health shops and even over the internet in the world.[84]

4.2.3. BENEFIT SHARING AGREEMENTS WITH THE SAN PEOPLE

As discussed above, while many stakeholders such as CSIR and other pharmaceutical and consumer product companies were involved in patenting and developing Hoodia-related products, all of these research and development activities were conducted without the acknowledgement of the San peoples who have used Hoodia for centuries and are the original owner of the traditional knowledge related to Hoodia. In addition, no prior informed consent was obtained from the peoples and no benefit sharing agreements were negotiated in its initial period.

In 2001, a British newspaper reported the biopiracy of Hoodia by the CSIR and other companies. In response to such report, the Working Group of Indigenous Minorities in Southern Africa (WIMSA) and other NGOs such as Biowatch provided information to the San people and the public, helping the people to form a South African San Council. Due to the international attention and criticisms caused by the media and NGOs, the CSIR decided to enter into benefit sharing negotiations with the San people.

Thus, in 2002, a memorandum of understanding (MOU) between CSIR and the South African San Council was reached and after the conclusion of the MOU, efforts to establish benefit sharing agreements between the two sides ensued.

Despite some difficulties, a benefit sharing agreement was finally reached between the two sides, resulting in the milestone payments and the royalties - 8% and 6% of the payments made to CSIR respectively – for the San people.[85] Subsequently, the two sides set up the San Hoodia Benefit Sharing Trust which was registered in 2005 to raise standards of living and

[83] Lindsay Stafford "Phytopharm Returns Hoodia Gordonii Rights to South African R&D Company" accessed 14th of June 2017 http://cms.herbalgram.org/heg/volume8/03March/PhytopharmHoodiaTransfer.html?ts=1497455818&signature=1c318f048c5ee2f8b58f69f60bb6cbc1

[84] Eugene Lotter, "Hoodia study produces 'frightening' results" *Health 24*, 19 October 2015

[85] Saskia Vermeylen, "Law as Narrative: Legal Pluralism and Resisting Euro-American (Intellectual) Property Law through stories", Journal of Legal Pluralism 61 (2010) : p.61

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well-being for the San people.[86] The Trust was represented by the CSIR, San Council, WIMSA, and an observer from the South African Department of Science and Technology.

Even though after the conclusion of the benefit sharing agreement, the San Council and San Trust faced some implementation challenges such as how to distribute the benefits and how to identify the holders of the traditional knowledge, this case is one of few successful benefit sharing cases involving indigenous peoples.

4.3. LESSONS FROM HOODIA CASE

In this section, on the basis of the analysis of two cases above, this paper would like to suggest some lessons with regard to prior informed consent and benefit sharing from Hoodia case.

4.3.1. LESSONS REGARDING PRIOR INFORMED CONSENT: INVOLVEMENT OF NGOS IN COOPERATION WITH INDIGENOUS PEOPLE

At first, based on the analysis of the two cases, this paper would like to suggest a lesson from Hoodia case with regard to the right of indigenous people to *prior informed consent* in respect of medical interventions or scientific research.

As discussed above, in the case of Havasupai people, they permitted the research project on the condition that the research should be conducted only to look for a link between their genes and diabetes. When they granted their consent on the project to the researchers at ASU, the tribe entered into the negotiation with little help from others even though they were at a disadvantageous position mainly due to lack of the ability to understand the consent form and English.[87] Such unequal status led to the unauthorized exploitation of their genes without their acknowledgement and did harm to the tribe.

On the other hand, in the case of the San people, they entered into benefit sharing

[86] Ibid.

[87] As discussed above, most of the tribe members have not completed high school education and they don't have an ability to understand English. In addition, the contents of the consent forms were somewhat different between the tribal members and tribal leaders, which casts doubt on the transparency of the process of obtaining prior informed consent from the tribe.

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negotiation with the help of NGOs such as the WIMSA and BioWatch. With the help of the organizations, they could understand the agreements more easily and cope with the negotiation in a more coherent manner by organizing the San Council.[88]

Based on the comparison of these two cases, this paper would like to argue that Hoodia case gives a lesson that when indigenous people can access help from outside such as NGOs, it could enhance their bargaining power and thus, enable them to enter into a negotiation on an equal footing. This is particularly so, given that most of the indigenous people use their own languages and they are not well educated and do not have legal or financial sources for a fair and equitable benefit sharing agreement.

Therefore, when indigenous people are approached by other entities such as researchers for the utilization of their genes for medical interventions or scientific research, if the people enter into the negotiation with the help of others such as an NGO or government in the country where they are living, it will enhance their capacity and bargaining power, which could increase the chance of granting an appropriate prior informed consent.

4.3.2. LESSONS REGARDING BENEFIT SHARING: ESTABLISHMENT OF A BENEFIT SHARING MECHANISM SUCH AS TRUST OR FUND

Although there was no mention of benefit sharing in the case of Havasupai tribe, considering that plenty of researchers conduct genetic or medical research involving indigenous people to find medical or academic benefits, it is essential that there is a mechanism for fair and equitable benefit sharing between the users of genes and indigenous peoples. In fact, the reason why the Havasupai tribe decided to participate in the research was they wanted to know why the incidence of type-2 diabetes within the tribe is really high and if possible, obtain medicines or get some treatment.

In Hoodia case, the San Hoodia Benefit Sharing Trust was established to distribute benefits to the San people who have conserved and used Hoodia for millennia although they faced some implementation challenges.

Therefore, although benefit sharing was not an issue in Havasupai case, based on the

[88] As discussed above, the WIMSA and other NGOs provided the relevant information regarding the exploitation and development of Hoodia to the San people, helping the people form the San Council. In addition, the WIMSA contributed to the establishment of the San Hoodia Benefit Sharing Trust and its member was one of the representatives of the Trust.

experience of the San people, this paper argues that benefit sharing mechanisms such as Trust or Fund should be established so that the indigenous people can benefit from the relevant research or medical intervention based on their genes in which the people participate.

V. CONCLUSION

Almost all indigenous peoples have suffered violations of their rights in almost all aspects of their lives over a long period of time. In particular, the unauthorized exploitation of biological resources that they have conserved and used for their survival for millennia and their own genetic information in their bodies by other entities such as multinational corporations or researchers has adversely affected their lives and culture in various ways.

However, while in the case of biological resources, global legally binding agreements have been adopted and enforced to tackle biopiracy cases despite some problems, as regards their own genetic information, only soft law instruments on a global level have been adopted and no specific provisions dedicated to protect the rights of indigenous people have been provided. Therefore, this paper argues that the 'Global Biomedical Convention' should be adopted and that provisions for the protection of the rights of indigenous people to their genetic information should be contained. Of various rights, this paper focuses on the rights of indigenous people to 'prior informed consent' and 'benefit sharing' in respect of medical interventions or scientific research and suggests some key elements of the relevant provisions to protect their rights in the Convention based on the analysis of some international biodiversity laws as well as some existing international biomedical laws.

As a result of the analysis, although most of the specific elements were drawn from the existing biomedical soft law instruments, this paper found that international biodiversity laws especially Nagoya Protocol could provide some procedural elements to the provisions in the Convention. In addition, this paper also conducts an analysis of a biopiracy case and a case of piracy of indigenous people's genetic information, based on which this paper found that the Hoodia case can provide some practical lessons: one lesson with regard to prior informed consent and another one regarding benefit sharing. Although these lessons drawn from international biodiversity laws and a relevant case were procedural in their nature, they could contribute to the protection of the rights of indigenous people to their genetic information. At the same time, when their rights of indigenous people are better protected, trust between the researchers and indigenous people could be built, which ultimately could contribute to the advancement of genetic and medical science as well.

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BIBLIOGRAPHY

BOOKS AND ARTICLES

Alexandra Winters, "Trespass to culture: The Bioethics of Indigenous populations' Indigenous Populations' Informed consent in Mainstream Genetic Research Paradigms", *American Indian Law Review* 231 (2016)

Allyn L. Taylor, "Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health", *American Journal of Law and Medicine* 25 (1999)

Barry Lynch et al, "Genotoxicity of dried Hoodia parviflora aerial parts", *Food and Chemical Toxicology* 55 (2013)

Constance Macintosh, "Indigenous Self-Determination and Research on Human Genetic Material: A Consideration of the Relevance of Debates on Patents and Informed Consent, and the Political Demands on Researchers", *Health Law Journal* Vol. 13 (2005)

Council of Europe, *Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (1997)

Daniel Robinson, *Confronting Biopiracy : Challenges, Cases and International Debates* (London : EarthScan, 2010)

Debra Harry, "Indigenous peoples and Gene Disputes", *Chicago Kent Law Review* 84 (2010)

Elisa Morgera et al, *Legal Studies on Access and Benefit-sharing* (Leiden: Brill, 2014)

_____, Unraveling the Nagoya Protocol, (the Netherlands : Koninklijke Brill, 2014)

Eugene Lotter, "Hoodia study produces 'frightening' results" *Health 24*

Jason Grant Allen, "Group Consent and the Nature of Group Belonging: Genomics, Race and Indigenous Rights", *Journal of Law, Information and Science* 20 (2010)

Kim TallBear, "Narratives of Race and Indigeneity in the Genographic Project", *Journal of Law, Medicine and Ethics* 35 (2007)

Konstantia Koutouki et al, "The Nagoya Protocol : Sustainable Access and Benefit Sharing for Indigenous and local communities", *Vermont Journal of Environmental Law*, Vol.13 (2012)

Laura A. Foster, "Situating Feminism, Patent Law and the Public Domain", *Columbia Journal of Gender and Law* 20.1 (2011)

LorrieAnn Santos, "Genetic Research in Native Communities", *Prog Community Health Partnersh*. 2(4) (2008)

Marc Ernest Trigilio, "The Convention on Human Rights and Biomedicine: Allowing Medical Treatment and Research without Consent on persons unable to give informed consent", *Suffolk Transnational Law Review* 22(2) (1999)

Matthew Rimmer, "The Genographic Project: Traditional knowledge and Population Genetics", *Australian Indigenous Law Review* 11 (2007)

Michelle M. Mello, "The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples", *The New England Journal of Medicine* 363 (2010)

Noalle Lenoir, "Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level" *Columbia Human Rights Law Review* 30:537 (1999)

Peter Buzas, "The Convention on Human Rights and Biomedicine: European consensus or lowest common denominator?", *Law Review of Kyiv University of Law* 327 (2015)

Ricardo Pepeira and Orla Gough, "Permanent Sovereignty over natural resources in the 21st century :
Natural Resources Governance and the Right to Self-Determination of Indigenous Peoples under International Law", *Melbourne Journal of International Law* Vol.14 (2013)

Rachel Wynberg et al, *Indigenous Peoples, Consent and Benefit Sharing* (London: Springer, 2009)

Rashwet Shrinkha, "Free Prior Informed Consent as a Right of Indigenous peoples", *Journal of National Law University* Vol.2 (2014)

Roberto Andorno, *Principle of International biolaw: Seeking common ground at the intersection of bioethics and human rights* (Bruxelles: Bruylant, 2013)

Rebecca Tsosie and Joan L. McGregor, "Genome Justice: Genetics and Group Rights", *Journal of Law, Medicine and Ethics* 35 (2007)

Robyn L. Sterling, "Genetic Research among the Havasupai: A Cautionary Tale", *American Medical Association Journal of Ethics,* Volume 13, Number 2 (2011)

Saskia Vermeylen, "Law as Narrative: Legal Pluralism and Resisting Euro-American (Intellectual) Property Law through stories", Journal of Legal Pluralism 61

Shawn H.E. Harmon, "The Significance of UNESCO's Universal Declaration on the Human Genome and Human Rights", *SCRIPT-ed Open Licence* 20 (2005)

Stephen P. Marks, "Tying Prometheus Down: The International Law of Human Genetic Manipulation", *Chicago Journal of International Law* 3 (2002)

Tara Ward, "The Right to Free, Prior, and Informed Consent: Indigenous Peoples'

Participation Rights within
International Law", *Northwestern Journal of International Human Rights* 10(2) (2011)

Thomas Greiber et al, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing",
IUCN Environmental Policy and Law Paper No. 83 (2012)

T.L. Knight et al, "Cultivation practices and manufacturing processes to produce Hoodia gordonii extract for weight management products", *Food and Chemical Toxicology* 50 (2012)

Vera Lu´cia Raposo and Eduardo Osuna, "European Convention of Human Rights and Biomedicine" in *Legal and Forensic Medicine,* ed. R.G. Beran (Berlin: Springer-Verlag, 2013)

Violeta Begirevi, "Basic norms of Bioethics: Informed Consent in UNESCO Bioethics Declarations", *Annals - Belgrade Law Review* 3 (2008)

W.C. McClatchey et al, "Ethnobotany as a pharmacological research tool and recent developments in CNS-active natural products from ethnobotanical sources", *Pharmacology & Therapeutics* 123 (2009)

INTERNET WEBSITES

'Havasupai Tribe and the lawsuit settlement aftermath' American Indian and Alaska Native Genetics Resource Center, accessed September 8th 2017, http://genetics.ncai.org/case-study/havasupai-Tribe.cfm

Lindsay Stafford "Phytopharm Returns Hoodia Gordonii Rights to South African R&D Company" accessed 14th of June 2017 http://cms.herbalgram.org/heg/volume8/03March/PhytopharmHoodiaTransfer.html?ts=1497455818&signature=1c318f048c5ee2f8b58f69f60bb6cbc1

"Research without patient consent", Who owns your body?, accessed September 7th 2017, http://www.whoownsyourbody.org/havasupai.html