BEYOND FINDERS KEEPERS: BIOPROSPECTING, PATENTS, AND HUMAN GENETIC MATERIALS

by

CHINENYE HELEN EZE

L.L.B., The University of Nigeria, 2014

L.L.M., The University of Ibadan, 2019

A THESIS SUBMITTED IN PARTIAL FULFILMENT OF

THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF LAWS

in

The Faculty of Graduate and Postdoctoral Studies

THE UNIVERSITY OF BRITISH COLUMBIA

(Vancouver)

August 2022

The following individuals certify that they have read, and recommend to the Faculty of Graduate and Postdoctoral Studies for acceptance, the thesis entitled:

BEYOND FINDERS KEEPERS: BIOPROSPECTING, PATENTS AND HUMAN GENETIC MATERIALS

submitted by Chinenye Helen Eze in partial fulfilment of the requirements the degree of Master of Laws

In Law

Examining Committee:

Graham Reynolds, Associate Professor, Peter Allard School of Law
Supervisor

Joost Blom, Professor Emeritus, Peter Allard School of Law
Supervisory Committee Member

ABSTRACT

From time immemorial, developing countries have used biodiverse genetic resources as drugs, food, and treatments. In the 1980s, bioprospecting became the new "gold rush." Developed countries targeted developing countries rich in biodiverse resources and collected genetic resources in most cases without informed consent or benefit sharing agreements. The illegal collection and use of genetic materials (including human genetic materials) led to outcries of biopiracy from developing countries. This biopiracy continues today

Some international laws were passed to regulate bioprospecting. The Convention of Biological Diversity (CBD), which entered into force in 1993, was the first international law to regulate bioprospecting. The Bonn Guidelines were passed in 2002 to regulate the implementation of the CBD. In 2010 the Nagoya Protocol to the CBD was passed to protect the traditional knowledge of Indigenous peoples.

These regulations have two significant shortcomings. First, the current law does not address the bioprospecting of human genetic materials. Second, the law does not address misappropriation through patents. This work will address these issues.

Using doctrinal and comparative research methodologies, this work will reach the following findings. First, bioprospecting applies to human genetic materials through population studies of targeted developing and Indigenous communities. Second, there are no laws to regulate the bioprospecting of human genetic materials. Third, the current national and international laws do not address the challenge of patent misappropriation. Fourth, the main proposal debated by developing countries is the "disclosure of source of origin' requirement. Lastly, the enforcement of the disclosure requirement is unharmonized; there are disagreements on what to disclose, how to disclose, and how to infuse the disclosure requirement into patent laws.

Ultimately, this work proposes to address the problem of misappropriation of human genetic materials through patents by re-imagining aspects of the TRIPS Agreement. In building this argument, it will rely on both critical IP theory and theories of new constitutionalism.

Lay Summary

This work will analyze the regulation of human genetic materials collected through bioprospecting using both doctrinal and comparative research methodologies. It will examine how patent laws facilitate the misappropriation of human genetic materials as well as the proposed solution of a requirement to disclose the source of origin.

This work will use critical IP theory and the theory new constitutionalism as the lenses through which to examine these issues. It will conclude that the TRIPS Agreement is the preferred method for enforcing disclosure of the source of origin and propose a solution to the politics of a consensus on amending the TRIPS to include this requirement.

Preface

This thesis is the original, unpublished, independent work by the author, Chinenye Helen Eze.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CBD- CONVENTION ON BIOLOGICAL DIVERSITY

PCT- PATENT COOPERATION TREATY

PLT- PATENT LAW TREATY

SPLT – SUBSTANTIVE PATENT LAW TREATY

TRIPS- TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY LAWS

UK- UNITED KINGDOM

UN- UNITED NATIONS

US- UNITED STATES

WIPO- WORLD INTELLECTUAL PROPERTY ORGANIZATION

ACKNOWLEDGMENTS

I am immensely grateful to my supervisor Professor Graham Reynolds for all the kindness, support, brainstorming, and proofreading. Thank you for believing in me and this work and for all the encouragement; you were not just a supervisor; you became family to me.

I am grateful to the University of British Columbia and the Allard School of Law. I am particularly thankful to Professor Jocelyn Stacey, Associate Professor and Associate Dean of Graduate and Professional Programs, and Joanne Chung for what you did behind the scenes to support me throughout my Master of Law program.

To my course mates, for all the lovely chats and ideas shared. It was lovely to connect and learn from each other. Despite the pandemic, we were able to form a beautiful bond.

To my family, My Father (Afam Eze) has believed in and supported my love for research and academic pursuits. To my mother (Obioma Eze), who sadly is no longer with us, I know she is proud of every milestone I've accomplished. To my baby boy (Obichukwu Nzekwe), who was three weeks old when I just started this program and is now two years old. You are a motivating factor and would be so proud of all Mummy has achieved. To all my Siblings (Ijeoma, Chioma, Ogechi, Daniel, and Chukwubuikem Eze), I cannot express how grateful I am for the gift of you all.

DEDICATION

Now to him who can do immeasurably more than all we ask or imagine, according to his power at work within us, to him be glory in the church and Christ Jesus throughout all generations, forever and ever! Amen. Ephesian 3:20-21(NIV)

CHAPTER ONE

GENERAL INTRODUCTION

1.1 INTRODUCTION

During the bloom of bioprospecting, rich biodiverse resources were discovered in developing countries[1]. Viewing these resources as "the common heritage of man," not owned by anyone,[2] developed countries have accessed, collected, and patented genetic materials without consent and without sharing benefits with developing countries.[3]

The result of these actions was outcries of exploitation and limited access to genetic resources by developing countries. The Convention on Biological Diversity[4] was adopted in 1992 to regulate bioprospecting. The CBD mandates its signatories to allow bioprospecting, provided informed consent and benefit sharing are reached on mutually agreed terms[5]. The CBD had two limitations. First, it only addressed bioprospecting of non-human genetic material.[6]

In addition, it did not mention how states could implement its access and benefit-sharing agreements provisions, especially in cases of misappropriation through patents.[7]

---

[1] Walter V. Reid, "Bioprospecting: A force for sustainable development". (1993) 27:9. Environ. Sci. Technology at 1732.

[2] Ibid

[3] Ibid.

[4] Ibid.

[5] The Convention on biological diversity is a multilateral treaty that came into force on December 29, 1993. it currently has 196 signatories.

[6] Secretariat of the Convention on Biological Diversity.2002. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization. https://Cbd:int/doc/publications/cbd-bonn-gdls-en.pdf

[7] Ibid.

Misappropriation through patents occurs when non-human genetic materials are accessed, collected, and patented in the absence of informed consent and benefit sharing agreements with the source of these genetic materials[8]. In the case of human genetic materials, misappropriation occurs when genetic materials are accessed, collected, and patented outside the terms of consent given and the terms of the benefit sharing agreement[9]. The inventor, in such cases, does not have the consent of the donor to commercialize the human genetic materials collected through bioprospecting.

The Bonn Guidelines to the CBD were passed in 2002 to provide guidelines for implementing the provisions of the CBD[10]. The Nagoya Protocol was adopted in 2010 to protect the traditional knowledge of Indigenous peoples and provide further guidelines for the enforcement of the CBD's provisions[11]. The Bonn Guidelines and Nagoya Protocol do not address the misappropriation of human genetic materials through patents. They also do not regulate the bioprospecting of human genetic materials.

Some developing countries[12] attempted to address the challenge of misappropriation through patents by imposing a requirement for patent applicants to disclose in his patent application the source of origin of the genetic resources used in his invention. This requirement (hereinafter referred to as the disclosure requirement) also requires the patent applicant to disclose whether informed consent was sought and a benefit sharing agreement was reached.

The requirement to disclose the source of origin was made a requirement for patentability by some countries[13]. However, developing countries faced two significant challenges in enforcing the disclosure of origin requirement. First, there was a lack of harmonization on how and what to disclose.

---

[8] Kshitij Kumar Singh, "Implications of Genetic patents on Human genetic Resources: Issues of Ownership, Benefit Sharing and informed consent. In : Biotechnology and Intellectual Property Rights. Springer, New Delhi. Online: https://doi.org/10.1007/978-81-322-2059-6_6

[9] Ibid.

[10] Gurdial Singh Nijar. 2011. The Nagoya Protocol on Access and benefit sharing of genetic resources: Analysis and implementation options for developing countries. Center of excellence for biodiversity. https://southcentre.int

[11] Ibid.

[12] Some of which are; Brazil, Costa Rica , India, and Andean Communities countries.

[13] Switzerland, Vietnam, Germany, Denmark, France.

While some countries made disclosure mandatory[14] , others made disclosure voluntary[15]. Furthermore, some countries required only the disclosure of the source of origin[16]; others required the disclosure of the source of origin, prior informed consent, and benefit sharing agreement[17].

The second challenge in enforcing the disclosure requirement was the problem of infusing the requirement into the patent law of developed countries. While some developing countries had incorporated the disclosure requirement into their patent laws, most developed countries did not accept or contain the requirement to disclose in their patent laws.

Developing countries made three significant proposals to enforce the disclosure of the source of origin. First is the Trips Amendment proposal[18]. The second is the patent law treaty amendment[19] and the laws of the last use outside patent law.[20]There have been numerous debates on these three proposals, with most developing countries pushing for the amendment of the TRIPS. There has been no consensus on this proposal to date.[21]

In 2000, Nuno Carvalho[22] proposed a solution to the challenge of enforcing the disclosure requirement. Carvalho, like other authors[23], agreed that the TRIPS Amendment proposal is the preferred option for harmonizing and enforcing the disclosure requirement.

---

[14] Switzerland, Federal Act on Patents , Article 49a. Art 4 European Union Regulation 511/2014EC requires a certificate of Compliance and attached a fine of 150,000 Euros for failure to disclose.

[15]Germany Patent Act 1980, Section 34(9) makes the disclosure of source of origin Voluntary. Denmark's Patent and Trademark office 2013, chapter 23(5) – Voluntary Disclosure, European Union.

[16] An example is Article 49a of the Swiss Patent Act.

[17] The Andean Community, Bolivia, Ecuador, Colombia and Peru.

[18] Brazil and India

[19] Switzerland

[20] European Union

[21] Lan Gross, "International Legal instrument relating to intellectual property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources". (2022). Online: < https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_43/wipo_grtkf_ic_43_non_paper.pdf>

[22] "Disclosure of the origin of Genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: The problem and the solution". (2000) 2 Wash U J.L & POLY at 375.

[23] Glowka Lyle, "Towards a certification system for bioprospecting activities. Commissioned by the Swiss state secretariat for Economic Affairs (2001) 41-45. Online: https://www.cbd.int/doc/meetings/cop/cop-06/other/cop-06-ch-rpt-en.pdf

He, however, pointed out that the politics of decision-making within the WTO would not allow the amendment of the TRIPS in the nearest future.

He analyzed the significant opposition against the TRIPS amendment, which requires that disclosure be made mandatory for patentability. He proposed that instead of the sanction of refusal to patent where a patent application fails to disclose, the sanction should be a refusal to enforce the patent until the requirement to disclose is fulfilled. He also proposed using the "fraudulent acquisition theory" to prevent the enforcement of patents acquired without prior informed consent and benefit sharing.

Carvalho was the first author to attempt to re-imagine the approach to enforcing disclosure of origin requirement[24]. Carvalho's work has two identified weaknesses. First, it does not address the misappropriation of human genetic materials. Second, it does not address the politics affecting the proposals for disclosure.

This work will build on Carvalho's attempt to re-imagine the enforcement of the disclosure requirement through the TRIPS in two ways. First, it will propose re-imagining disclosure through an Amendment of the TRIPS proposal using the critical IP theory and the new constitutionalism theory. Secondly, it will propose that the disclosure of requirements be made mandatory for the patentability of patent inventions from human or non-human genetic resources.

Following the introduction of Carvalho's principle, several countries, especially developing countries, have added mandatory guidelines for disclosing genetic material origins to their patent laws[25]. Although this measure reduced the incidences of biopiracy in these countries, it did not address the issue of misappropriation through patents. Eventually, these countries recognized that national disclosure of origin was inadequate to

[24] "Disclosure of the origin of Genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: The problem and the solution". (2000) 2 Wash U J.L & POLY at 375.

[25] South Africa (Section 30 of the Patents Amendment Act, Act No. 20 of 2005), India (Article 10 (4)(d)(ii) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005. Norway (Section *(b) of the Patents Act No. 9 of December 15, 1967. (Consolidated version of 2016). Andean Community (Article 26 of Decision No. 486 establishing the common Industrial property Regime 2000), Vietnam (Article 23:11 of Circular No. 01/2007/TT-BKHCN of February 14, 2007, guiding the implementation of the government's Decree No. 103/2006/ ND_CP of September 22, 2006), Switzerland (Article 49(a) of the Federal Act of June 25, 1954, on Patents for invention)

address the challenges in regulating bioprospecting[26]. The first limitation is the transboundary nature of patent systems, where biological resources can be collected under one jurisdiction and patented under another[27]. The patenting of genetic materials may be illegal in the donor's country, but it cannot be enforced outside the donor's country. Second, a donor has no legal remedy for a patent granted in a country that does not implement the disclosure requirement[28]. Moreover, the Carvalho principle, like the CBD, did not address patenting human genetic material.

The Nagoya Protocol on Access to Genetic Materials and the Fair and Equitable Sharing of Benefits Arising from their Utilization is a supplementary protocol to the CBD adopted in 2010. The Nagoya Protocol made guidelines for access to genetic resources and traditional knowledge in genetic resources extending its coverage to human genetic materials. The Nagoya Protocol also provided benefit-sharing agreements and policies for member states to ensure compliance within their territories. However, the Nagoya Protocol did not address the issues arising in the transboundary patenting of inventions from human genetic materials. It did not address enforcing informed consent and benefit-sharing agreements across borders.

This work attempts to address the transboundary challenge in enforcing prior informed consent and benefit-sharing in patenting inventions from human biological materials. To achieve this, it will argue that disclosure requirements should be implemented as an amendment to the TRIPS Agreement.

The limitations in implementing the Carvalho principle at the national level led to debates and proposals by developing and other countries on strategies for implementing disclosure of origin through international patent laws.

---

[26] Selim Louafi, Brendan Tobin. *User Measures to resolve potential conflicts between the WTO and the CBD*. In Martha Chouchena Rojas, Manuel Ruiz Muller, David Vivas and Sebastian Winkler. *Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD*. (IUCN, Gland, Switzerland, and Cambridge: 2005).

[27] World Trade Organization. *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity*. IP/C/W/368/Rev.1. (2006) Online < https://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf>

[28] Ibid.

These proposals are summarized as the TRIPS amendment proposal proposed by a group of countries represented by Brazil and India[29], the PCT amendment proposal submitted by Switzerland[30],and the Disclosure outside Patent law proposal presented by the EU.[31]

The different opinions by countries on the implementation strategy have led to a lack of conclusion on an international standard for enforcing disclosure of origin[32]. Although this work will analyse the strengths and weaknesses of each proposal, it will focus on and argue for the TRIPS Amendment proposal.

The TRIPS amendment proposal recommends that member states mandate patent applicants to disclose the country of origin of the genetic materials and traditional knowledge used in inventions. It also proposes that the patent applicant provide evidence of prior informed consent and benefit-sharing before a patent can be granted. This work will argue that the amendment of the TRIPS is most suitable to ensure harmonization of patent laws on enforcement of prior informed consent and benefit-sharing.

The originality of this work is first its argument that bioprospecting applies to human and non-human genetic materials. Second, this work will propose re-imagining the regulation of bioprospecting under the TRIPS Agreement using the Critical IP theory and new constitutionalism theory. Third, this work will suggest that the TRIPS Agreement amendments should define biotechnological patents that include inventions from human and non-human genetic materials. Also, the requirements for patenting biotechnological inventions include a mandatory disclosure requirement.

---

[29] Other countries in this group include Bolivia, Columbia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and other African and Developing Countries.

[30] The PCT proposal was to amend the WIPO's Patent Co-operation Treaty to allow domestic laws to mandate disclosure during patent applications. Failure to meet these requirements could lead to refusal or if the patent is granted it can be invalidated if fraudulent intent is discovered.

[31] Disclosure outside Patent law was proposed by the European Union to mandate patent applicants to disclose the source or origin of genetic materials and the consequence or failure to meet this requirement should be outside patent law. It could be criminal or civil action.

[32] Jacques de Werra, "Fighting against Biopiracy: Does the Obligation to disclose in Patent applications truly help?"Vanderbilt Journal of Transnational Law, (2009) 42:1. 143-179. Online < http://archive-ouverte.unige.ch/unige:1480>.

It will argue that previous debates and literature have focused on prior informed consent and benefit-sharing to avoid biopiracy and ensure benefit-sharing from profits. In the case of non-genetic materials, consent is given with consideration for commercialization.

In the case of human genetic materials, human genetic materials are donated chiefly for research purposes.[33] The challenge in collecting human genetic materials is not just obtaining prior informed consent but ensuring compliance with the specific terms for which consent was given. The issue in patenting human genetic material is not whether informed consent was granted, or a benefit-sharing agreement reached but the terms on which it was provided, and the agreement contacted.

The argument for international laws to mandate these ethical requirements is to ensure that before a patent is granted, there was prior informed consent to commercialize such human genetic resources. It also protects citizens of developing countries from exploitation through "future use" of their genetic resources in a manner not covered by the initial agreement.

This work is divided into six Chapters. Chapter one will lay the foundation of our arguments. It will analyze the existing literature and the gaps. This work will examine the subject of patenting human biological materials and how to enforce the ethical requirements of prior informed consent and benefit-sharing by amending TRIPS. It lays the foundation for adopting Critical IP and new constitutionalism as our theoretical Framework. Lastly, this chapter defends our choice of doctrinal and comparative research methodology for this work.

Chapter two will introduce bioprospecting. It will examine the history of bioprospecting, both with respect to genetic and non-genetic materials. It will analyze the challenges of bioprospecting and the problem of misappropriation through patents.

[33] Carlo Petrini, Ethical and Legal considerations regarding the ownership and commercial use of human biological materials and their derivatives. J Blood Med. 2012; 9:193. Online: < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3440234/pdf/jbm-3-087.pdf>

Finally, this chapter will examine the importance of bioprospecting and why regulating the bioprospecting and the problem of misuse of patents is essential—the challenges in obtaining and enforcing prior informed consent and issues of benefit sharing. Chapter three will examine the international framework created to curb biopiracy in bioprospecting and the shortcomings in these laws. Chapter Four will review the proposals by national laws to regulate biopiracy, the critique of these laws, and the need to reimagine the regulation of bioprospecting. Chapter Five will analyze the possibility of re-imagining the bioprospecting regulation through the TRIPS Agreement amendment. It will adopt the Critical IP theoretical framework in recognizing, deconstructing, and re-imagining using the new constitutionalism theory. Lastly, Chapter Six will point out the findings and recommendations of this work.

1.2 RESEARCH QUESTIONS

1. Does bioprospecting apply to human genetic materials?

2. Should prior informed consent and benefit sharing be made patentability requirements?

3. What are the ways in which patent laws could be revised to include these requirements?

4. Which method is most effective for enforcing these requirements?

1.3 RESEARCH OBJECTIVES

1. To analyze how patent laws regulate biotechnological innovations involving human genetic materials.

2. To analyze how patent laws can be effectively modified to ensure prior informed consent and benefit-sharing are enforced.

3. To analyze the possibility of harmonizing patent laws by modifying the TRIPS provisions.

1.4 THEORETICAL FRAMEWORK

1.4.1 CRITICAL IP THEORY

This work will adopt the theoretical framework of Critical IP theory. It will argue that the patent system aims to create a balance between protecting the rights of the inventor to benefit from his invention and the social benefit of an invention[34]

Critical IP theory posits that the interests of those in power are represented in the economic, social, political, and legal systems. A central tenet of Critical IP theory is that the law should establish meaningful and transformative social progress toward equality. Critical IP theory argues for a methodology to address the legal system in which the law operates and not just the letter of the law.

The Critical theorists believe that the law plays a role in creating social inequalities by allocating and controlling the flow of power. Secondly, the law is indeterminate and can be manipulated by people in power to achieve their aims. Also, the law is political and can be used to create social inequalities and class structures.

Critical IP theorists balance these arguments about the law and social inequality by highlighting that the law can also be used to limit and transform the interests of powerful parties. They posit that the approach to achieve this balance is by adopting the law as a way of doing politics. This approach will help to reshape and restrain the power wielded by the powerful.

Critical theory can be used to resist the exploitation of legal structures and institutions reinforced by intellectual property laws in the field of intellectual property.

---

[34] Margret Chon. *Intellectual Property research and critical theories.* in Irene calboli and Lila Montagnani eds. *Handbook on Intellectual property research.* (Seattle: Edward Elgar Press, Forthcoming. 2018) Online <https://ssrn.com/abstract=3219966>

The pertinent question is, can critical IP theory play a role in reducing inequalities and social injustice in the area of Intellectual property? Indeed, we agree with Carys J. Craig[35] that it can. Her argument is supported by examining the achievements of critical feminist and critical race theories in the intellectual property field. Critical feminist theory and critical race theory have shown that it is possible to challenge the status quo of the law, identify its contradictions, and formulate arguments that raise awareness of its shortcomings. Also, its tools can be used to create more discussions about the need for change.

This work will adopt the Critical Social Justice approach. The critical social justice theorists aim to "infuse IP with a progressive social consciousness." It uses the law to empower historically marginalized communities and countries to recover losses suffered because of social, economic, and legal bias. This empowerment role the law plays in social justice is balanced with the need to maximize the economic output of the IP system.

According to Lateef Mtima[36], the courts have the responsibility to balance the economic interests of intellectual property with its role in the societal good. For social justice to be achieved in Intellectual Property, it is necessary to balance the interests of all stakeholders, creators, distributors, and users. Intellectual property commodification became predominant in the 20th century. The effect of this focus on commoditization is that the economic rewards of an IP project or field became the primary consideration in the IP legal system.

Critical Social Justice theorists argue that the principal goal of IP is not just economic rewards but to promote arts and science. An emphasis on the financial rewards in intellectual property that allows a measure of injustice or perpetuates inequality will not aid the promotion of the arts and science. One of the social justice goals is to balance the economic and commercial rewards of IP.

The IP system must be restructured to provide fair and inclusive participation of all concerned parties to achieve social justice. Equitable inclusion of concerned parties should be upheld irrespective of class, race, wealth,

---

[35] *Critical Copyright law and the Politics of IP. Research Handbook on Critical Legal Theory,* edited by Emilios Christodoulidis, Ruth Dukes, & Marco Goldoni, (Seattle: Forthcoming 2019, Edward Elgar Publishing 2019) Online: <https://digitalcommons.osgoode.yorku.ca/cgi/viewcontent.cgi?article=3715&context=scholarly_works>

[36] "IP social justice theory; Access, inclusion , and Empowerment". (2020) Gonzaga Law Review 55:3, 401-420.

gender, ethnicity, or group, among others. IP social justice theory mandates assessing the interest of all parties, including the producers, donors, distributors, users, and other concerned parties. This assessment should consider not just economic interests but the cultural, technological, social values, and other factors that contribute to the actualization of self-actualization.

In this work, we argue that for change to occur, the prevailing patent systems must be reviewed to reduce the inequalities affecting developing countries. This work will examine the assumption that patent law contains the tools necessary for structural transformation. We agree with the view of Craig that IP law, particularly patent law, is primarily controlled by the politics of wealthy and developed countries. This work will advance the argument for social justice; in this work, we will adopt the roadmap laid out by Margaret Chon[37]; recognizing, deconstructing, and reconstructing or re-imaging.

With respect to the category of "recognizing", this work examines the politics of economic rewards that have governed court decisions on patenting human genetic materials. It will analyze the social inequalities perpetuated in bioprospecting and how patent laws favor developed countries over developing countries. It will examine the injustice suffered by donors in developing countries with no legal recourse where their genetic materials have been commercialized, first because of the "no-property rule in human genetic materials," and second because of the patent system and its strict adherence to the patentability requirements.

With respect to the category of "deconstructing", this work will examine the political debates at international conventions and meetings on infusing "source of Origin" into patent systems. It will explore proposals by the United States insisting that States include the source of Origin in their domestic laws only or bilateral agreements. It will also analyze the arguments against the modification of TRIPS agreements and the attitude of the WIPO and international organizations towards these ongoing debates. Lastly, this work will examine

---

[37] *Intellectual Property research and critical theories.* In "Handbook on Intellectual property research" Irene calboli and Lila Montagnani eds. (Seattle:Edward Elgar Press, Forthcoming. 2018) Online <https://ssrn.com/abstract=3219966>

how patentability requirements apply to human biological inventions and human genetic materials. This work will also investigate the attitude of developed countries like the United States to the requirements for the patentability of human biological materials and how this perpetuates social injustice.

Lastly, this work will reconstruct and re-imagine. It will make a case for the modification of TRIPS to include the ethical requirements of prior informed consent and benefit-sharing as patentability requirements. These requirements will apply to inventions including those with human biological material origin. Also, the need for prior informed consent will not be limited to consent for access and collection but consent for future uses not contemplated in the agreement, particularly patents. In re-imagining the regulation of bioprospecting, this work will adopt the new constitutional theory in its arguments.

1.4.2 NEW CONSTITUTIONALISM THEORY

As stated above, this work will also attempt to re-imagine and reconstruct the regulation of bioprospecting using the new constitutionalism theory. The constitutionalism of IP begins with the progressive integration of IP with fundamental rights[38]. Fundamental rights in IP re-enforce trade-related market-friendly human rights. The constitutionalism of IP aims to identify, address and categorize the problem arising from trans-border nation-state issues.

International Intellectual property has expanded beyond its formal hedges. At first, IP was governed by a classical convention regime.[39] Examples of these classical conventions include the Berne Convention for the protection of Literary and Artistic works 1887 and The Paris Convention for the protection of Industrial property 1967. In 1994, the Agreement on the Trade-related Aspects of intellectual property rights (TRIPS

[38] The Transformation of Global Intellectual Property Protection. In Global Intellectual Property Protection and New Constitutionalism. (United Kingdom: Oxford University Press, 2021)

[39] The Paris Convention protecting industrial property and the Berne Convention protecting Copyright.

Agreement) marked a new type of intellectual property regime. Intellectual property is now governed globally by old and new treaties, bilateral Trade Treaties, and development and cooperation treaties, amongst others.

According to Tuomas Mylly and Jonathan Griffiths[40], other norms such as Human rights, international investment law[41] now apply to IP rights and seem to grant complimentary protection. These norms include international investment laws, property ownership security, private IP regulation, and IP-specific counter-norms. Examples of IP explicit counter norms are the convention on biological Diversity, Food and Agricultural Organization (FAO), World Health Organization (WHO), and Human rights instruments under the United Nations (UN) or the Council of Europe.

The counter norms help to strengthen patent laws with new measures, and counter norms also help the interpretation of existing international patent treaties on the issues in dispute. Counter-norms represent different sectors outside the patent law system. These provide overlapping protection for IP. The problems in IP are not strictly traditional but cut across various aspects of the law. IP law is no longer strictly restricted to copyright, Patent, trademarks, and other IP laws.

These new subdivisions politicize IP in a new way. These broad aspects of IP create contemporary constitutional discourses, and constitutional discourses based on nation-state or regional laws do not cover the broadening transformation of IP.

In this work, new constitutionalism will be used to re-imagine bio-prospecting regulation. Specifically, this thesis will argue for the use of IP counter norms in interpreting the debate of developed countries against the disclosure of origin argument. It will specifically use Articles 7 and 8 of the TRIPS agreement to argue for the

[40] Tuomas Mylly and Jonathan Griffiths. *The Transformation of Global Intellectual Property Protection. In Global Intellectual Property Protection and New Constitutionalism*. (United Kingdom: Oxford University Press, 2021)

[41] Ibid.

amendment of the TRIPS to include the requirement to disclose as criteria for patenting biotechnological patents.

1.5 RESEARCH METHODOLOGY

This work will adopt both doctrinal and comparative methodologies.

1.5.1 DOCTRINAL APPROACH[42]

The doctrinal approach can best be described as traditional[43]. It has a positivist jurisprudence outlook and involves sifting through case law, legislation, and existing literature to find the available and missing variables in the proposed research[44].

This work will adopt the doctrinal research method to help answer how the patent law system can enforce the requirements of prior informed consent and benefit-sharing. This work will also review existing literature on the harmonization of patent laws to make a case for or against the harmonization of patent laws by modifying the TRIPS. My approach in this proposed thesis is to deal with the micro and macro questions that arise from my research objectives.

One of the objectives of this work is to analyze the requirements of prior informed consent and benefit-sharing in the collection of human biological materials. This work will argue that the informed consent necessary for a patent to be granted is not just the consent to collect samples. While most literature reflects the need for prior informed consent before collecting sample materials, it neglects to focus on the need to obtain informed consent to obtain a patent when inventions are created.

---

[42]Terry Hutchinson, *Doctrinal Research: researching the jury* in "Research Methods in law" Dawn Watkins and Mandy Burton ed. (2018, London; Routledge).

[43] Ibid.

[44] Ibid.

Also, this work will examine the issue of benefit sharing and how obtaining patents without evidence of benefit-sharing will affect the donor. It will also analyze the possibility of enforcement of shares in royalties or profit from a patent based on evidence of benefit-sharing filed during a patent application. This means that benefit-sharing should extend beyond the agreement for which consent was given to collect. Where a patent application shows a human material base, there must be evidence of the benefit the donor will accrue from the patent for it to be valid.

Secondly, this work will adopt the doctrinal method to analyze the possibility of harmonizing patent laws under TRIPS. The analysis aims to modify TRIPS to mandate proof of prior informed consent and benefit-sharing agreement as requirements for biotechnological patents. This work will evaluate the current position of the law and the possibility of reform.

To achieve this, the provisions of the TRIPS will be analyzed. In particular, this work will focus on Article 29 of TRIPS, which specifies the criteria for a patent application to be granted,

This modification of TRIPS will create the international law framework for infusing bioethics into patent law systems. The structure and provisions of TRIPS harmonize an aspect of Patent inventions: the pharmaceutical industry, and it also supports the argument that harmonization of the disclosure requirement is possible. TRIPS also makes provision for developing and least developing countries, an aspect which this work considers essential in regulating the collection and patenting of human biological materials.

The provisions of the Convention on Biological Diversity, The Nagoya Protocol, and the patent laws of two select jurisdictions, the United States and Brazil, will also be analyzed.

1.5.2 COMPARATIVE APPROACH[45]

In additional to the doctrinal method, this work will also adopt comparative research methodology. In adopting a comparative methodology, this work intends to answer two questions, "what is being compared and why?"[46]

The functionalist approach will be adopted in comparing two countries: the United States of America (US) and Brazil. Konrad Zweigert first postulated the functionalist approach in 1971[47]. The functionalist approach examines events, not just the rules.[48]

It focuses on case law and compares legal systems based on the response of their courts to similar situations. Furthermore, the functionalist approach can be used to compare institutions (legal or non-legal) that play similar roles in a legal system. Finally, the functionalist approach can be used to evaluate several laws to show which would better achieve a function.

One of the justifications for using comparisons is their power to extract hypotheses and reject invalid conclusions. The United States Patent and Technology Office has been recorded to issue over 3000 new DNA-related patents annually in a study by the National Academy of Sciences[49]. This puts the US at the forefront of biotechnological research and patenting human biological materials[50]. Conversely, Brazil is a developing nation whose laws expressly prohibit the patenting of innovations from human genetic materials[51].

---

[45]Geoffrey Samuel: Comparative law and methodology, Dawn Watkins and Mandy Burton ed. (2018, London; Routledge).

[46] Matthew Y. H. Wong Methods in comparative Politics, in M. Y. H, comparative Hong Kong Politics (Palgrave Macmillan, 2017).

[47] Konrad Zweigert, and Hein Kötz, An Introduction to Comparative Law. Translated by Tony Weir.(Amsterdam, New York, Oxford: North-Holland Publishing Co., 1977), International Journal of Law Libraries, 7(3), 290-295. doi:10.1017/S0340045X00000356

[48] Ibid.

[49] National Academy of science. *Reaping the Benefits of Genomic and Proteomic Research:* Intellectual Property Rights, Innovation, and Public Health(Washington; National Academies Press, 2005).

[50] Timothy Caulfield, Robert M. Cook- Deegan, F Scott Kieff and John P Walsh. *Evidence and anecdotes: An analysis of human gene patenting controversies*. (2006). 24. 1091-1094. Nature biotechnology.

[51] Articles 10 IX and Article 18, III of the Brazilian Intellectual property Act.

Brazil allows prospecting and collecting of human and non-human samples for research purposes only. In comparing the US and Brazil, this work aims to highlight two major controversial issues in patenting human biological materials[52]:

1. That developed countries like the US have dominated the patenting of human biological materials.

2. That developing countries like Brazil are trying to protect and control the use of their biological materials through national patent laws, the protection of which seems limited.

The comparison of the US and Brazil also aims to show the differences in the approach of their patent offices to patenting human biological materials. It is also useful in evaluating the possibility of harmonizing different patent systems.[53]

This work will adopt the functionalist approach to examine whether harmonization is possible under the framework of the TRIPS. The TRIPS allows member states to make policies and laws on gene patenting.

This work will argue that different countries have national laws to protect genetic materials collected from their land. However, these laws are binding only within their jurisdiction or in jurisdictions with bilateral agreements.

Some of these laws specify that evidence of obtaining prior informed consent and benefit-sharing agreement must be provided before a patent should be granted. While these laws may be binding within the jurisdiction of the donor country or state, they may not be enforceable in another country or state.

This is the challenge for developing countries like Brazil, whose patent law system expressly prohibits patenting of human biological materials.[54] Brazilian patent law defines patents as a form of property[55] and, based on the principles of human dignity, does not allow human genetic materials to be patented as property.

This prohibition also applies to biological materials even where it has been isolated from the person.

---

[52] Safrin S. "Hyper-ownership in a time of biotechnological promise: The international conflict to control the building blocks of life". (October 2004) 98:4 .A JILaw 641 – 685. Online < https://doi.org/10.2307/3216691>

[53] Ibid

[54] Articles 10 IX and Article 18, III of the Brazilian Intellectual property Act.

[55] Articles 11 to 21 Civil Brazilian codes.

Brazil only allows the donation of human body parts based on the principles of altruism and solidarity in support of scientific research[56]. This means that materials donated to biobanks should not be shared with third parties or used for analysis with the intent to patent without the prior consent of the Donor[57]. However, one challenge remains - Brazil can enforce its laws on patenting human biological materials outside its jurisdiction? Can Brazil bring an action for the patent to be revoked based on its national laws, where a patent has been granted in another country?

Another argument this comparative analysis will make for harmonization is based on the criteria for patentability. The TRIPS agreement does not define patentability criteria: invention, novelty, and others. Article 27.1 of TRIPS provides that:

> "Patents shall be available for any inventions, whether products or processes, in all fields of technology provided that they are new, involve an inventive step, and are capable of industrial application."

Developing countries like Brazil reject patents on human biological materials on the ground that it does not meet the patentability criteria of novelty and a non-obvious inventive step. The Brazilian Patent office considers inventions from human genetic materials as a mere discovery.[58] In contrast, the USPTO considers the degree of human effort and creativity needed to develop an invention or a discovery.[59]This broad definition allows the US to obtain patents for many biological patents.

---

[56] Fernandes, Márcia Santana et al. "Brazilian legal and bioethical approach about donation for research and patents of human body parts." Journal of community genetics vol. 8,3 (2017): 199-208. doi:10.1007/s12687-017-0303-y

[57] Ibid.

[58] Marcia S. F, Lucia S. Jose R. Goldim, Judith M. C. "Brazilian Legal and bioethical approach about donation for research and patents of Human Body parts".(2017) 8 J. Community Genet. At 199-208.

[59] Ibid.

Comparative law goes beyond a mere description of the countries compared to possibly recommending policies based on the strengths and weaknesses discovered.[60] To achieve this, the US and Brazil will be compared in this work to show the different contexts that make harmonization a necessity. The United States, from the plethora of landmark cases, *Diamond v. Chakrabarty*[61], the *Hagahai* case[62], and the *Guayami* people's case,[63] has made giant strides in biotechnological research and is actively involved in bioprospecting. The US, however, has no moral or ethical review provision in its patent law system.

After the public outcry in the *Hagahai* case, the international community recognized the need for a system of ethically reviewing patent applications. The ethical review aims to ensure that the fundamental ethical principles of prior informed consent and Benefit-sharing are adopted.

This work will garner the available data from the UBC Library, Hein Online, and Lexis-Nexis, among other sources. My focus will be on external law and not just the words but their meaning in the context of a statute or a case. After collecting this data, a comparison of the concepts in the select legal systems will be done to examine their similarities and differences.

1.6 LITERATURE REVIEW

A significant body of literature exists regarding the bioprospecting of non-human genetic materials. Several authors have argued the need to regulate patenting of non-human genetic materials. This section will examine the challenges of bioprospecting from developing to developed countries.

[60] Ibid.
[61](1980) 447 U.S 303
[62] Supra at note 1.

[63] Marina L. Whelan, *What if any are the Ethical obligations of the U.S patent office? A close look at the biological sampling of indigenous groups. (*2006) 5:1 DTLR.

The first challenge is a lack of informed consent and Benefit sharing agreement. The second challenge is that the laws governing bioprospecting does not extend to human genetic materials.This literature examined will also analyze the importance of regulating the bioprospecting of human genetic materials, the challenge of regulating human genetic materials and the suggestions by Authors on how to regulate the patenting of human genetic materials addressed.

Thomas A. Kursar et al.[64] states that a large portion of the world's diversity can be found in developing countries. The challenge, as they frame it, has been how to harness the economic value of biodiversity without exploiting the source of origin.

Kursar et al. identify the challenge of biodiversity as the lack of definition of what constitutes informed consent and specifications on benefit-sharing arrangements. The authors conclude that to derive the benefits of biodiversity, developing nations must strike a balance between facilitating bioprospecting and protecting their right to own genetic materials.

Tony Howard[65] his work points out that the increase in biotechnological inventions and patents has changed the issues debated on intellectual property between developing and developed countries.

Safrin Sabrina[66] her work discussed one of the problems that commodification and commercial of human genetic materials had caused. Before the controversies that arose from patenting inventions from human biological materials, these materials were seen as the common heritage of man. No-one had exclusive ownership of these materials, and countries shared their genetic materials freely. The introduction of commodification and commercial led to more stringent laws, especially by developing countries, to restrict the exploitation of their human genetic materials.

---

[64] Thomas A. Kursar, Catherina C. Caballero-George, Todd L. Capson, Luis Cubillia-Rios, William H. Gerwick, Mahabir P. Gupta, Alicia Ibanez, Roger G. Linington, Kerry L. McPhail, Eduardo Ortega-Barria, Luz I. Romero, Pablo N. Solis, and Phyllis D. Coley. 2006. "Securing Economic benefits and Promoting conservation through Bioprospecting". (2006) 56:12. Bioscience at 1005.

[65]"The Legal Framework surrounding patents for living materials in Joanna Gibson, Patenting Lives". (Routledge, New York, 2016)

[66] *Hyper-ownership in a time of biotechnological promise: The international conflict to control the building blocks of life. (*October 2004) American Journal of International Law, 98:4 at 641 – 685. Online <https://doi.org/10.2307/3216691>

Constance Macintosh[67] her work explains the reasons why. First, genetic data is lucrative, and the profit made from human biological materials has made population studies a lucrative area of research. In 1996 United States genomics companies made an estimated 427.6 million dollars from patents on human genetic materials. According to Macintosh, this figure has increased over the decade. These population studies focus on remote, indigenous communities and developing countries believed to have unique genes.

Macintosh states that one of the challenges with population studies is the possibility of a change of intent during the research. Most population studies involving Indigenous people start with a non-commercial purpose, which is communicated to the Indigenous group when informed consent is sought. Consent, if granted, will be based on the intent and details of the study communicated to the group or people.

Where the study's intent changes from research to commercial, these researchers do not inform the donor communities or country or enter a benefit-sharing agreement for the patent. According to Macintosh, this is a significant reason for distrust among Indigenous groups and the controversies surrounding numerous population studies.

These issues were discussed by Michalopoulos Constantine[68], who pointed out that developed countries may view bioprospecting as legally within the ambit of the TRIPS and carried out for the welfare of the people. Indigenous communities and developing countries have different views.

In instances where the genetic materials obtained are patented in the developed country, access becomes difficult for the Indigenous community or the developing country it was derived from primarily because of the high price placed due to difficulties in obtaining a license.

The question remains how patent law can protect these developing countries and Indigenous communities.

---

[67] *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*. (2005) Health Law Journal. 13 at 213-251.

[68] "Special and differential treatment of developing countries in TRIPS", TRIPS issues Paper, Quaker United Nations Office: Geneva. 2003 2 (online) < https://www.quno.org/sites/default/files/resources/Special-Differential-Treatment-in-TRIPS-English_0.pdf>

Gary E Marchant[69] points out that there is no consensus on the ethical issues to guide the patenting of human genetic materials. He identifies three areas of contention in patenting human biological materials: whether genes should be patentable, how they should be collected regarding prior informed consent and benefit-sharing agreements, and whether patents are used to restrict access to medical and biotechnological innovations.

He argues on the issue of the patentability of genes that most arguments against patentability are based on morality and religious beliefs. He concludes that the TRIPS agreement forbids the blanket prohibition on biotechnological inventions. While countries can regulate the patenting of human biological materials, they cannot outrightly prohibit it.

On the issue of how samples are obtained, he points out that the scientific norm in human genetic research is that donors do not retain any property rights in their donated genetic samples. He states that they have no right to compensation and claims in any patented inventions that may arise. He acknowledges that collecting and patenting non-human genetic materials requires no consensus on how they should be regulated. The principal contention in non-human genetic materials is biopiracy by developed countries on the non-human genetic materials of the developing countries. Two issues at the forefront of ethical debates to regulate the patenting of non-human genetic materials are prior informed consent and benefit-sharing. He analyses the applicability of these moral requirements to patenting human genetic materials.

He analyses the cases of the Guyana tribe and the Canavan's patent. He concludes that numerous international medical laws and policies have settled the issue of prior informed consent as guidelines for collecting human genetic materials. Also, he analyses the problem of benefit-sharing. He concludes that despite the provisions of Article 19 of the international declaration on human genetic data and Article 15 of the Convention on Biological Diversity that mandates benefit-sharing, it remains controversial.

---

[69]Marchant G E, *Genomics, Ethics, and Intellectual Property*. In "Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices" A Krattiger, RT Mahoney, L Nelsen, et al ed. (MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A., 2007) Available online at <www.ipHandbook.org>.

He identifies one of the challenges of benefit sharing in research on human genetic material as deciding who to compensate, the country as a whole or the individual donor? He concludes that unless a consensus is reached on the issues of prior informed consent and benefit-sharing, each matter would be decided on a case-to-case basis.

While the views of Gary Merchant are laudable, he does not address the challenge of implementing the requirements of informed consent and benefit sharing agreements.. In contrast, several medical and ethical laws and policies have been made to guide the collection of human genetic materials. These policies do not address the issue of enforcement within patent laws. This issue of how these ethical requirements can be infused and enforced in patent law has been discussed by some other authors.

In 2000, Nuno Pires de Carvalho[70] established what has become referred to as the Carvalho principle. Carvalho proposed that patent laws be amended to include disclosure of origin in their patent applications. The Carvalho principle also requires evidence of prior informed consent and benefit-sharing to be included in the application. He also states in his work that for this requirement to be enforceable, it must be included in the patent laws of each state.

Although some countries have adopted the Carvalho requirement, there is some limitation to the application of his proposal. First, Carvalho argues that introducing the need for disclosure into the TRIPS agreement as a requirement for patentability will conflict with the provisions of the Convention of Biological Diversity. Instead, he suggests that disclosure of source and prior informed consent be introduced as a condition for enforcing patent rights and not granting a patent.

Secondly, he argues that the requirement should apply only to the biotechnology field and natural genetic resources. Carvalho, in his work, refutes the possibility of modifying the TRIPS stating that developing countries have made efforts to introduce and enforce revealing source of origin as a requirement for patentability.

[70]"Disclosure of the origin of Genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: The problem and the solution". (2000) 2 Wash U J.L & POLY at 375.

These efforts at the time of writing his paper had not been successful. He points out a primary reason for the failure to amend as the argument of developed countries like the US that the country-by-country approach was preferable.

He, therefore, proposes that disclosure source of origin, which will entail evidence of informed consent and benefit-sharing, should not be introduced as a requirement for patentability. Instead, there should be a law to stop the enforcement of a patent that does not reveal the source of origin.

The questions that arise from Carvalho's proposal are: how can the enforcement of a patent be stopped? Who determines whether a patent is enforceable after it has been granted? It also does not address the complexities of benefit sharing, including whether a donor is entitled to any benefit of discoveries for which there was no benefit agreement? Should the donor individual or country be compensated in some way?

Selim Louafi et al.[71] point out that by 2010, 50 countries had adopted legislative and administrative policies and methods to establish the parameters of such private transactions. These measures align with the CBD and the Bonn Guidelines on Access and Benefit-Sharing adopted in 2002. However, the CBD and other legal mechanisms to regulate introspection have proven insufficient.

Louafi et al. also argue that there is no conflict between the TRIPS and the CBD, and it can be analyzed or defined as interdependent rather than conflicting. Developing and implementing an effective governance system will require not just a modification of laws and policies but an analysis of the network of actors and institutions on which its implementation will depend.

Louafi et al. suggest user measures, particularly certificate of origin, to govern the access and use of genetic materials. They say this can be used to monitor trade and the use of genetic resources, and it could provide evidence of the right to transfer and use resources. They point out that for user measures to work, they must be integrated into the already existing system of the requirement for disclosure of information in the Patent system.

---

[71] Selim Louafi, Brendan Tobin. *User measures to resolve potential conflicts between the WTO and the CBD.* In Disclosure requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD. Martha Chouchena Rojas, Manuel Ruiz Muller, David vivas and Sebastian Winkler eds. (IUCN, Gland, Switzerland; 2005)

Jacques De Werra[72] summarizes the proposals debated by countries internationally to ensure compliance with disclosure of origin, namely the TRIPS disclosure proposal, the PCT disclosure proposal, and the mandatory disclosure proposal.

De Werra points out that the TRIPS disclosure proposal is a preferable option but notes that developed countries have rejected the suggestion. However, his arguments in this work focus on benefit-sharing concerning cultural property, and his proposal does not explicitly apply to genetic materials.

Audrey R. Chapman[73] proposes a solution that seems like the proposal by the European Union to use systems outside patent law to enforce disclosure. She argues that an analysis of international human rights laws such as the universal declaration of human rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) shows an obligation on member states to approach intellectual property laws from the human rights perspective.

One of her significant propositions is that ethical and human rights should be explicitly included in intellectual property laws as part of the criteria for evaluating patent applications.

She suggests that an independent body should be created to handle these evaluations. This body should have the jurisdiction to invalidate an application if it infringes on human rights provisions or is inconsistent with ethical provisions. She also suggested infusing human rights and ethics into intellectual property laws based on the level of development of the society as well as its cultural orientations.

While Chapman's proposed framework is laudable, her work does not offer a framework for how bioethics can be incorporated into the patent law systems of countries that are not member states under these laws.

---

[72] 2009. *Fighting Against Biopiracy: Does the obligation to disclose in Patent applications truly help?* Vanderbilt Journal of Transnational Law. (2009) 42:1 at 143-179.Online: < http://archive-ouverte.unige.ch/unige:1480>.

[73] Chapman, Audrey R. *Human Rights perspective on intellectual property, scientific progress and access to the benefits of science.* Intellectual Property and Human Rights, (2007) WIPO Publication 763 (E) .

As noted above, the available literature does not address the challenge of enforcing the requirements for informed consent and benefit sharing in the patenting human genetic materials. While most literature recognizes the need for prior informed consent and benefit-sharing to be included in patent laws applications, others recognize the challenges developing countries and Indigenous people face because of biotechnological patents.

This work will argue that bioprospecting should be extended to include human genetic materials. The work will also recommend that the disclosure requirement should be applied to the bioprospecting of human genetic materials. Lastly, this work will recommend that the disclosure of origin requirement be enforced through the re-imagining of the TRIPS Agreement.

CHAPTER TWO

INTRODUCTION TO BIOPROSPECTING

2.0 INTRODUCTION

This chapter will lay a foundation for the arguments and recommendations in this work. It will begin by defining bioprospecting and how the bloom of biotechnology affected bioprospecting in the 1980s. It will also argue for expanding the concept of bioprospecting to include the collection of human genetic materials from developing to developed countries. It will say that biopiracy exists in commercializing human genetic materials through patents. Although the collection of human genetic materials for research is not new in the medical field, biotechnology has extended the collection and use of human genetic materials beyond medical law and ethics. One of the ways biotechnologies have developed the collection and patenting of human genetic materials is through population studies. Population studies have been defined as a discipline that considers the characteristics of a population as opposed to genes in a particular individual. Human genetic materials have been collected from developed countries and transferred for research and use in developed countries through population studies. This chapter will analyze why the collection of human genetic materials through bioprospecting should be recognized as a subset of bioprospecting and regulated accordingly.

2.1 DEFINITION AND EVOLUTION OF BIOPROSPECTING

Throughout history, biological resources have been tapped for medicinal purposes across all regions

of the globe. Bioprospecting is "the systematic search for, and the development of, new sources of chemical compounds, genes, micro- and macro-organisms, and other economically

valuable biological products."[74] Bioprospecting of genetic materials is not new.[75]

[74] Mateo, Nicolas & Nader, Werner & Tamayo, Giselle, Bioprospecting. In Encyclopaedia of biodiversity. Simon E. Levin (Washington DC: Academic press, 2001)_471-488.

[75] Ibid.

In developing and African countries, genetic materials were used to cure and diagnose diseases. In developed countries, plants and animal extracts were used as complementary and alternative medicine in clinical and medicinal practice.[76] In the early 1960s, biodiversity prospecting was not popular among researchers or pharmaceutical companies,[77]and the technology needed to research new drugs was largely unavailable. In the early 1980s, however, research on natural products increased[78], and large pharmaceutical companies developed automated technology for screening the chemicals in genetic effects[79].

According to the Nuffield's Council on Bioethics, the History of patenting DNA and Gene sequences as an invention can be traced to the 1970s and 1980s when the first biotechnology companies were formed in the United States.[80]The science of biotechnology deals with manipulating living organisms or their components using genetic engineering to produce valuable products, typically commercial ones like pharmaceuticals.[81] The potential of biotechnology to create a cure for incurable diseases has increased the number of biotechnological Patent applications filed.[82] It has also extended biotechnological research to human DNA and Gene sequence[83].

[76] Edwin L. Cooper. *Bioprospecting: A CAM Frontier.* Advance Access Publication. (Feb 2005) Online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1062155/>

[77] Walter v. Reid. "Bio-prospecting: A force for sustainable development". Energy and Fuels Journals. (1993). 27:9 at 1732.

[78] Ibid.

[79] Ibid.

[80] Nuffield Council on Bioethics. Human Tissue Ethical and Legal Issues. April 1995. London.

[81] I. A. Oyemitan. *African Medicinal spices of Genus Piper*. In "Medicinal spices and Vegetables from Africa" Victor Kuete (ed.). Academic Press. (2017; Cameroon) 581.

[82] Gupta, V., Sengupta, M., Prakash, J., & Tripathy, B. C. *An Introduction to Biotechnology. Basic and Applied Aspects of Biotechnology*, (2016) at 1–21. Online: < https://doi.org/10.1007/978-981-10-0875-7_1>

[83] Ibid.

In 1980 the Bayh-Dole Act was passed in the US, enabling Universities and Public institutes to seek patents for their inventions and retain royalties[84]. The research for genetic innovations introduced a new culture to the University and research environment where profit through patents was made alongside the academic aspect of scientific research and publications. This practice, encouraged by the US government, spread to other countries worldwide.

Some authors have identified the 1980s as the bloom of biotechnology. Human genetic and non-human genetic resources can be retrieved through bioprospecting, which is the systematic search for them in plants, animals, and microorganisms in the wild[85].

The focus of most bio-prospecting research for genetic materials has been in developing countries believed to be rich in biodiversity[86]. These raw materials have been used to discover the cure for several illnesses. The pharmaceutical industries at the time took the position that all genetic resources were the common heritage of humankind and were open to access and collection[87].

Furthermore, the evolution of biotechnology has translated human biological materials into innovative raw materials.[88] Researchers and pharmaceutical companies could simply access, collect, and profit from genetic materials from developing countries without seeking their consent or sharing the derived benefits[89].

---

[84] Dennis Patrick Leyden and Albert N. Link. *The Bayh-Dole Act of 1980 in Public Sector Entrepreneurship: U.S Technology and Innovation Policy*. (Oxford University Press, United Kingdom, 2015). Online: <DOI:10.1093/acprof:oso/9780199313853.003.0005>.

[85] Ten Have, H., Patrão Neves, M. *Bioprospecting In: Dictionary of Global Bioethics*. (2021). Springer. (Online) < https://doi.org/10.1007/978-3-030-54161-3_95>

[86] Ibid.

[87] Walter v. Reid, Bioprospecting: A force for sustainable development. Energy and Fuels Journals. Environmental sci. Technology. 1993. 27:9. 1732.

[88] B. R Jeffers. *Human Biological materials in research: ethical issues and the role of stewardship in minimizing research and risks*. ANS Adv. Nurs Sci. (December, 2001) 24(2) at32-46.Online: <DOI: 10.1097/00012272-200112000-00005>.

[89] Walter v. Reid. "Bio-prospecting: A force for sustainable development". Energy and Fuels Journals. Environmental sci. Technology. (1993). 27:9 in 1732.

There were no policies to ensure developing countries could control access to their resources and reap the benefits of this access. The collection of these raw materials has raised novel ethical and legal issues. Developing countries, especially in the 1990s, increasingly complained that developed countries exploited their natural resources often without their consent and subsequent compensation[90]. Developing countries described these actions by researchers and biotechnological companies as biopiracy[91]. Governments began to restrict access to their genetic materials in order to protect their resources from undue exploitation.

Brazil is one of the richest developing countries in terms of biodiversity resources. In response to the challenge of biopiracy, Brazil implemented numerous national policies to restrict access to its genetic materials. In response to the action of developing countries like Brazil, the Convention on Biological Diversity was made. Its function was to balance the protection of biodiverse resources and the right of Biodiversity rich countries to control access and use of their genetic resources. However, the convention on biological diversity focused on curbing the biopiracy of genetic materials.

The Erosion, Technology, and Concentration group defined biopiracy as the "appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek to patent or intellectual property rights over these resources and knowledge." Biopiracy is the illegal use or appropriation without the consent of parties. In bioprospecting of genetic materials, it refers to the use of a Country's genetic resources without giving such country recognition or the benefits that accrue.

The definitions of biopiracy, however, identifies appropriation concerning plants, animals, and traditional knowledge,[92]and it does not recognize biopiracy in the unauthorized use of human genetic materials. The collection and use of human genetic materials from developing countries and Indigenous communities have been described simply as "research" or "population studies."

---

[90] Ibid.

[91] Helene Boussard, Aphrodite Smagadi. "The principle of Benefit-sharing in the utilization of natural plant and human genetic resources: beyond the property and no-property rights paradigms". Journal International De Bioethique. (2006). 17 at29-53.

[92] https://www.merriam-webster.com/dictionary/biopiracy.

This work argues that the definition of bioprospecting should be expanded to include "human genetic materials." Firstly, this work will argue that access, collection, and use of human genetic materials for medical use and research differ from the collection and use of samples during population studies.

Also, this work will argue that where developed countries access and collect human genetic materials from a particular community or tribe for research purposes, it is bioprospecting of human genetic materials. There are two common ways bioprospecting of human genetic materials occurs.

In some instances, developing countries and Indigenous communities invite researchers from developed countries to help them find a cure for a disease affecting their country or community.

In the case of the Havasupai tribe and the NIH[93] of 1984, the Hagahai people in Papua New Guinea were inflicted with an unknown illness. For the first time they made contact outside their tribe, seeking help. In 1991 the United States National Institute of Health (NIH) obtained a patent for the T-lymphotropic virus found in the blood of the indigenous people of Hagahai in Papua New Guinea.

The NIH scientist who collected the biological samples from the group claimed to have entered a profit-sharing agreement with the tribe. When the patent application was filed, there was a public outcry against biopiracy and bioprospecting by interest groups. The NIH withdrew the patent due to the protests of the Indigenous community and non-governmental organizations. It is important to note that the patent would have been granted to the NIH if it hadn't been withdrawn, as the invention met the requirements of the United States patent law system. Another way bioprospecting of human genetic materials may occur through population studies. Scientists may come together to analyze a population, tribe, or community.

Population-based studies "aim to answer research questions for a defined population." Research is the key to development and advancement in all areas.

[93] Nanibaa' A. Garrison. 2013. Genomic Justice for Native Americans: Impact of the case on Genetic Research. Sci Technol Human values. 38(2): 201-223.

Scientific research, especially genetics, opens a pathway for profit-making and political and academic advancements for those involved[94]. There may be different reasons for a proposed population study. An example is a human genome project (HGP) population study.

Most population studies on human genetic materials start with academic and scientific goals[95], and the aim is usually to contribute to scientific knowledge in an area or expand scientific research. This intent is presented to the Donor or, in the case of a community, the requisite authority when seeking consents to collect and study human biological materials.

Bioprospecting of human genetic materials could occur because of an invitation from a country or community or for population studies. Where researchers from developed countries collect samples of human genetic materials from developing countries for research or commercialization, it should be seen as "bioprospecting." In population studies and sample collection through an invitation, scientists target countries or communities in search of possible lucrative genes.

The difference in biopiracy of non-human and human genetic materials is how it occurs. In the bioprospecting of non-human genetic materials, biopiracy occurs when genetic materials are appropriated through unauthorized access, collection, and use.

In the case of human genetic materials, human genetic materials cannot be appropriated through unauthorized access, and human genetic materials are primarily accessed after consent has been obtained. In the bioprospecting of human genetic materials, the challenge is not obtaining consent or benefit sharing agreement but the "use" of these samples outside the terms for which consent was granted.

---

[94] 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.* (2005) Health Law Journal. 13 at 213-251.

The typical way misappropriation occurs unauthorized commercialization through patents. In the next section, this work will examine the problem of Patents and the features of patents that increase misappropriation and the need to regulate bioprospecting.

2.2 THE PROBLEM OF MISAPPROPRIATION THROUGH PATENT

Misappropriation of genetic materials through patent rights can occur in several ways. One of the ways misappropriations can occur is when inventions are made from genetic materials collected without informed consent and benefit-sharing agreements[96].

Another way misappropriation of genetic materials occurs is when informed consent is granted for a particular purpose and commercialized through patents without permission[97].

This is called change of intent to commercial purpose. Also, this occurs mainly where human genetic materials are collected[98] because, unlike non-human genetic materials, access and collection rarely occur without informed consent. For consent to be granted, specific terms of what the biological materials would be used for and the benefit to accrue to the donor would be reached. Where the researcher or developed country uses the human genetic materials outside the terms agreed upon in creating an invention and obtaining a patent, it is deemed a change of intent to commercial purpose. This should also be seen as misappropriation through patents.

The challenge with misappropriation through patents is that action before the court on the grounds of lack of prior informed consent or benefit-sharing may not be enough to revoke a patent. Inventions made from genetic materials can be patented if the invention meets the requirements for patentability.

---

[96] Perrault, Anne & Olivia, Maria Julia, *Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement on the Road to Hong Kong WTO Public Symposium,* (April 21 2005, Geneva). ICTSD/CIEL/IDDRI/IUCN/QUNO. Online: <http://www.ciel.org/Publications/PIC_PerraultOliva_Apr05.pdf>.

[97] Gurdial Singh Nijar. *The Nagoya Protocol on Access and benefit sharing of genetic resources: Analysis and implementation options for developing countries In "*The Human Genome Diversity Project and the patenting of life: "Indigenous people cry out"*Foster, Meika. Ed (*2011). Canterbury Law Review 7 at343.

[98] Article 8(a) of the Nagoya protocol.

Patents are governed by patent laws, and every country defines the factors that qualify an invention for patentability within its patent laws and as shaped by the international framework.

Furthermore, the law of some developed countries like the US does not mandate the patent applicant to seek the donor's informed consent or reach a benefit-sharing agreement as a requirement for patentability. Therefore, in these jurisdictions, additional mechanisms, laws, and policies are needed to ensure that informed consent and benefit-sharing can be enforced in patent applications. Authors and developing countries have proposed different approaches to implementing prior informed consent and benefit-sharing agreements through patent laws.

This chapter will define Patents and the requirements for patentability in the US and Brazil. This chapter will also examine the disclosure of origin proposal and the debates by States on how to enforce the conditions of prior informed consent and benefit sharing through disclosure of origin. It will also examine how the critical IP theory can reveal what is at stake in these debates.

2.2.1 Definition of Patents

A patent is the granting of a property right by a sovereign authority to an inventor. [99] Patents grant inventors exclusive rights to use their inventions for a limited time to prevent others from exploiting them[100]. The claims in patent applications describe the specific nature of an invention's protection. An infringement occurs when a person commercially exploits any part of an invention protected by the patent claim without the authorization of the patent owner[101].

A patent does not give the holder unlimited power to exploit their invention[102]. The power of a patent holder is subject to existing law and whether similar patents on the invention exist and overlap.

---

[99] Will Kenton, Patent. 2022. Online: Investopedia ,< https://www.investopedia.com/terms/p/patent.asp>

[100] Nuffield Council on Bioethics. The Ethics of patenting DNA. A discussion Paper. https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf.

[101] Ibid.

[102] Nuffield Council on Bioethics. The Ethics of patenting DNA. A discussion Paper. https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf.

The TRIPS Agreement does not define "Patents" as a term.[103] The explanatory TRIPS module defines a patent as the rights a patent office in a jurisdiction gives an applicant[104]. It is the exclusive right to exploit an invention for a limited time and the right to sue for infringement for the exploitation of the invention without authorization.[105]

The national laws of different jurisdictions define an invention and exclude certain materials from being defined as inventions.[106] For an applicant to get a patent for an invention, he must apply in the jurisdiction he seeks protection.[107] Each country's patent laws set out the requirements for an invention to be patentable.[108] These requirements are discussed in the following subheading as patentability requirements.

2.2.2 Patentability and the Requirements for Patentability

a) Definition of Patentability

To better understand the requirements of patentability, it is essential to explain patentability as a term. Creating an invention does not guarantee a party a patent. An invention is merely an idea the inventor has for the machine, process, article of manufacture, or composition of matter that can be useful.[109]

The law of a Country or region defines patentability and whether an invention is patentable.

---

[103] UNCTAD-ICTSD. Explanatory note: The methodology in resource book on TRIPS and development. Cambridge: Cambridge University Press. 2005. pp. Xi-Xiv. doi.10.1017/CB09780511511363.002.

[104] Ibid.

[105] Nuffield Council on Bioethics. The Ethics of patenting DNA. A discussion Paper. https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf.

[106] Chandra Nath Saha and Sanjib Bhattacharya, *Intellectual property rights: An overview and implications in pharmaceutical industry.* (2011)J. Adv Pharm Technol Res. 2(2) at 88-93. Online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/pdf/JAPTR-2-88.pdf>

[107] Ibid.

[108] What are the requirement for an invention to be patented? King Business and Patent law. https://jckinglaw.com/ip/patent-services/invention-patent-requirements/

[109] Matthew T. Latimer, *Patenting inventions arising from biological research.* Genome Biology,(2005) 6(1) at 203. Online: <doi:10.1186/gb-2004-6-1-203>.

The patent laws of Brazil reflect an effort to control patentable subject matters. This is consistent with the nature of Brazil as a developing country rich in biodiversity. The US, on the hand, is recognized as the country with the most biotechnological innovations. The patent laws of the US are liberal and give room for all kinds of subject matters to be invented. The only option available to a compliant after the patent is granted is redress in court.

In Brazil, a discovery is deemed patentable when it qualifies as an invention or utility model. Article 8 of the Industrial property law of Brazil[110] provides that for an invention to be patentable, it must meet the requirements of Novelty, inventive step, and industrial application. Article 9 of the Industrial property law provides that:

"*An object of practical use, or part thereof, shall be patentable as a utility model if it is susceptible to industrial application, presents a new shape or arrangement, and involves an inventive step, resulting in functional improvement in its use or manufacture."*

Inventions from human biological materials must also satisfy the requirements of novelty, inventiveness, and utility[111]. Biotechnological inventions from human genetic materials in Brazil are more difficult to patent than electronics and mechanics[112].

On the other hand, the US code title 35 gives a vague definition of an invention, *"The term invention means an invention or discovery."*

The United States Code Title 35[113] also states, "*A person may obtain a patent if he invents or discovers any new and useful process, the machine, manufacture or composition of matter or an improvement to existing inventions."*

---

[110]Intellectual property Rights, National Legislation Brazil. Industrial Property Law. Law No. 9 279 of May 14, 1996.

[111] Matthew T. Latimer, *Patenting inventions arising from biological research.* Genome Biology, (2005) 6(1) at 203. Online: <doi:10.1186/gb-2004-6-1-203>.

[112] Matthew T. Latimer, *Patenting inventions arising from biological research.* Genome Biology, (2005) 6(1) at 203. Online: <doi:10.1186/gb-2004-6-1-203>.

[113] Section 35 of the United States Code Title 35 – Patents Appendix L Consolidate Patent Laws – March 2021.

Section 102 and 103[114] provide the conditions for patentability, novelty, and non-obviousness, giving inventors and patent applicants a large berth.

b) Requirement for Patentability

As stated above, the Patent laws of a Country or region define whether an invention is patentable. For an invention to be the subject matter of a patent application, it must be patentable under national law. The laws of different Countries expressly define whether a subject matter can be patentable. In this subsection, we will examine the patentability requirements modelled by a developing and developed country (Brazil and the US).

Furthermore, Article 18 lists the inventions that are not patentable in Brazil:

1. if it is contrary to morality, decency, or public health and safety.

2. If it is substances, materials, compounds, elements, products, or modifications from them.

3. If it's living beings, whether it is the whole being or parts of it. The exception is where it is from transgenic microorganisms and meets patentability requirements.

For instance, under the Brazilian Intellectual property Act[115], inventions from human genetic materials are not patentable [116]. Under the US patent Act,[117] there are no prohibited subject matters. The Act states:

> "Whoever invents or discovers any new and useful process, the machine, manufacture or composition of matter, or any new and useful improvements thereof, may obtain a patent, therefore, subject to the conditions and requirements of this title."

The implications of these provisions under the US law seem to be that there are no limits on the range of possible patentable subject matters.

---

[114] Ibid.

[115] Article 10(ix) and Article 18(iii).

[116] Section 1.43, Article 10(IX) of the Industrial Property Law 1996.

[117] 35 U.S.C,2020. Section 101.

US courts have, however, prohibited certain subject matters. For instance, the US supreme court held in the case of Association for *Molecular Pathology v. Myraid Genetic Inc*[118] that the human gene in its natural form cannot be patented on the basis that it is a "product of nature."

In the US, where an invention is not a prohibited subject matter, the applicant must prove that the invention meets the requirements provided under the national law. These include:

i) Novelty:

This is the first criteria an invention must fulfil.

Under the United States Patent law, an invention is novel when there is no existing patent, publication, or disclosure to the public.

An invention is not deemed novel if prior art can be established and proved, and where the applicant cannot prove he invented the subject matter of the patent application. For a gene to qualify as a novel, additional work must be done to isolate it from its natural state.[119]A gene can only be patented in its isolated State.[120]The Gene itself cannot be patented[121]

ii) Inventive or non-obvious:

Article 14 of the US Code states, "A utility model shall be considered an inventive step if, for a person skilled in the art, it does not result patently or obvious from the state-of-the-Art." Under US law, this criterion is called non-obviousness. An invention will not be patentable if the difference between it and prior inventions is predictable and does not require any skill or industry knowledge to create invention.

---

[118] 2013. 569 US 576.

[119] Intellectual property in Genomics. National Human Genome Research Institute. (August , 2019). Online: < https://www.genome.gov/about-genomics/policy-issues/Intellectual-Property>

[120] Ibid.

[121] Ibid.

An invention must also satisfy the inventive or non-obvious criterion. This criterion means the invention would not be evident to a skilled person on the subject. There have been arguments that isolated genes do not meet this criterion. The discovery of unique genes has been attributed to luck and chance[122]. The process of isolating a gene is seen as a routine industrial process[123]. Every decade has its techniques for isolating a gene or DNA as an invention. In the 1990s, the *"in silico"* technique was used to identify genes[124].

The *"in silico"* technique involved using a computer program to match a human gene sequence with an existing animal sequence with a similar function.[125] A patent application can be filed for the diagnostic and therapeutic use garnered from the identified similarities. Over the years, other techniques have been used to identify and isolate diseased genes.

This section provides how the invention does not affect its patentability. Section 35 U.S.C. 103(PRE- AIA) (b) defines a biotechnological process and excludes inventions made through biotechnological from the definition of non-obvious subject matter. The USA supreme court examined the guidelines for determining obviousness in *KSR International co. v. Teleflex inc. (KSR)*[126].

In this case, the Supreme Court described the circumstances in which a patent may be deemed obvious when the invention combines familiar elements according to known methods.

This will likely yield predictable results and will be deemed obvious.[127] The main factor used in determining non-obviousness is the predictiveness of the invention or the improvements to the current invention compared to prior art based on established functions[128].

---

[122] Intellectual property in Genomics. National Human Genome Research Institute. (August 2019). Online: < https://www.genome.gov/about-genomics/policy-issues/Intellectual-Property>

[123] Ibid.

[124] Matthew T. Latimer, *Patenting inventions arising from biological research.* Genome Biology, (2005) 6(1) at 203. Online: <doi:10.1186/gb-2004-6-1-203>.

[125] Ibid.

[126] 550 U.S. 398, 82 USPQ 2d 1385 (2007).

[127] Ibid.

[128] 2141 Examination Guidelines for determining obviousness under 35 U.S.C 103 (R-10 2019). https://www.uspto.gov/web/offices/pac/mpep/521h

iii) Utility or industrial application:

An invention must be useful and patentable, and this is called the utility requirement in Brazil. An invention is deemed to satisfy this criterion if it shows a specific, substantial, credible utility[129].

The differences between the subject matter and patentability requirements between Brazil and the US show the challenge of using patentability requirements under national laws to regulate patents. It also indicates that the patent laws of a country determine what inventions enjoy patent protection. The fact that developing countries make laws prohibiting a particular subject's patent will not protect their rights in developed countries. The need to protect these rights led to the proposal that patent laws be amended to include a requirement that the source of origin of the invention should be disclosed. The proposal for disclosure of origin will be examined further in the following subheading.

2.3 BIOPROSPECTING AND PATENTING OF HUMAN GENETIC MATERIALS: SO, WHAT?

During the biotechnology bloom, bioprospecting focused on genetic materials like fauna and plant species.[130] Modern scientists have shifted the focus of bioprospecting to remote, Indigenous, and developing populations.[131]

This research aims to detect and isolate unique genes that cause diseases.[132] The invention of genomics created powerful tools for detailed gene research. Biotechnological research into human genes further expanded with partnerships with pharmaceutical firms.[133]

---

[129] USPTO Utility examination guidelines. Fed Reg. 66: 1092, 5 Jan 2001.

[130] David J. Faye. *Bioprospecting, Genetic patenting, and indigenous populations. Challenges under a structure common*. Journal of World intellectual property. (November 2005) at 401 Online: <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1747-1796.2004.tb00213.x>

[131] David J. Faye. *Bioprospecting, Genetic patenting, and indigenous populations. Challenges under a structure common*. Journal of World intellectual property. (November 2005) at 401 Online: <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1747-1796.2004.tb00213.x>

[132] David J. Faye. *Bio-prospecting, Genetic patenting, and indigenous populations. Challenges under a structure commons*. Journal of World intellectual property. (November, 2005) at 401 Online: <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1747-1796.2004.tb00213.x>

[133] Ibid 402.

The broad provisions of the US patent law that allowed the patenting of gene inventions further encouraged genomics evolution.[134] The focus of this research was to isolate human genes to create new drugs, treatments, and therapies.[135] Even before any breakthrough in genetic research in the form of a discovery or a patentable product, and genetic data is lucrative. It is even more interesting where Indigenous isolated populations are involved.

As with any other research, undeniable changes could occur to the blueprint of these studies during course of the project.[136] These changes might also affect the purpose of the study, the agreement on which consent was sought and given, and the benefits that could accrue to the individual or tribe and the research institute involved.

There is, however, no legal framework to compel researchers or pharmaceutical companies to seek consent for any modifications that occur after the study has begun or an invention has been discovered and is about to be patented. An example that buttresses this point is the case of the Island of Tristan Da Cunha. Three hundred blood samples were collected from the small tribe to facilitate a study into a possible cure for Asthma.

The research institute involved in the project was Samuel Lunenfield institute, an affiliate of Toronto. The research institute and the Samuel Lunenfield research institute agreed that the Island of Tristan Da Cunha Indigenous group would receive free pharmaceutical-based treatment if the drugs were developed based on information from the samples taken[137].

In 1995, Sequana theraupics, the genomics company affiliated with the Lunenfield research institute, identified and could patent the genes predisposed people to Asthma. They sold the licensing rights to the Boehringer institute for 70 million US dollars. It is also important to note that the agreement or consent was given to the Samuel Lunenfield institute, not to Sequana theraupics.

---

[134] Ibid 402.

[135] Ibid 403.

[136] President's Commission for the study of ethical problems in biomedicine and biomedical research. 1982. Making Health care decisions (1). Washington, DC. US Government Printing office.

[137] Chennells R.S, *Introduction*. In "Equitable Access to Human Biological Resources in Developing Countries" Roger Scarlin Chennells ed. (Springer Cham: Switzerland, 2016) Online: < https://doi.org/10.1007/978-3-319-19725-8_1>.

Whether the Indigenous people were aware of the partnership the research institute had with Sequana theraupics or if they understood what it would mean for any drug that was produced and patented is an issue that is not covered in the scope of this work.

It, however, brings to the fore how misappropriation of human genetic materials might occur and the need for laws to regulate the bioprospecting of human genetic materials.

No law currently governs the collection and patenting of human genetic material collected during bioprospecting in developing countries. The major challenge in regulating the collection and patenting of human genetic materials is that individuals have no property rights in their human biological materials. The irony is that an individual with no property rights in his human genetic materials under the law can transfer property rights to a researcher, institute, or blood bank to which he donates. The arguments on the property rights of human genetic materials are beyond this work's scope. However, the issue of misappropriation through patents gives property rights through intellectual property law to an inventor without the consent of the Donor country or individuals. For equity of the Donor to be achieved, his contribution to the creation of an invention should be acknowledged. His consent should be sought and obtained, and a benefit sharing agreement should be reached before a patent is obtained.

2.3.1 THE IMPORTANCE OF REGULATING THE BIOPROSPECTING OF HUMAN GENETIC MATERIALS

Human Genetic research has the potential to improve human health and financially contribute to society.[138] However, there is a need for laws to address the issues of "equity and ethics" in the collection and patenting of human genetic materials. The danger of unregulated bioprospecting of human genetic material is the abuse of human rights by exploiting the body and abusing human dignity. It was the same challenge the world faced during the gold rush that ravaged lands, broke spirits and led to the deaths of many Indigenous peoples[139].

---

[138] Julia Mahoney. *The market for Human Tissue*, (2000) VIR. L. REV. 86 at 163.

[139] Monique K. Mansoura and Francis S. Collins, *Medical implications of the Genetic Revolution*. (1998) 1 J. HEALTH CARE L., & POL'Y at 329 .

If the exploitation of genetic materials continues without regulation, it would affect people's choice to participate in genetic research. As pointed out in Chapter One, countries like Brazil have laws that regulate how human genetic materials should be collected and used. Under Resolution 441/2011 from the National Health council submitted to the Brazilian ministry of Health, human genetic materials can only be donated for research purposes to aid the search for cures for various diseases[140]. Where these human genetic materials are collected from Donors or biobanks on mutually agreed terms of use for research purposes and are later commercialized, it would discourage future study participation. Map studies are necessary to identify genetic diseases, and genetic mutations or environmental factors mainly cause genetic diseases.[141] It is therefore essential to have the cooperation and participation of different countries in genetic research for good mapping and study of genetic diseases.

Genetic research also has the potential to improve human health and financially contribute to society[142]and this is another reason why informed consent should be obtained before commercialization through patents. Furthermore, benefit sharing agreement is reached on the profit from the patent so that the donor, whether an individual, community, or country, can also benefit.

In the next Chapter, this work will analyze the international laws governing human and non-human genetic materials and critique the shortcomings of these laws.

[140] Fernandes, Márcia Santana et al. "Brazilian legal and bioethical approach about donation for research and patents of human body parts." Journal of community genetics vol. 8,3 (2017): 199-208. doi:10.1007/s12687-017-0303-y

[141] Monique K. Mansoura and Francis S. Collins, *Medical implications of the Genetic Revolution*. (1998) 1 J. HEALTH CARE L., & POL'Y at 329 .

[142] Julia Mahoney. *The market for Human Tissue*, (2000) VIR. L. REV. 86 at 163.

CHAPTER THREE

ANALYSIS OF INTERNATIONAL LAWS REGULATING BIOPROSPECTING

3.0 INTRODUCTION

The bloom of biotechnology raised ethical and legal issues in bioprospecting. The ethical issues are the unauthorized access and collection of biodiverse resources and misappropriation of traditional knowledge without a benefit-sharing agreement with the donor. The misappropriation of biodiversity resources was mostly against developing countries that are recognized as rich in biodiversity.

The unauthorized collection and misappropriation of genetic materials from developing countries led to outcries of bio-piracy. There was a need for laws to regulate bioprospecting. The need to regulate bioprospecting and ensure the protection of the traditional knowledge of developing countries led to the formulation of the Convention on Biological Diversity (CBD). The CBD proposed that bioprospecting be permitted only where there has been informed consent and benefit-sharing based on mutually agreed terms.

However, the misappropriation of biodiversity was not restricted to non-human genetic materials.

It also extended to include human genetic materials. Although the collection of human biological materials for research is not new in the medical field, biotechnology has, however, extended the collection and use of human genetic materials beyond the scope of medical law and ethics.

One of the ways biotechnologies has advanced the collection and patenting of human genetic materials is through population studies. Through these studies, human genetic materials have been collected from developing countries and transferred for research and use in developed countries.

This chapter will analyze the proposed solutions to misappropriation through patents that have been proposed through international law. It will examine the CBD and Nagoya protocol's informed consent and benefit-sharing proposal. This chapter will also critique the provisions of the CBD, the Nagoya, and the ethical and medical laws concerning the challenges of bio-prospecting human genetic materials. It will mainly analyze the difficulties of enforcement where human biological materials are collected from developing countries for research in developed countries.

3.1 INTERNATIONAL LAWS REGULATING BIOPROSPECTING

This section will examine the international laws and guidelines regulating bioprospecting.

3.1.1 THE CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity (CBD) was adopted in 1992 to regulate bioprospecting.[143] It was passed to ensure that Donor countries are protected and compensated for the economic utilization of their biodiversity[144]. The CBD highlighted two main considerations in bioprospecting: Prior informed consent and fair and equitable sharing of benefits arising from using genetic materials[145].The genetic resources covered by the CBD are animals, plants, micro-organisms, and traditional knowledge[146].

One shortcoming of the CBD is it does not address the challenge of misappropriation through patents. A second is that it does not address human genetic resources. A third shortcoming of the CBD is its failure to provide guidelines on how to access and prior informed consent can be obtained and how benefit-sharing terms can be reached.

---

[143] Damodra A. "Traditional Knowledge, Intellectual Property rights and Biodiversity Conservation: Critical issues and key challenges". (2008) Journal of Intellectual property rights. 13(5) at 509-513.

[144] Ibid.

[145] Article 15(2),(4),(5), and (7).

[146] Introduction to Access and Benefit-sharing: convention on biological diversity: ABS. Available at https://www.cbd.int/abs/infokit/revised/web/all-files-en.pdf

This shortcoming, among other reasons, made the implementation of the CBD difficult. Though signed and adopted in 1992, the CBD did not become operational until 1999.[147] As discussed below, in 2002 the Bonn Guidelines were passed to address the challenge of how to implement the solutions of prior informed consent and benefit-sharing.

3.1.2 BONN GUIDELINES ON ACCESS TO GENETIC RESOURCES AND FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THEIR UTILIZATION

In 2002, parties to the Convention on Biological Diversity met at their sixth conference, where they adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization. These guidelines were adopted to aid the implementation of the CBD's access to genetic resources and benefit-sharing provisions.

These guidelines aim to aid parties in developing legislative, administrative, or policy measures on access, benefit-sharing, and implementation. Article 25 of the Bonn Guidelines provides that it was, amongst other reasons, established to create a system of implementing prior informed consent in line with Article 15 of the CBD. The guidelines outline the elements of an informed consent system[148]. Furthermore, the Bonn Guidelines provide model steps for obtaining consent.[149]

The Bonn Guidelines, like the CBD, have their limitations. First, it is voluntary and non-binding on member states[150]. The Bonn Guidelines are also limited to non-human genetic materials. Additionally, the guidelines do not address the peculiarities of obtaining informed consent for collecting human genetic materials.

[147] Global biodiversity outlook 1

[148] Article 27 of the Bonn Guidelines

[149] Article 36 of the Bonn Guidelines

[150] Supra at Note 12.

3.1.3 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.

In 2010, the Nagoya Protocol to the CBD[151] was adopted to address the issue of access to and benefit-sharing of genetic materials. It extended to points concerning traditional knowledge and Indigenous people[152]. The Nagoya Protocol has two main aims: to serve as a guideline for the utilization of non-human genetic resources and as an instrument to facilitate national governance and international cooperation in Indigenous research[153]. The Nagoya Protocol was adopted as a Supplementary Protocol to the CBD [154] to correct some of the CBD's limitations[155]. However, like the CBD and Bonn Guidelines, the Nagoya Protocol does not make provision for human genetic materials[156].

This lacuna shows the need for international law reform to guide the collection and use of human genetic materials obtained through bioprospecting.

3.2 ANALYSIS OF THE CBDS PROPOSAL

There are numerous ethical and medical laws and policies governing the issues of informed consent for human genetic materials[157]. These guidelines specify how samples can be collected and used for medical research[158].

---

[151] It was adopted on 29th October 2010, in Nagoya Japan.

[152] Damodra A. "Traditional Knowledge, Intellectual Property rights and Biodiversity Conservation: Critical issues and key challenges". (2008) Journal of Intellectual property rights. 13(5) at 509-513.

[153] Ibid.

[154] It was adopted on 29th October 2010, in Nagoya Japan.

[155] Gurdial Singh Nijar. "The Nagoya Protocol on Access and benefit-sharing of genetic resources: Analysis and implementation options for developing countries". (2011) Center of excellence for biodiversity. Online: <https://southcentre.int>

[156] Ibid.

[157] The convention on Human rights and Biomedicine. 1997 (ETS No. 164), The Declaration of Helsinki 2007. The CIOM (Council for the international organization of medical sciences) Ethical Guidelines for Biomedical research involving human subjects, The Helsinki declaration 2000 and 2005.

[158] The CIOM (Council for the international organization of medical sciences) Ethical Guidelines for Biomedical research involving human subjects, The Helsinki declaration 2000 and 2005.

However, ethical rules and medical laws do not apply to patent applications[159]. The scope of this work will not examine or analyze medical laws on access to and collection of human genetic materials. This work will, however, refer to some ethical guidelines on informed consent and Benefit-sharing. It will examine informed consent and Benefit-sharing under the Convention of Biological Diversity, Bonn Guidelines, and the Nagoya protocol.

As noted above, in the last two decades bioprospecting of human genetic materials has occurred mostly in the context of population-based studies[160]. Under the CBD, informed consent has focused on permission to collect biological samples and use them for a specified purpose. While this may suffice for non-human genetic materials, for human genetic materials, samples in most circumstances cannot be collected without prior informed consent. The misappropriation in such cases is not in the collection without informed consent, but the "use" of collected materials for purposes and in a manner the donor did not consent to.

This section will examine the ethical requirements of informed consent and benefit-sharing in accessing and collecting human biological materials in bioprospecting.

3.2.1 Informed consent:

Informed consent can be better described as an idea than a term to be given a precise definition. It has been called several things over the years: informed consent in medical science,[161] prior informed consent under the Convention on Biological Diversity[162] and free, and prior informed consent as mentioned in the United Nations Declaration on the Rights of Indigenous People, amongst others.[163]

---

[159] Principles of medical law and Ethics. April 3, 2022. Online: AMBOSS. <https://www.ambross.com/us/knowledge/principles-of-medical-law-and-ethics>.

[160] Ibid.

[161] Pierre- Christian Labeau, "Free , Prior and informed consent in International law" (June 24 2010), Online: Global https://lexology.com/library/detail.aspx?g=7.

[162] Article 15 of the Convention for Biological Diversity.

[163] Pierre- Christian Labeau, "Free, Prior, and informed consent in International law". Global; (June 2010). Online:< https://lexology.com/library/detail.aspx?g=7>.

This work will follow the definition of informed consent used by the American Anthropological Association. Anthropological research approaches informed consent as a dynamic and continuous process initiated as early in the research process as possible with the person or group being studied and continues throughout the project.[164] This definition is consistent with argument that informed consent is not a one-off process but a continuous one.

Informed consent is given based on mutually agreed terms as stipulated under the Convention on Biological Diversity.[165] Where there is a change of the intended use international laws and guidelines[166] mandate the donee to seek consent for any future use not mutually agreed to by the parties.

In the last decade, developing, least developed countries and Indigenous communities have been the target of bioprospecting for innovative discoveries. Developed countries like the US and UK believe there are unique and undiscovered genes among Indigenous peoples and developing countries[167]. However, there is no international framework to govern how the samples are collected during bioprospecting and to ensure that access and use of the collected samples are according to mutually agreed on terms for which consent was granted.

The Convention on Biological Diversity and 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) are the only binding international law provisions on accessing and benefit-sharing of genetic materials.

[164] American Anthropological Association 1997, Code of Ethics of the American Anthropological Association (Final Draft, March 1, 1997).

[165] Article 15 of the Convention of biological diversity.

[166] Nagoya Protocol and Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.

[167] 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". (2005) Health Law Journal. 13 at213-251.

These laws do not, however, address the issue of access to and collection of human biological materials.[168]

Article 15 of the CBD provides:

"……. Access where granted, shall be on mutually agreed terms, and access to genetic materials shall be subject to prior informed consent". The above provision is restricted to non-human genetic materials.

3.2.2 Benefit Sharing:

Benefit-sharing builds on a legal and ethical origin, the ethical origin of distributive justice, goodwill, and equity[169]. Benefit-sharing from the utilization of human genetic materials is based on two primary rights: the right to self-determination and the freedom to autonomy. The right to self-determination is a legal human rights provision and bioethics autonomy principle.

This section will briefly introduce the concept of benefit sharing and analyze benefit-sharing from two angles—first, the legal and ethical policies and laws that define and govern benefit sharing, and second the issue of benefit sharing in the case of a patent using human genetic materials.

In 1983, the Food and Agriculture Organization of the United Nations[170] identified genetic resources as the common heritage of humanity. The concept of the common heritage of humanity means that genetic resources should be available for all humanity regardless of their jurisdictional location.[171]

---

[168] Conference of Parties to the Convention on Biological diversity, decision 11/1 1995, at 22: "human genetic resources are not included within the framework of the convention". Article 9 of the Bonn guidelines exclude human genetic materials from its scope of application. 6th ordinary meeting of the conference of parties to the convention on biological diversity, Decision Vi/24, Access and Benefit-sharing as related to genetic resources, Section A Bonn Guidelines on Access to Genetic Resources and Fair and equitable sharing of the Benefits Arising out of their utilization.

[169] Q. Renzong, "Human genome, and philosophy: What ethical challenge will human genome studies bring to the medical practices in the 21st century". (January 2002) Comptes Rendus de l Académie des Sciences - Series III - Sciences de la Vie 324(12) at 1097-102 . Online: <DOI:10.1016/S0764-4469(01)01400-7>

[170] The FAO is a specialized agency of the United Nations found in 16 October 1945. The FAO has 195 signatories.

[171] L. Glowka, A guide to designing legal frameworks to determine access to Genetic resources. (Gland, Switzerland Cambridge and Bonn: IUCN, 1998) 4.

Non-genetic materials were at first used for the basic needs of human food, shelter, and clothing.[172] The research was extended to using non-genetic human materials for medicine, cosmetics, and chemicals.[173]

This extension brought profit and benefit to biotechnological and pharmaceutical companies; benefits which were not returned or shared with the Donor. As research for commercialization increased, the exploitation of genetic resources without consent or benefit-sharing agreements with the Donor country led to the fight against biopiracy.[174] Benefit-sharing emerged from the need to balance the rights of researchers with donors. Developing countries began to restrict access of any kind to their genetic materials. This emphasized the need to regulate the issue of benefit sharing.

The FAO international undertaking was revised in 1991, putting the genetic resources under the control of the contracting parties.[175] The Convention on Biological Diversity (CBD) was adopted in 1992 to provide fair and equitable benefits sharing[176], replacing the FAO operation of the Common Heritage of Mankind. The CBD reaffirmed that States have sovereignty over genetic resources[177], and the CBD established the principle of Benefit-sharing in Article 15. Since CBD does not apply to Human genetic materials, the regulation[178] of benefit sharing in this area is a concern.

---

[172] Q. Renzong, "Human genome, and philosophy: What ethical challenge will human genome studies bring to the medical practices in the 21st century". (January 2002) Comptes Rendus de l Académie des Sciences - Series III - Sciences de la Vie 324(12) at 1097-102 . Online: <DOI:10.1016/S0764-4469(01)01400-7>

[173] Ibid.

[174] Clayton E. W, Barbara J. E, James W. H and Rothstein M. A. "The law of genetic privacy: applications, implications, and limitations". Journal of law and the biosciences. (2019) 6(1). Online:<Onhttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC6813935/ >

[175] Food and Agriculture organization of the United Nations. Genetic resources. Online: < https://www.fao.org/genetic-resources/en/>

[176] Article 15

[177] Article 1, 6, 8, 10, and 15.

[178] Supra at note 12.

The structure of benefit-sharing under the CBD is based on biodiversity conservation and the need to ensure the benefits accrue to the stakeholders and the society.[179] Benefit-sharing under the CBD operates on the principle of distributive justice. Distributive justice ensures that negotiated benefits are distributed among all shareholders. The question to contemplate is whether this can apply to human genetic material. The benefits that accrue and are distributed for non-human genetic materials differ from human genetic materials.

In Greenberg's case, the families donated samples because they needed information[180] and wanted answers to why a small percentage of Jewish children were affected by the Canavan disease.[181]This was also the case with the Havasupai tribe in 1990.[182] Four hundred Havasupai tribe members gave samples to researchers from the ASU (Arizona State University) to understand why adult members of their tribe had type 2 diabetes.

The researchers during their study could not establish a link between the genes of the Havasupai tribe to Type 2 Diabetes. The samples were stored and distributed to other researchers for schizophrenia, ethnic migration, and population inbreeding studies; these subjects were taboo in the Havasupai culture. The Havasupai tribe never received the benefit for which their samples were given and sued the ASU for misuse of their DNA samples.

The Human Genome Organization (HUGO), the World health organization (WHO),[183] and Article 15 of the Universal declaration recognize benefit sharing for research participants.[184]

---

[179] Stefan Jungcurt, Access and Benefit sharing under the CBD and Access to materials for Research in Designing the Microbial Research Commons proceedings of an International Symposiums. National Research Council (US) Board on Research Data and information (ed). (Washington DC; National Academies Press (US), 2011).

[180] Greenberg v. Miami's children's hospital research institute. 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

[181] Ibid.

[182] Beauchamp. T.L. "Informed consent: its history, meaning and present challenges". (2010) 20(4) Cambridge quarterly of Healthcare Ethics at 515-523.

[183] WHO , PROPOSED International guidelines on ethical issues in medical genetics and genetic services (1998). The WHO proposes that in cases where the genetic research produces diagnostic tests or new therapies, "equity requires that donors or the community generally should receive some benefits.

[184] HUGO Ethics committee, statement on Benefit sharing, 9 April 200, 3. HUGO advocates that "there must be prior discussions with groups or communities on the issue of benefit sharing" and that "profit making entities dedicate a percentage (1-3%) of their annual net profit to health care infrastructure and or to humanitarian efforts.

It is further protected in Article 1(1) of the international covenant on civil and political rights 1966 and Article 1(1) of the International Covenant on Economic, social and cultural rights. The provisions of this law ensure the protection of Donor samples and their political identity, which is linked to their genetic information.

These international laws also attempt to define the scope of benefit sharing. In 1996, the HUGO Ethics committee suggested several forms of benefit sharing.[185] The committee recommended prohibiting the use of compensation to encourage participation in research. They encouraged other types of compensation or benefits like health care provisions, local training, Joint ventures, technology transfer, and humanitarian purposes.[186]

In 2000, the HUGO committee published a statement on benefit sharing.[187] The statement recommended that companies that make profits from utilizing human genetic materials dedicate 1-3% of their annual profits to humanitarian efforts. The UNESCO universal declaration on bioethics and human rights[188] has also made two recommendations for sharing benefits. First, the benefits of biotechnological research on human genetic materials should be applied to the international community, particularly in developing countries.[189] Secondly, gifts should not be used as inducements for research participants.[190]

The provisions of these international laws suggest that benefits sharing where human genetic materials are involved should not include monetary compensation. This leads to the second issue this section will analyze—whether Benefit sharing should accrue from the commercialization of innovation from human genetic materials.

---

[185] HUGO Ethical, legal and social issues committee. 1996.Statement on the principled conduct of Genetic research. Online:< https://www.biodiv.org/doc/meetings/abs/abswg-01/information/abswg-01-inf-04-en.pdf>

[186] Ibid.

[187] Clint Genet.2000. "HUGO Ethics committee statement on Benefit Sharing". (2000) 58 at 364-366. Online:<http://www.blackwell-synergy.com/doi/abs/10.1034/j.1399-0004.2000.580505.x>.

[188] Published in 2005.

[189] Article 15(1) of the universal declaration on bioethics and human rights.

[190] Article 15 (2) of the universal declaration on bioethics and human rights.

In *Greenberg v. Miami Children's Hospital Research Institute,*[191] the plaintiffs were four parents of children who had the Canavan disease. They approached Matalon a doctor at the Miami children's hospital to research the root cause of the Canavan disease among Jewish children. They provided samples for their children for the research and connected them with other affected families. They also linked him to three non-governmental organizations with a Canavan disease registry.

In 1993, Matalon discovered the Canavan Gene and developed a genetic test. The Miami Children's hospital obtained a patent on the gene in 1997 and 1998 and began licensing tests to identify the Canavan disease.

The plaintiff claimed against Dr. Matalon and the Miami Children's Hospital Research Institute a lack of informed consent, breach of fiduciary duty, fraudulent concealment, and misappropriation of funds. The suit sought to block off Miami's Children's Hospital's commercial use of the Canavan gene and recover damages of $75,000 derived from royalties collected on the Canavan test.

The court dismissed all claims except the claim on unjust enrichment against the Miami Children's Hospital. The Court recognized the plaintiffs had invested their time and resources for which they should be compensated. However, the Court determined that the plaintiff's claims did not entitle them to benefits from the patent obtained. Elliot Marshall, in his work on this case, points out that patient groups now work out legal agreements in advance to cover the possibility of a patent discovery and that benefits from the royalties are shared appropriately.[192]

The above case is an example of the issues of benefit sharing that may arise where human genetic material is patented without clear definitions on benefit sharing from patents. This work will critique the laws regulating bioprospecting and highlight their shortcomings in the following subheading.

[191] 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

[192] Families sue Hospital, scientists for control of Canavan Gene. Science 10 Nov 2000. 29 (5494) 1062.

3.3 CRITIQUES OF THE INTERNATIONAL FRAMEWORK REGULATING BIOPROSPECTING.

Under this section, this work will examine and critique the shortcoming of the CBD's approach to informed consent and benefit sharing. It will analyze the effect of the lack of a legal framework for the bioprospecting of human genetic materials. One shortcoming of the CBD, as discussed in the following section, is that it does not regulate the bioprospecting of human genetic materials.

3.3.1 It does not regulate the bioprospecting of human genetic materials:

Neither the CBD nor the Nagoya protocol regulates the bioprospecting of human genetic materials. This raises challenges in defining how informed consent and benefit sharing requirements apply in this context. This work will address two issues concerning obtaining informed consent for human biological materials. First is the issue of a lack of international laws to regulate access to and collection of human genetic materials during bioprospecting. Second is the issue that arises where the parties did not contemplate the case of future use or use before consent was granted.

There are no ethical policies and international laws to govern how human biological materials can be collected and benefit sharing reached during bioprospecting. There are numerous ethical and medical laws and procedures governing the issues of informed consent for human genetic materials. These guidelines specify how samples can be collected and used for medical research[193]. However, ethical rules are not binding outside the context of medical practice, and medical-related research is at its most persuasive[194].

Bioprospecting of human genetic materials has occurred mostly as population-based studies in the last two decades.[195] In population-based studies, research questions are posed and answered concerning a defined group of people.[196]

---

[193] The CIOM (Council for International organization of medical sciences) Ethical Guidelines for Biomedical research involving human subjects, The Helsinki declaration 2000 and 2005.

[194] Nuffield Council on Bioethics: Human Tissue: ethical and legal issues. (1995) Online:http://nuffieldbioethics.org/wp-<content/uploads/2014/07/Human-tissue.pdf>

[195] Ibid.

[196] Roselind Lieb, *Population-Based study*. In Encyclopedia of Behavioral Medicine Gellman M. D., Turner J.R. (eds) (Springer , New York: 2013). Online:<https://doi.org/10.1007/978-1-4419-1005-9_45>.

Researchers, in this case, are not bound by medical ethics in collecting and using human genetic materials. This is because the intent of the research could change, and some laws compel a researcher to comply with the terms for which consent was granted.

Second, the issue is a change of research intent. Most research on human genetic materials starts with academic and scientific goals,[197] and the aim is usually to contribute to scientific knowledge in an area or expand scientific research. This intent is presented to the Donor or, in the case of a community, the requisite authority when seeking consent to collect and study human biological materials. When consent is given, the donors believe that the consent terms will be adhered to. The challenge arises where these collected samples are used in a manner not agreed upon and consented to by the donor individual or country.

Two common scenarios can arise during research; the first is the need for collaboration with other scientists and other scientific institutes and bodies. In this case, human biological samples collected can be stored in a biobank[198] or transferred to a researcher who was not a party to the agreement with the Donor.[199]

The second scenario is the possibility of commercializing an innovation discovered in the research by pharmaceutical or biotechnological companies who may have been present from the beginning of the project or may become involved as the study progresses.[200] This work will focus on the second scenario, which involves pharmaceutical or biotechnological companies leading to commercializing products derived from human genetic materials. Two cases emphasize the need for laws to regulate how consent is sought and obtained and how human samples from bioprospecting are used.

---

[197] Collins F. S, Leslie F, "The Human Genome Project". (1995) 19(3) Alcohol Health Research World at190-195. Online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875757/>.

[198] An example of such an instance in the case of the Nuu-Chanulth tribe of Vancouver Island, the University of British Columbia was accused of misusing samples collected from them by distributing them to other research institutions for varying purposes. This they claimed was done outside the scope of the original consent

[199] Ibid.

[200] Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018) – Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction. Online:<https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter12-chapitre12.html#c>

In 1992, a patent was filed on behalf of the US department of commerce on samples obtained from a Guaymi woman who was part of the Guaymi Indians in Panama. The US claimed that the illiterate woman gave "oral informed consent" to the research. However, the tribe and the Donor did not know about the subsequent discovery or patent application.

The President of Guaymi General council wrote to the US secretary of commerce when news of the Patent application broke out. In the letter, he demanded the withdrawal of the application because it had been made without obtaining the consent of the Guaymi community or its traditional leaders.

The President of the Guaymi council further argued that what was being patented was not an invention, but a discovery of an antibody discovered in the blood of the Guaymi woman. The letter also demanded information on the benefits that would accrue to the Guaymi people. The protests by the Guaymi peoples and Indigenous rights groups pressured the US to withdraw the Patent. The second case was that of the Hagahai tribe in Papua New Guinea.[201]

The informed consent process has been criticized as a mere political and material practice to fulfil the obligations to obtain consent.[202] It does not always reveal the true intents and procedures for which samples collected will be used.[203] This is partly because of the complicated nature of obtaining informed consent, especially among developing countries and indigenous peoples.[204]

Some developing countries have beliefs and restrictions on how human and non-human genetic materials should be used. Brazilian intellectual property law prohibits the collection and utilization of human genetic materials for commercialization.[205]

---

[201] Bioethics and Patent law: the cases of Moore and the Hagahai People. WIPO Magazine.September 2006. 5. https://www.wipo.int/wipo_magazine/en/2006/05/article_0008.html.

[202] Klaus Hoeyer et al, "Informed Consent: The Politics of intent and Practice in Medical Research ethics". (2014.) 43(1) Annual review of Anthropology at 347-362. Online: < https://10.1146/annurev-anthro-102313-030413>.

[203] Klaus Hoeyer et al. Informed Consent: The Politics of intent and Practice in Medical Research ethics.2014. Annual review of Anthropology. 43(1): 347-362. https://10.1146/annurev-anthro-102313-030413.

[204] 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". (2005) 13 Health Law Journal at 213-251.

[205] Articles 10 IX and Article 18, III of the Brazilian Intellectual property Act.

Articles 11 to 21 of the Brazilian Civil codes provide that human genetic materials are not patentable and can only be donated for research purposes. Where a developed country like the US collects human genetic materials from Brazil, the intent is usually research. Where the goal of the research changes and the samples collected are commercialized through patents, Brazil has no recourse in international law.

The absence of international law in this area means where developed countries had obtained prior informed consent before the samples were collected, there is no legal duty on them to seek consent before accepting a patent. The transboundary nature of bioprospecting enables researchers to move samples from one jurisdiction to another. There is a need for international laws to ensure compliance with mutually agreed terms on the use of collected samples, especially in the case of commercialization through patents.

Most literature has focused on the need for informed consent before accessing and collecting non-human genetic materials. There has, however, been little research on informed consent where there is a change of intent in human and non-human genetic materials. The work will argue the need for informed consent before human biological samples collected and utilized are commercialized through patents.

Some international laws and guidelines have addressed the issue of change of intent in bioprospecting. These laws, however, apply to non-human genetic materials.

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization acknowledges that a change in research intention could occur. Article 34 of the guidelines provides that prior informed consent can only be granted for a specified use. It offers that arrangements should be made for fresh consent to be sought when genetic material is used or transferred to a third party in a manner not specified in the terms for informed consent. It also advises that the agreement for prior informed consent should expressly state the need for informed consent for unforeseen changes in use. This provision also addresses the challenge of enforcement of terms of informed consent. If applied strictly, the issues surrounding the unauthorized use of genetic materials would be significantly reduced.

Furthermore, The Nagoya protocol addresses the issue of change in the intent of the research in Articles 8 and 15 of the Nagoya Protocol.

Article 8(a) provides for Non-commercial research and states that:

> In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:
>
> (a) create conditions to promote and encourage research that contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.

These laws, as stated above, do not apply to human genetic materials. There should also be international laws addressing a change of research intent. The law should also mandate the researcher to seek informed consent before utilizing samples collected for any use not contemplated in the original agreement.

3.3.2 It does not protect the Traditional Knowledge of developing countries:

The Nagoya Protocol was adopted as a Supplementary Protocol to the CBD to correct some of the limitations of the CBD. For instance, Article 6 of the Nagoya Protocol for Access and Benefit-sharing provides for the protection of traditional knowledge and the challenges of accessing and collecting samples from Indigenous people[206]. This was of the significant shortcomings of the CBD. The Nagoya protocol however did not address the bioprospecting of human genetic materials. Also, the Nagoya Convention attempts to address the ethical issues in obtaining consent and benefit-sharing of genetic materials of Indigenous peoples.[207]

[206] Gurdial Singh Nijar. The Nagoya Protocol on Access and benefit sharing of genetic resources: Analysis and implementation options for developing countries. (2011) Center of excellence for biodiversity. Online: <https://southcentre.int>

[207] Gurdial Singh Nijar. 2011. The Nagoya Protocol on Access and benefit sharing of genetic resources: Analysis and implementation options for developing countries. Center of excellence for biodiversity. <https://southcentre.int>

3.3.3 The CBD provides no system or mechanism for enforcing compliance:

Despite the provisions of the CBD and the Nagoya Protocol, enforcing the ethical requirements of prior informed consent and benefit-sharing has been challenging. The major challenge is where innovation from human or non-human genetic materials is commercialized through a patent. Two factors cause this challenge. First, the patent grant laws are separate from human rights and ethical considerations in conducting research. Also, a patent will not be revoked for failure to obtain prior informed consent, where this is not a requirement for attainability.

There are 182 signatories to the Convention on biological diversity. Some countries have attempted to make laws to protect Donors and their families and ensure compensation. For instance, the Estonian government mandates research to obtain informed consent for health Data and DNA samples in their gene banks. These samples were identified with codes and not made anonymously, so that information about the research could be given back to the participants and families.

This chapter has analyzed the international laws governing the bioprospecting of human and non-human genetic materials and their limitations. It has also examined the importance of regulating the bioprospecting of human genetic materials. In the next chapter, this work will examine the national laws adopted by some countries to regulate bioprospecting and address the challenge of misappropriation through patents.

CHAPTER 4

NATIONAL LAWS AND PROPOSALS TO REGULATE BIOPROSPECTING

4.0 INTRODUCTION

As discussed above, the CBD[208], the Bonn Guidelines[209], and the Nagoya Protocol[210] proposed a solution to the challenges in the bioprospecting of genetic materials. The proposed solution mandated researchers to obtain prior informed consent and reach benefit-sharing agreements with donor countries. These requirements have helped reduce biopiracy challenges through the unauthorized collection of Genetic materials from developing countries. However, the CBD and Nagoya Protocol only regulates non-human genetic materials. As well, they do not regulate the collection of human genetic materials through bioprospecting. They also do not address the problem of patents on inventions from genetic human and non-human materials[211].

Countries began to make regulations to address the gaps in international law, particularly the enforcement of informed consent Benefit Sharing and misappropriation through patents. This Chapter will analyze states' attempts to regulate bioprospecting, the shortcomings of these laws, and the proposals for a harmonized law.

---

[208] Convention on Biological diversity (CBD) entered into force on the 29th of December 1993.

[209] The Bonn Guidelines on Access to Genetic resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization 2002. Parties to the Convention on biodiversity met at their sixth conference and adopted the Bonn Guideline.

[210] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable sharing of Benefit Arising from their utilization to the convention on Biological Diversity. It was adopted on 29th October 2010, in Nagoya Japan.

It entered into force on 12 October 2014. 90 days after the deposit of the fiftieth instrument of ratification.

[211] Pablo Damian Colmegna, Njoseph Alvaro Gonzales Pariente; Magdalena Belen Rochi Monagas; Maria Florencia Garcia; Maria Paloma Espnosa Alonso, "Disclosure of the Origin of patented Genetic resources: Will a Plurilateral Agreement be a possible option?" 2018 International Economic law clinic.

4.1 PROPOSALS FOR DISCLOSURE OF SOURCE OF ORIGIN

Disclosure of origin, also known as disclosure of the source of origin, was first proposed by civil society groups in 1997. It was a proposal to aid developing countries in protecting their traditional knowledge and genetic materials from misappropriation through patents[212]. Disclosure of origin requirement was first introduced as a requirement that a patent application discloses the country which is the source of the genetic materials or traditional knowledge in the invention.

As bio-prospecting and biotechnological research advanced, a new proposal for disclosure of the origin of genetic resources arose.[213]The cross-border nature of bioprospecting raised new concerns about enforcing informed consent and benefit sharing concerning patent rights for inventions.[214]

The new proposal of disclosure of origin requirement mandated patent applicants to disclose the source of genetic resources and proof of prior informed consent and benefit sharing agreements.[215]

The disclosure requirement also attached the sanction of rejection or invalidation of the patent for failure to comply.

Developing countries have been able to address some of the concerns related to the misuse of these resources and knowledge through the inclusion of disclosure requirements into national laws.[216]

---

[212] AJ Park, Disclosure of origin of genetic resources and traditional knowledge in the patent regime. LEXOLOGY. (September, 2018). Online:<https://www.ajpark.com/insights/disclosure-of-origin-requirements-in-new-zealand-patents-regime>.

[213] Alison L. Hoare, Richard G. Tarasofsky, "Asking and Telling: "Disclosure of Origin" requirements in Patent Applications make a difference?" (April 2007) 10(2) The Journal of Worlds Intellectual property at 149-169. Online: <https://doi.org/10.111/j.1747-1796.2007.00318.x>

[214] Micheal Blakeney, Proposals for the disclosure of origin of Genetic resources in Patent applications.(2022) Queen Mary Intellectual Property Research institute. Online: <https://www.researchgate.net/publication/237325587_Proposals_for_the_disclosure_of_origin_of_Genetic_Resources_in_Patent_Applications>.

[215] Dominic Keating, "Access to Genetic Resources and Equitable Benefit sharing through a new disclosure requirement in the Patent system: An issue in search of a Forum". (2005) 87 J Pat and Trademark office Soc'y at 525-526.

[216] Pablo Damian Colmegna, Njoseph Alvaro Gonzales Pariente; Magdalena Belen Rochi Monagas; MAria Florencia Garcia; Maria PAloma Espnosa Alonso, " Disclosure of the Origin of patented Genetic resources : Will a Plurilateral Agreement be a possible option?" (2018) International Economic law clinic.

For instance, Article 31 of Brazil's provisional measure No.2[217] mandates a patent applicant to disclose the country of origin. Article 16[218] requires that where there is a commercial use of genetic materials and traditional knowledge, evidence of informed consent, benefit sharing, and mutually agreed terms must be provided.

Several States have enacted laws to enforce the requirements of disclosure of the source of origin in Patent applications through three main approaches.[219] These approaches are[220] the Voluntary disclosure requirements, the Mandatory disclosure of requirements, and the Mandatory disclosure of Prior informed consent, benefit sharing, and mutually agreed on terms.

4.1.1 Voluntary disclosure requirement[221]:

This type of disclosure requirement is optional for Patent applicants and does not require a patent applicant to provide proof of obtaining prior informed consent and benefits sharing. Voluntary disclosure does not also attach sanctions or legal consequences for failure to disclose.

The European Union adopted this approach in 1998 under the European Union Directive 98/44 EC on the legal protection of biotechnological inventions. The directive "encourages" the patent applicant to disclose the geographical origin where the invention is from plant or animal materials. Failure to comply with the disclosure requirement does not affect the invention's patentability.

---

[217] 186-16 cited in Micheal Blakeney. Proposals for disclosure of origin of Genetic resources in Patent applications. Queen Mary's Intellectual property Research institute. Online: <Researchgate.net/publication/237325587_proposals_for_the_disclosure_of_origin_of_Genetic_Resources_in_Patent_Applications>.

[218] Brazil Provisional Measure No. 2 ibid.

[219] Zhengyuan Liao, "Disclosure requirement of source of origin in Patent law: the Pros and Cons of the "layer" between patents ad genetic resources and traditional knowledge". 2021. 10(4) Journal of Civil and legal sources .

[220] Zhengyuan Liao, "Disclosure requirement of source of origin in Patent law: the Pros and Cons of the "layer" between patents ad genetic resources and traditional knowledge". 2021. 10(4) Journal of Civil and legal sources .

[221] World Trade Organization. TRIPS: Reviews, Article 27.3(b) and related issues. Background and the current situations. https://www.wto.org/english/tratop_e/art27_3b_background_e.htm

Germany has also adopted this voluntary approach to disclosing the source of origin under the Germany Patent Act of 1980. Section 34(a) of the patent act provides that an invention from plant or animal origin "should" include information on the source of origin. The requirement for disclosure does not, however, affect the patentability of a patent. Some authors describe the voluntary approach to disclosure requirements as a mere formality.

4.1.2 Mandatory disclosure requirement of the source of Origin[222]:

This is a requirement for disclosure provided in the patent law or another access and benefit sharing arrangement. The patent applicant must disclose the source of origin and traditional knowledge under the national patent law.

Under this disclosure requirement, the law attaches a sanction where the patent applicant fails to comply. Countries like Switzerland and Vietnam have adopted this approach. In article 49a of the Federal Act on Patents, an applicant must include information on the source of genetic resources in his patent application. Where the inventor or patent applicant does not know the place of origin of the genetic materials his invention is derived from, he must submit a statement to that effect. Article 81 provides a time limit for the applicant to comply and provide the source of origin or pay a fine of up to 100,000 Frances.

4.1.3 Mandatory Disclosure Requirement of Prior informed consent, Benefit-sharing, and mutually agreed on terms[223]:

Mandatory disclosure requires not just disclosure of the source of origin but also that access and benefit sharing, prior informed consent, and mutually agreed on terms.

---

[222] Jacques De Werra . Fighting Against Biopiracy: Does the obligation to disclose in patent Applications truly help? 2009.42:1 Vanderbilt Journal of Transnational law at 143-179. Online:< https://www.archive-ouverte.unige.ch/unige:1480>.

[223] Hengyuan Liao, "Disclosure requirement of source of origin in Patent law: the Pros and Cons of the "layer" between patents ad genetic resources and traditional knowledge". 2021 10(4) Journal of Civil and legal sources.

[223] World Trade Organization. TRIPS: Reviews, Article 27.3(b) and related issues. Background and the current

Where an applicant fails to show evidence of prior informed consent or benefit sharing, there are legal consequences such as revocation or withdrawal of a patent or patent application. This disclosure requirement facilitates compliance with the access and benefit sharing agreement under the convention of biological diversity and the Nagoya Protocol.

However, the disclosure requirement's effectiveness was limited without an international law setting out the terms of disclosure of the source of origin and the consequences for non-compliance. The need for international regulations to create the obligation for the requirement to disclose the source of origin has led to different international debates.

Developing countries have made proposals before different international forums such as the conference of the parties to the CBD, the WTO, the WIPO standing committee on Patents, the WIPO intergovernmental committee on intellectual property and Genetics resources, Traditional knowledge and Folklore, and the WIPO PCT Reform Working Group, among others. There has been no consensus on this debate because of the differing opinion of states[224]. The next subheading will examine the proposals made by states to enforce compliance with the disclosure of origin requirement.

4.2 PROPOSALS ON THE ENFORCEMENT OF THE DISCLOSURE OF SOURCE OF ORIGIN

The debates on disclosure of origin are based on different countries' proposals on how and which International intellectual property regime can be used to enforce compliance with the requirement to disclose[225].

Sadly, the focus of these debates is not just the conservation of biodiversity and regulation of bioprospecting but the economic interest of some countries.[226] This work will examine the proposals to disclose under the different patent international bodies and the recommendations to amend international patent laws to include the requirement to disclose source of origin.

---

[224] WIPO Intergovernmental committee on intellectual property and Genetic resources, Traditional Knowledge and Folklore, the protection of traditional knowledge: Updated draft Gap Analysis, WIPO/GRTKF/IV/3816.

[225] Mahendra Pratap Singh Shekhawat, Manvendra Singh Shekhawat and Reneeta Pal, "The Doctrine of Disclosure of Origin requirement". 2022: ii (iii) Indian Journal of Integrated research in law.

[226] Ibid.

4.3 ENFORCEMENT UNDER PATENT BODIES

The proposals to implement the requirement disclosure were made to three central bodies: the committee of the CBD, the Standing committee of the WIPO, and the TRIPS council. There were also proposals for disclosure outside patent laws and the use of bilateral contracts.

4.3.1 DISCLOSURE OF ORIGIN WITHIN THE CBD[227]

At the 6th conference of the convention of biological diversity,[228] the need to establish disclosure of origin in patent applications was addressed.

The panel of experts, an Ad-hoc open-ended Working group on access and Benefit-sharing, and the 6th conference committee argued that the disclosure of genetic resources aids the enforcement of compliance with prior informed consent and mutually agreed on terms on benefits sharing.

The USA is one of the challenges developing countries face in enforcing the CBD's requirement of prior informed consent and benefit-sharing. However, a signatory to the CBD[229] has not ratified its provisions. The US is at the forefront of bio-prospecting and biotechnological research, and its failure to ratify the CBD meant that countries had to resort to contractual agreements to enforce prior informed consent and benefit-sharing arrangements. It also made developing countries seek alternative legal regimes to implement the disclosure requirement under the WIPO treaty and the TRIPS Agreement.

4.3.2 DISCLOSURE OF ORIGIN UNDER THE WIPO

In 1999, a proposal was made to the WIPO standing committee on patents to create a patent law treaty. There was a proposal for a Patent Law Treaty (PLT) to harmonize patent office procedures.

---

[227] CBD request to WIPO on the interrelation of Access to Genetic resources and Disclosure Requirements establishing an adequate framework for a WIPO response, Background note. Dec 2004. Center for Environmental law. https://www.ciel.org/wp-content/uploads/2015/03/CDB_Request_WIPO_Dec04.pdf.

[228] 7th-19th April 2002, Hague. Netherlands.

[229] Convention on Biological diversity. List of parties. https://www.cbd.int/information/parties.shtml.

Colombia proposed the introduction into the PLT of the requirement of proof that a genetic material used in the invention was legally acquired. The proposal also specified that the country of origin be mentioned, and evidence of prior informed consent provided. The proposal of Colombia was criticized as introducing a substantive matter into a procedural law.

The PLT was adopted in 2000. It entered into force in 2005[230]. The PLT is open to members of WIPO and or parties to the Paris Convention[231].

Parties for and against the proposal agreed to debate the proposal along with the substantive Patent law treaty (SPLIT) in 2003. The SPLIT draft proposed in articles 13(4) and 14(3) that the contracting parties be mandated to comply with the laws on access to genetic resources and protection of traditional knowledge[232].

In 2000, Geneva submitted a proposal for disclosure of origin before the WIPO General Assembly on behalf of a group of Latin American Countries and the Caribbean (GRULAC). The proposal suggested the creation of a standing committee to provide practical methods to protect Intellectual property rights in traditional knowledge and genetic materials.

In May 2004, the United States, Japan, and the European Patent Office submitted their proposal that the SPLIT be limited to issues of novelty, prior art, the time frame of the patent, and inventive steps.[233] Developing countries insisted that disclosing the origin of genetic resources, traditional knowledge, and patentability be addressed in the draft. The lack of consensus led Standing Committee on Patent law to refer the proposed treaties to the WIPO general assembly.[234] An agreement has still not been reached between parties.[235]

---

[230] WIPO. Summary of Patent Law Treaty 2000. Online:< https://www.wipo.int/treaties/en/ip/plt/summary_plt.html>

[231] Ibid.

[232] WIPO General Assembly. Fifty-fifth Session. Geneva, July 14 to 22 2022. Online: < https://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_55/wo_ga_55_6.pdf>

[233] International Bureau. "ENLARGED" CONCEPT OF NOVELTY: INITIAL STUDY CONCERNING NOVELTY AND THE PRIOR ART EFFECT OF CERTAIN APPLICATIONS UNDER DRAFT ARTICLE 8(2) OF THE SPLT. Online:<https://www.wipo.int › scp › novelty › documents> December, 2004.

[234] WIPO Member states approve Diplomatic conferences for two proposed Accords. Geneva, July 21, 2022. PR/2022/893. Online: https://www.wipo.int/pressroom/en/articles/2022/article_0009.html

[235] Ibid.

4.3.3 DISCLOSURE OF ORIGIN DEBATES WITHIN THE TRIPS COUNCIL

In 2001, signatories to the World Trade Organization Agreement met in Doha, Qatar. The purpose of this meeting was to negotiate certain subjects and discuss implementation issues in the agreement.[236] Developing countries raised concerns on issues of implementation of the current WTO agreements[237]. One of the issues raised is a proposed review of some TRIPS agreement provisions. Some countries suggested that the TRIPS provides geographical indications protection for wines and Spirits to be extended to other products.[238]

They also proposed a review of the patentability of plants and animal inventions under the TRIPS.[239] These issues were reserved for further deliberations.

In 2002, several proposals were made within the WTO TRIPS Council. One of the significant proposals was for the amendment of Article 27(3)(b) or 29 of the TRIP agreement patentability requirements to include:

a) The source of origin of genetic materials used in an invention.

b) Traditional knowledge used in the invention

c) Evidence that prior informed consent was obtained, and a Benefit-sharing agreement was reached with the source of Origin.

Developed countries like the US have criticized this proposal for several reasons. The first argument is that Intellectual property law is not a tool to regulate the access and use of genetic materials, bioprospecting, or the commercialization of inventions through patents.

The US instead suggests the use of bi-lateral contracts between countries.

---

[236] World Trade Organization. The Doha Declaration Explained. https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

[237] World Trade Organization. The Doha Declaration Explained. https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

[238] Ibid.

[239] Ibid.

4.4 ENFORCEMENT UNDER INTERNATIONAL PATENT LAWS

The Proposals on implementing disclosure of origin can be summarized as:

The TRIPS amendment, Patent Cooperation Treaty Amendment, Disclosure through other laws and the use of other laws and use of national legislation and courts.[240]

4.4.1 THE TRIPS AMENDMENT PROPOSAL[241]:

The TRIP amendment proposes that patent applicants be mandated to disclose the country of origin of genetic materials and traditional knowledge used in their inventions. The patent applicant must also provide evidence of prior informed consent and mutually agreed on terms for benefit sharing. The US is the main opposer of the TRIPS amendment proposal. This was proposed by Brazil, India, Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, and Thailand to amend the TRIPS agreement.

4.4.2 PATENT COOPERATION TREATY AMENDMENT[242]:

Switzerland proposed to amend WIPO's PCT to allow domestic laws to mandate disclosure during patent applications. Failure to meet these requirements could lead to a refusal, or if the patent is granted, it can be invalidated if fraudulent intent is discovered.

Cuba also supported the proposal to amend the Patent Cooperation Treaty of WIPO[243]. Under this amendment, members will be allowed to gradually amend their national laws to enforce disclosure requirements.

---

[240] World Trade organization. TRIPS : Reviews, Article 27.3(B) and Related issues. Background and the current situation. Wto.org/english/tratop-e-/trips-e/art27_3b_background_e.htm.

[241] World Trade organization. TRIPS : Reviews, Article 27.3(B) and Related issues. Background and the current situation. Wto.org/english/tratop-e-/trips-e/art27_3b_background_e.htm

[242] World Trade organization. TRIPS : Reviews, Article 27.3(B) and Related issues. Background and the current situation. Wto.org/english/tratop-e-/trips-e/art27_3b_background_e.htm

[243] Jonathan Carr, "Agreements that divide: TRIPS VS. CBD and proposes for mandatory disclosure of source in Patent Applications". 2008. 18 J. Transnational L and POL'y at 131.

Switzerland proposed that the disclosure requirement be formal rather than substantive. Where a patent application fails to disclose, the applicant will be given some time to satisfy the requirement under the Patent Cooperation Treaty; where the applicant fails to disclose for fraudulent reasons, the patent can be invalidated even after the patent is granted.

The PCT amendment proposes a system of informing foreign sources of the details of Patent applications. This would ensure that countries are informed of the patent application connected to them in another country.

4.4.3 DISCLOSURE OUTSIDE PATENT LAW[244]:

This was proposed by the European law to mandate Patent applicants to disclose the source of origin of genetic materials, and the consequence for that meeting this requirement should be outside patent law.

The European communities proposed a change through the intergovernmental committee on Intellectual property and Genetic resources, traditional knowledge, and Folklore (IGC) of WIPO. This proposal puts the duty on each country to enforce the disclosure of origin in the patent application.

The IGC proposal is a formal and not a substantive requirement. Under this proposal, where a patent has been granted without disclosure of origin, the legal sanctions can only be administrative and Civil sanctions.

4.5 CRITIQUES OF THE DISCLOSURE REQUIREMENT

In this subsection, this work will outline the challenges of the current proposals before the international IP bodies. These challenges include the fact that tehre are numerous proposals on the method of enforcement of disclosure of Origin, the Lack of clarity of the proposals for disclosure of origin, and The politics and economic stakes in the proposals

[244] World Trade organization. TRIPS : Reviews, Article 27.3(B) and Related issues. Background and the current situation. Wto.org/english/tratop-e-/trips-e/art27_3b_background_e.htm

1. **Numerous Proposals on the method of enforcement of disclosure of Origin:**

Some Authors have argued that disclosure of origin can be better enforced through the Mandatory disclosure agreement than the voluntary disclosure agreement[245]. They argue that some countries have included mandatory disclosure of origin requirements in their patent laws. These mandatory disclosure requirements can, however, only be enforced within the jurisdiction of these countries. It cannot be enforced outside the jurisdiction, except both parties have a contractual agreement.

The purpose of the disclosure of origin is to reduce the misappropriation of genetic materials by ensuring compliance with obtaining informed consent and benefit sharing agreement[246]. Where the disclosure is merely voluntary and has no sanctions for non-compliance, it defeats the purpose of the disclosure of origin requirement. It means a party can choose whether to disclose the source of origin of his invention, which could have been obtained without informed consent

2. **Lack of Clarity:**

There is a need for clarity on what disclosure of origin requires and what is being disclosed. As stated above, if disclosure of origin aims to prevent misappropriation,

merely saying the source or origin of the materials used in creating the invention is insufficient.

Furthermore, there have been arguments that one purpose of disclosure of origin is to enforce the provisions of Article 15 of the CBD. The proposals on disclosure of Origin should also specify what proof of informed consent and benefit sharing entails. Is it sufficient that the patent applicant obtained consent before collection and reached a benefit-sharing agreement with the donor? Should there also be consent to commercialize where there is a change of intent to a commercial one after consent has been obtained for a different use?

---

[245] Joshua D. Sarnoff and Carlos M. Correa, "Analysis of options for implementing disclosure of origin disclosure of origin requirements in intellectual property applications". United Nations Conference on Trade and Development (UNCTAD). 2005 Digital commons@American University Washington College of Law. Traditional knowledge and culture.

[246] Ibid.

3. **Applicability to Genetic human resources:**

The disclosure of origin requirement was first formally proposed at the sixth conference of parties (COP) to the convention on biological diversity (CBD) in 2002. The arguments for enforcing this requirement have been tied to the need to ensure compliance with Article 15 of the CBD. The provisions of the CBD apply solely to non-genetic materials. No international law explicitly addresses the bioprospecting of human biological materials. This seems to have been left to the ethical committees of medical boards.

This lacuna created a means for the misappropriation of human genetic materials through patents. Although some authors have argued that the requirement of disclosure of origin applies to inventions from human and non-human genetic materials,[247] this view is not reflected in debates before the international IP regimes.

Furthermore, the debates on inventions from human genetic materials have followed a different trail.

The debates on inventions from human genetic materials first analyzed the question of the appropriateness and morality of patenting human genetic materials[248]. The debates have centred on the ethics of patenting genes and the issue of commodification of human tissue as a breach of human rights.

Patent offices like the USA, Canada, and Japan have separated issues of ethics and morality from their patent laws[249]. This debate did not deter the grant of patents on inventions from human genetic materials in such countries. The USPTO grants patents on inventions from isolated human genes that meet the requirements for patentability, and the inventor must describe the sequence's isolation and its use for it.

[247] Timothy Caulifield, E. Richard Gold and Mildred K. Cho, "Patenting human genetic materials: refocusing the debate". 2000 1 (3) Nat. Rev. Genet at 227-231.

[248] Ibid.

[249] Timothy Caulifield, E. Richard Gold and Mildred K. Cho, "Patenting human genetic materials: refocusing the debate". 2000 1 (3) Nat. Rev. Genet at 227-231.

The debates on patenting of human genetic materials have shifted over the years. The focus was no longer on the patentability of the gene but on the issue of ownership and property rights in human genetic materials[250]. There has been no consensus on the issue, and the courts have repeatedly held that property rights do not exist in human genetic materials separated from the body.[251] This legal principle has affected the Donors ability to sue for misappropriation of his genetic materials without his consent and any agreements on benefits sharing.

However, issues of misappropriation in bio-prospecting human genetic materials take a different form. The focus of the Donor in such cases is not just that prior informed consent was obtained but that the terms for which consent was given are honoured.

This is because it is almost impossible for the biological materials of an individual, community, or state to be taken without the consent of the donor. The issue in contemplation is the purpose for which the sample was given.

Where a researcher obtains consent from a community, state, or individual for one purpose and uses it for another, there should be a form of legal redress available to such a Country.

The challenge is where a patent has been obtained on an invention from human genetic materials without the consent of the Donor to commercialize; the donor can only obtain damages. The lack of "informed consent" on commercialization is insufficient to overturn such a patent. The ethics of using human biological materials within the terms of consent granted cannot be enforced in patent applications without an amendment of the patent law.

[250] Pila, J. 2020. Property in human genetic material: An old legal question for a new technological age. Online:< http://www.law.ox.ac.uk/research-and-subject-groups/property-law/blog/2020/05/property-human-genetic-material-old-legal>

[251] Pila, J. 2020. Property in human genetic material: An old legal question for a new technological age. Online:< http://www.law.ox.ac.uk/research-and-subject-groups/property-law/blog/2020/05/property-human-genetic-material-old-legal>

For disclosure of origin to apply to inventions from human genetic materials, the law should be amended to specify the applicability of informed consent and benefit sharing in bio-prospecting human genetic materials, and certain amendments must be made to the current proposals for disclosure of origin. This work will critique the current proposals for disclosure of origin in the following subheading.

4.The politics and economic stakes in the proposals:

Patents constitute an effective form of commercialization in the biotechnology industry.[252]

Biotechnological patents are fuelled by bioprospecting, and the increase in bioprospecting and misappropriation of genetic materials has made regulating it necessary.[253]

The regulation of bioprospecting has focused on its enforcement through patent laws in the last decade.

Some authors noted that the push for regulation of biotechnological patents could affect developed nations' economies. The US is one of the countries at the fore of biotechnological research and inventions. The US has also been one of the countries that opposed the proposals for amendments to international laws seeking more regulation for patenting inventions from genetic materials. Unfortunately, the US patent practice also affects the international patent law system[254].

---

[252] Joshua D. Sarnoff and Carlos M. Correa, "Analysis of options for implementing disclosure of origin disclosure of origin requirements in intellectual property applications". United Nations Conference on Trade and Development (UNCTAD). 2005 Digital commons@American University Washington College of Law. Traditional knowledge and culture.

[253] Alison L. Hoare, Richard G. Tarasofsky. Asking and Telling: "Disclosure of Origin" requirements in Patent Applications make a difference? (April, 2007) 10(2) The Journal of Worlds Intellectual property at 149-169. Online:< https://doi.org/10.111/j.1747-1796.2007.00318.x>

[254] Joshua D. Sarnoff and Carlos M. Correa, " Analysis of options for implementing disclosure of origin disclosure of origin requirements in intellectual property applications". United Nations Conference on Trade and Development (UNCTAD). 2005 Digital commons@American University Washington College of Law. Traditional knowledge and culture.

The result is that some authors have suggested other methods of enforcing the requirements of enforcing informed consent and benefit sharing outside the patent system. These suggestions still beg whether another law can invalidate a patent granted where an invention has fulfilled the patentability requirements. If this was the case, the proposal should be to amend the CBD to include provisions invalidating patents that do not fulfil the requirements under Article 15.

Over the years, the reports from the different intellectual property bodies have been inconclusive on the disclosure of origin, stating that members have not reached a consensus. Does the question remain if the failure to adopt a proposal is because of the different proposals by states or simply a question of politics and power imbalance? Can developed countries not make their profits where the law mandates them to disclose the source of origin? Will the mandatory disclosure of origin requirement hinder bioprospecting? This work will attempt to analyze these questions in the debates on disclosure of origin under the next subheading.

4.6 OTHER APPROACHES PROPOSED BY COUNTRIES

Several authors have written about disclosure of origin and the options for enforcement. For instance, Kollia Paraskevi[255] opines that the proposal for the Mandatory disclosure of the source of origin is better incorporated through the TRIPS agreement[256]. The territorial nature of IP means that implementing disclosure requirements in developing countries would not ensure compliance in foreign countries.

Disclosure of origin requirement must be enforced through international law to be binding and significantly economically. Developed countries have often dismissed concerns in patent law that are not economically related. The political analysis of developed countries shows no effort by developed countries to consider mandatory disclosure of Origin requirements.

Kollia, however, posits that a failure to meet the disclosure of origin requirement should not invalidate an invention, and the patent application should be given time to remedy this.

---

[255] Disclosure of Origin in Patent law: How to Enforce it best? MIPLC Master thesis (2012/2013). http://www.miplc.de/research/

[256] Article 64 of TRIPS Agreement.

4.6.1 CERTIFICATION SYSTEM:

Kollia[257] states that an alternative to the TRIPS amendment is the use of a certification system. The certification system provided by the Nagoya protocol would provide evidence that the applicant obtained informed consent and a benefit-sharing agreement was reached.

The weakness of this system is that it would also require incorporation into developed countries. There is a problem with different countries having different requirements for certification of compliance. Furthermore, the different stages and bureaucratic processes a Donor would go through to get certified.

4.6.2 USE OF A WORLDWIDE DATABASE

Glowka Lyle[258] on the other hand, suggested the creation of a Worldwide database to improve the search for prior art[259]. Developing countries raised concerns about how this database could misappropriate their genetic resources and traditional knowledge rather than remedy it. This is because the traditional knowledge of Indigenous people would be put in the public domain without their consent.

Japan suggested an online authentication system that would give access to only verified patent office personnel. The challenge with this solution is first, databases alone would not prevent the misappropriation of Traditional Knowledge or Genetic resources. The suggestion did not include a system of ensuring developed countries use it.

This chapter has analyzed the attempts by countries to regulate bioprospecting, particularly misappropriation through patents. There is currently a lack of consensus on enforcing the proposal of disclosure of the source of origin requirement. The next chapter will propose the re-imagining of the regulation of bioprospecting through the TRIPS Agreement. It will do so with the help of both Critical IP and New constitutionalism theory.

---

[257] Disclosure of Origin in Patent law: How to Enforce it best? MIPLC Master thesis (2012/2013). http://www.miplc.de/research/

[258] Towards a certification system for bioprospecting activities. Commissioned by the Swiss State Secretariat for Economic Affairs (2001) 41-45

[259] WIPO, Patent system, and Genetic Resources- Documents submitted in Japan. WIPO/GRTICFIC/9/13 20April 2006. Para 24; WIPO. Joint Recommendation on the use of Databases for Defensive protection with Genetic Resources- Document submitted by the Delegations of Canada and others. WIPO/GRTICF/IC/24/7 28 March 2013. 1-3.

CHAPTER FIVE

RE-IMAGINING BIOPROSPECTING THROUGH THE TRIPS

5.0 INTRODUCTION

Civil societies and developing countries proposed disclosure of origin as a mechanism for curbing the misappropriation of genetic materials through patents. On the other hand, misuse of human genetic materials occurs when human genetic materials are used in a manner the Donor did not consent to and will not be compensated for.

Disclosure of source of origin was proposed to mandate a patent applicant to disclose the source of origin of the genetic materials used in the invention. It may also prove that informed consent was sought and a benefit-sharing agreement reached. The nature of patents, however, makes enforcing the disclosure of the source of origin requirement difficult. Patents are territorial. Each country's patent laws determine the criteria for patentability, the time frame and protection for a patent granted, and the grounds for revocation of a patent. A patent that has fulfilled the requirement for patentability under the patent law will therefore not be invalidated by the provisions of another law or contract. Some developing countries have incorporated the disclosure of origin requirement into their local laws[260]. Misappropriation through patents occurs because most developed countries are not required to disclose the origin source. Developing countries made different proposals to enforce the disclosure of origin requirement in developed countries.

The main proposal by developing countries was to enforce the disclosure requirement through international law and bodies. Consequently, different countries made the proposals to incorporate disclosure of origin before the WIPO for the PCT and the WTO for the TRIPS.[261]

These proposals were for an amendment of the PCT or the TRIPS for the disclosure of origin requirement to be included as a voluntary or mandatory requirement for patentability.

---

[260] Brazil, Viet Nam, South Africa, Norway among others.

[261] The Trips Amendment proposal by Brazil, Chile, Colombia, Ecuador, Peru, Thailand, The African group and African Caribbean and Pacific group. The Patent Cooperation Treaty Amendment by Switzerland, Disclosure outside patent law by the European Union.

The debates on these proposals have been inconclusive, and the issue of misappropriation through patents has remained unaddressed. Applying critical IP theory, this work argues that the challenge of enforcing the disclosure of origin requirement was a political one. It takes the position that the debate against disclosure of origin is not about maintaining the objectives of the TRIPS but about avoiding regulations of inventions from genetic and human genetic materials. Through the critical IP theory, this work identified that patenting of bioprospecting human genetic materials is not regulated. That obtained informed consent is an on-the-surface action. That disclosure of origin for human genetic materials should include evidence of informed consent to commercialize through patents and share the benefits of the patented invention.

This work has also deconstructed the arguments of developed countries led by the US to reveal an attempt to protect the profits and biotechnological stock projections at all costs. The US's disputes, laws, and actions show the approach of profit maximization at the expense of the rights of Donors. Finally, Chapter three proposed re-imagining the regulation of bioprospecting through the amendment of the TRIPS.

This Chapter will attempt to re-imagine the regulation of bioprospecting to address the issues of misappropriation of human genetic resources through patents and harmonize the enforcement of the disclosure of origin requirement. It will do so by making a case for the amendment of the TRIPS agreement to include the disclosure of origin requirement. It will proceed in three parts. First, this chapter will give an overview of the TRIPS agreement and its features that make it preferable to other international patent treaties to enforce the disclosure of the source of origin requirement.

Second, it will make a case for the modification of Article 27.3b on the requirements of patentability and specification on what to disclose for human and non-human genetic materials. Lastly, it will examine possible approaches to the debate against the TRIPS amendment from Authors and through the theoretical lens of new constitutionalism.

5.1 EXAMING BIOPROSPECTING THROUGH CRITICAL IP THEORY

One of the goals of the critical IP theory is to address power hierarchies within and among groups without denying the liberty of market-based economies.[262] Critical IP theory posits that privileged social groups are over-represented in the economic, political, and social legal system.[263] The critical IP theory also argues that liberal institutions and systems contribute to the inequalities in a system by using their influence and structure within that system to maintain the status quo.[264]

As previously mentioned, the US strongly opposed the proposal to amend the TRIPS provisions on patentability provisions to include a mandatory requirement to disclose the source of origin.

The TRIPS amendment proposal is not limited to the disclosure of the source of the genetic material.[265]The disclosure requirement includes proof that informed consent was obtained and benefit sharing agreement was reached.[266]

The US has argued that Article 27(b)(3) TRIPS agreements should not be extended to issues of bioprospecting[267]. The US further argued that the TRIPS did not specifically address bio-piracy of genetic materials because that is beyond the TRIPS' purview and is better regulated under national laws[268].

---

[262] Chon, Margaret, Intellectual Property Research and Critical Theories. Handbook on Intellectual Property Research 2018. (Irene Calboli and Lillà Montagnani, eds. Edward Elgar Press, Forthcoming), https://ssrn.com/abstract=3219966.

[263] Ibid.

[264] Joshua D. Sarnoff and Carlos M. Correa, "Analysis of options for implementing disclosure of origin disclosure of origin requirements in intellectual property applications. United Nations Conference on Trade and Development (UNCTAD). (2005) Digital commons@American University Washington College of Law. Traditional knowledge and culture.

[265] Ibid.

[266] Joshua D. Sarnoff and Carlos M. Correa, "Analysis of options for implementing Disclosure of origin Requirements in intellectual property applications". 2005.1. American University Washington College of law. Online: <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1002&context=pijip_trad_knowledge>

[267] Ibid.

[268] Council for the Trade related aspects of intellectual property Rights, communication from the United States. Article 27.3(B), relationship between the TRIPS agreement and the CBD , and the protection of traditional knowledge and folklore, Para. 4. IP/C/W469 (Mar. 13, 2006).

The US proposed that member countries must create laws to enforce disclosure requirements. The US further argued that modifying the TRIPS to include disclosure requirements would create "legal uncertainty and other negative consequences."[269]

Brazil is one of the leading proponents of this proposal and is recognized as one of the most biodiversity-rich countries in the World.[270] Brazil was also the first signatory to the CBD and has included a mandatory disclosure requirement in its national laws[271]. Like other developing countries, Brazil responded to the US proposal for contract-based enforcement as inadequate to address the challenge of misappropriation, bad patents, and illegitimate bioprospecting.

From the critical IP theorist perspective, social change can only occur if the existing legal system is re-imagined. The aim of re-imagination is a reduction in inequality affecting the weaker groups. The argument and insistence on systems change can be seen as impractical because of the law and the push back by existing legal powers. This is the case in the debates for disclosure of origin, particularly the proposal for Mandatory disclosure through the TRIPS Amendment.

Despite the seemingly obvious reasons and need for mandatory disclosure of origin, developed countries have opposed this proposal. According to the Pacific research institute, any uncertainty about patent protection could reduce biotechnological and pharmaceutical research in developed countries by 25% by 2025.[272]

---

[269] Ibid.

[270] Trade-related aspects of intellectual property Rights, communications from Brazil: Review of the provisions of article 27.3(b), IP/C/W/164 (Oct. 29, 1999).

[271] Craig, Carys J., Critical Copyright Law and the Politics of 'IP'. Draft chapter for Emilios Christodoulidis, Ruth Dukes & Marco Goldoni (eds), Research Handbook on Critical Legal Theory (Edward Elgar Press, 2019),Online:< https://ssrn.com/abstract=3287377>

[272] Timothy A. Wolfe and Benjamin Zycher, "Biotechnological and Pharmaceutical Research and development investment under a patent-based Access and Benefit sharing regime". (May, 2005). 2. Online:<https://www.wipo.int/export/sites/www/meetings/en/2006/scp_of_ge_06/presentations/scp_of_ge_06_zycher.pdf>

Biotechnological companies in developed countries are also projected to lose over $144 million in profit from such uncertainty.[273] Developed countries like the US do not also consider the economic impact bio-piracy has on developing countries. Developing countries have complained of the injustice of paying royalties to biotechnological companies for inventions from their genetic resources.

The question is, how can the interests of both developing and developed countries be protected? Critical IP theorists believe that the law has tools for transforming a system. For change to occur within the Patent system, the law and the system must be reformed. To reimagine the existing patent system, the following steps outlined by Margaret Chon[274] should be adopted:

5.1.1. RECOGNIZING:

The concept of recognizing proposed by Margret Chon[275] identifies the constructed shared social constructs and concepts. It also frees up space for rethinking existing social and legal arrangements rather than revisiting the politics of what is possible.

The first step in this work is identifying that the concept of bioprospecting applies to human genetic materials like non-human ones. This work recognizes that medical laws and ethics[276] do not regulate the bioprospecting of human genetic materials. It also recognizes that the international[277] and national laws regulating bioprospecting do not apply to human genetic materials, and neither addresses the challenge of misappropriation through patents.

---

[273] Ibid.

[274] Intellectual Property Research and Critical Theories. Handbook on Intellectual Property Research 2018. (Irene Calboli and Lillà Montagnani, eds. Edward Elgar Press, Forthcoming), https://ssrn.com/abstract=3219966.

[275]

[276] CIOM Guidelines, FAO, etc.

[277] The Convention on Biological diversity, the Bonn guidelines and the Nagoya Protocol.

The second step is to identify the hypocrisy in the debates for the proposed solution to disclose the source of origin requirement. The hypocrisy of developed countries, mainly the US, shows in their actions in protecting their economic interests only. According to Keith Aoki:[278]

> "The hypocrisy of western demand for intellectual property protection is twofold: not only do developing countries pay a high premium for the patented products that are re-introduced in their countries (Yet made from local resources), but developing countries are unable to use the intellectual property framework to protect against the piracy of their own indigenous and local resources and knowledge."

The arguments of the US show the hypocrisy of the debates. It is not promoting bioprospecting. It is also not about balancing access to biodiversity; it is simply to maintain the economic stake of developed countries through patents.

The US stance against the amendment of the TRIPS is not peculiar to the TRIPS. The US argument that any amendment of the TRIPS Agreement would cause uncertainty is not to maintain the TRIPS standard but simply the US trying to block any avenue that would force it to observe the laws regulating bioprospecting. Our argument is based on the attitude of the US to laws that attempt to control bioprospecting. The US has continually argued that Intellectual property rights and regulations are inappropriate for regulating bioprospecting.

When the CBD was first signed into law, the United States was not a signatory.[279] It argued both that the provisions of the CBD were unbalanced,[280] and that the CBD sought to transfer technology from developed to developing countries.[281]

---

[278] "Neo-colonialism, Anticommons property and biopiracy in the (Not-so-brave) New world order of international intellectual priority protection". (1998) 6 IND. J. GLOBAL STUD. 11, at 47-50. (1998).

[279] Greg K. Venbrux, "When two worlds collide: ownership of Genetic resources under the convention of biological diversity and the agreement on Trade-related Aspects of Intellectual Property Rights". (2005) 5 U. PITT J. TECH, L. & POL'Y at 5.

[280] Ibid.

[281] Ibid.

The US also argued that the CBD would impede biotechnological innovations and research and reduce access to biodiversity.[282]

The CBD, however, puts no responsibility on developing countries to recognize the patent protection from developed countries.[283] Developing countries like Brazil argued that they had a right to protect and control how their biological resources are used. The US has signed the CBD but never ratified it.[284] Some Authors believe that the US became a party because it thought it would cost more if it didn't become a signatory.[285]

The move to become a party without signing is itself political and not an effort to comply with bio-prospecting regulations. In applying the concept of recognizing, this work identifies the reasons for the US opposition of the disclosure requirement.

The US argued that the debates and proposals for disclosure of origin should be fact-based. The US pointed out that developing countries like Peru assumed that genetic materials collected from foreign countries were obtained illegally. Peru had submitted papers citing "bad patents," misappropriation, and bio-piracy as the main reasons the TRIPS should be amended. The US claimed that national disclosure of origin requirements and contracts between contracts requiring proof of informed consent and benefit sharing would suffice to deter misappropriation.

Countries like Brazil argued that this would not prevent patent offices from granting a patent where has genetic materials were taken without permission. There would be no means of enforcing compliance in a state with no disclosure requirement. The US argued that the chances of a "bad patent," a patent granted on illegally obtained genetic materials, is rare. There is, however, no way of proving which intentions are based on unlawfully genetic materials that there is no obligation to disclose.

---

[282] Ibid.

[283] Ibid.

[284] Greg K. Venbrux, "When two worlds collide: ownership of Genetic resources under the convention of biological diversity and the agreement on Trade-related Aspects of Intellectual Property Rights". (2005) 5 U. PITT J. TECH, L. & POL'Y at 5.

[285] Ibid.

The US further argued that it may be difficult to determine the "source of origin" of genetic materials. The issue of disclosure of origin is irrelevant in such cases. The response of developing countries is to name the country the genetic material was initially obtained from as the source of origin. The applicant should also provide proof that the genetic materials were obtained initially after informed consent and benefit-sharing agreements were reached.

Using the critical IP theory, this work also recognizes that to regulate bioprospecting properly, the proposed law must be amended to include human genetic materials.

The law should also include a mandatory requirement to disclose informed consent and benefit sharing before a patent is granted and be capable of enforcing the disclosure of origin requirements in developing and developed countries. These requirements can be best fulfilled under the TRIPS amendment proposals for the because the feature of the TRIPS Agreement. These features are examined below:

A The Features of the TRIPS Agreement:

The Trade-related Aspect of intellectual property rights agreement (TRIPS) was signed in 1994 after multilateral negotiation[286]. The TRIPS covers all areas of intellectual property rights: Patents, Copyright, Trademarks, and Geographical Indications. TRIPS was established for two reasons[287]:

First, before the TRIPS was signed, there was no universal law providing guidelines and incentives for multiple types of intellectual property protection. Second, TRIPS also provided international harmonization of the intellectual property system of countries to reduce piracy. The TRIPS Agreement also linked intellectual property rights to international free trade. In so doing, it obtained the signature and ratification of 164 countries, both developed and developing[288]. For instance, the United States, Japan, and the European Union are all signatories to TRIPS.

---

[286] Paul Katzenberger and Annette Kur. TRIPS and Intellectual Property in Friedrich - Karl Beier and Gerhard Schridoer eds. from GATT to TRIPS- The agreement of the Trade-Related Aspects of the intellectual property rights. 1996.

[287] Ibid.

[288] Ibid Paul Katzenberger et al . 14.

Furthermore, TRIPS harmonized Intellectual property laws by providing minimum standards of protection for intellectual property rights that signatories enacted in their domestic Intellectual property laws[289].

The proposal to amend the TRIPS Agreement to include disclosure of the source of origin requirement is because of the features of the TRIPS mentioned above. Developing countries first sought to enforce disclosure of origin through implementation at the nation-state level[290].

It was, however, not practical for developing countries to have disclosure of origin in their patent laws while developed countries where the patents are sought do not have such regulations. Patent laws, as stated above, are territorial; the laws of developing countries do not influence the grant of a patent in developed countries. There were also different approaches to the disclosure of origin requirement.

While some countries made disclosure of origin voluntary and have no sanctions for non-compliance, others made disclosure mandatory[291] and created additional sanctions for non-compliance[292]. There was also a difference in what to disclose under the source of origin requirement disclosure.

Some countries require just a disclosure of the source of Origin[293]; others require disclosure of the source of origin and evidence that prior informed consent and benefit-sharing agreement have been reached.[294]

---

[289] The TRIPS Agreement, WORLD TRADE ORGANIZATION, https://perma.cc/9EZ6-PSVH. 2017

[290] Joshua D. Sarnoff and Carlos M. Correa, "Analysis of options for implementing Disclosure of origin Requirements in intellectual property applications". 2005.1. American University Washington College of law. Online: <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1002&context=pijip_trad_knowledge>

[291] Countries like Switzerland and Vietnam have adopted this approach.

[292] Panama was one of the first countries to introduce a mandatory requirement to disclose the source of origin which include prior informed consent and a benefit-sharing agreement. Brazil also requires disclosure of informed consent and Benefit-sharing where there is commercial intent.

[293] AJ Park. Disclosure of origin of genetic resources and traditional knowledge in the patent regime. LEXOLOGY. https://www.ajpark.com/insights/disclosure-of-origin-requirements-in-new-zealand-patents-regime

[294] Dominic Keating, "Access to Genetic Resources and Equitable Benefit-sharing through a new disclosure requirement in the Patent system: An issue in search of a Forum. 2005. 87 J Pat and Trademark office Soc'y 525: 526

The features of the TRIPS Agreement discussed above make it the preferred multilateral trade instrument to ensure harmonization of how to disclose under the disclosure of origin requirement.[295] For instance, the TRIPS also has many developed countries as its signatories.[296] This will ensure that the provision on disclosure of origin is adopted and incorporated into the Patent laws of developed countries.

To achieve this, the TRIPS amendment proposal recommends an amendment to the TRIPS Agreement to make disclosure of the source of origin a requirement for patentability. This amendment should include a definition of Biotechnological Patents separate from other types of patents. This definition should also specify that it covers inventions from human genetic and non-human genetic materials.

5.1.2. DECONSTRUCTING:

The second stage of critical IP, as identified by Margaret Chon, involves engaging the tools of intellectual inquiry to expose and identify what has been foregrounded, and what has been suppressed, in legal discourse and meaning. Some authors have pointed out the problem of the over-liberalization of patentability under the National Patent laws of developed countries like the US. This is reflected in the porous definitions and wide berth of definitions of terminologies like "Prior Art," "Disclosure," and "utility," amongst others. In this deconstructing phase, this work acknowledges the power struggle between developing countries to protect their rights and developed Countries to protect their economic interests.

Developing countries have argued in the TRIPS amendment proposal that there is a conflict between the CBD and the TRIPS Agreement. The proposal argues that the TRIPS, unlike the CBD, treats biological resources as the common heritage of humankind. Deconstructing this work shows that developed countries have argued for access to biodiverse resources based on the convention of biological diversity.

[295] WORLD TRADE ORGANIZATION. TRIPS: A more detailed overview of the TRIPS Agreement. Overview: the TRIPS Agreement. https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[296] For instance France.

Amending the TRIPS to include specific provisions to acknowledge the provisions of the CBD and protect against bioprospecting would further protect developing countries from bio-piracy and misappropriation of their human and non-human genetic materials.

In 2001, the US responded to the arguments of a conflict between the CBD and TRIPS and stated that both laws address different issues. This work also acknowledges the dominance of the analysis of Patents as a tool to aid economic advancement.

From the arguments of the US, this work recognizes the political interplay between developing countries like Brazil and Bolivia and developed countries. As mentioned above, the decision to amend the TRIPS is based on the majority votes, and the dominant view is economic advancement in favour of developing countries.

For Critical IP theorists, there is no separation of law from politics[297]. When the Law ascribes rights and protects privileges concerning valuable resources, it plays a crucial role in allocating power and controlling its flow. In the debates for disclosure of Origin, the law is not the tool controlling power but is itself controlled by influential countries. According to Craig[298], the law can be used to legitimize the exercise of power, and it must be able to limit, channel and transform the interest of the powerful.

Some authors have argued that disclosure of origin would be better enforced as a mandatory requirement.[299]

Some Authors believe that an amendment is highly unlikely with the current political reality in the debates.[300]This belief has led to alternative proposals by authors and proposals before intellectual property forums.[301]

---

[297] Craig, Carys J., "Critical Copyright Law & the Politics of 'IP'" (2019). Online:<https://digitalcommons.osgoode.yorku.ca/scholarly_works/2715>

[298] Ibid.

[299] Joshua D. Sarnoff and Carlos M. Correa. Analysis of options for implementing disclosure of origin disclosure of origin requirements in intellectual property applications. United Nations Conference on Trade and Development (UNCTAD). Digital commons@American University Washington College of Law. Traditional knowledge and culture. 2005.

[300] Timothy A. Wolfe and Benjamin Zycher. Biotechnological and Pharmaceutical Research and development investment under a patent-based Access and Benefit sharing regime. 2005. 2.

[301] Ibid.

In deconstructing the issues raised in the arguments and proposals, the challenge of regulating bioprospecting is not the choice of law but the politics of "consensus." Deconstructing this work shows that the TRIPS Agreement in its current form cannot regulate the bioprospecting of human genetic materials and curb misappropriation through patents

Furthermore, the TRIPS Agreement does not address the trade-related challenges of patenting inventions from human genetic materials. The collection and use of human genetic materials under medical and human rights laws is different from the commercialization of inventions from human genetic materials. The TRIPS agreement as a multilateral negotiation should be amended to address the trade-related challenges of patenting inventions from human genetic materials.

5.1.3 RE-IMAGINING:

A critical approach requires refashioning not just the legal rules but also the institutions and structures in which these laws operate.[302] According to Margret Chon,[303] the critical IP method would describe the alternative proposed to re-imagine IP law.

The Critical IP method adopted would describe the history of the proposed alternative or current application and the opportunities in the legal system that can be exploited and generalized in the service of progressive politics. This work will first build on the argument of Nuno Carvalho.[304] Carvalho, in his work in 2001, was the first author to re-imagine the regulation of bioprospecting through TRIPS in a manner that could resolve the problem of "a lack of consensus."

---

[302] Robert W. Gordon. *Some critical theories of Law and their critics*, in "The Politics of Law: A Progressive Critique" .David Kairys (ed) (1998) 641, 655. 1988, 3rd Ed.

[303] Chon, Margaret, Intellectual Property Research and Critical Theories. Handbook on Intellectual Property Research 2018. (Irene Calboli and Lillà Montagnani, eds. Edward Elgar Press, Forthcoming),Online:< https://ssrn.com/abstract=3219966>.

[304] "Requiring Disclosure of Origin of Genetic Resources and Prior Informed consent in Patent Applications without infringing the TRIPS Agreement: The problem and the solution". 2000. 2:1 WUJP.

Carvalho, in his article, examines how the disclosure of origin requirement can be enforced in the patent application by the World Trade Organization members nationally, regionally, and internationally without infringing the TRIPS Agreement. This work will build on the attempt by Nuno Carvalho to re-engineer patent law through the fraudulent procurement principle.

As pointed out in the previous chapters, developing countries faced challenges in implementing the provisions of the CBD, particularly Articles 15(5) and (7). Countries have sought to identify the genetic resources used in patent applications so that benefits could be demanded. Developing countries also proposed the amendment of Article 27.3(b) of the TRIPS Agreement.

The council suspended this review for TRIPS. Developing countries also proposed the modification of Article 29 of the TRIPS agreement that establishes the requirements for patentability to include the disclosure of origin requirement. Nuno Carvalho argued that this requirement would conflict with the TRIPS Agreement if it were made a condition for patentability.

He examines the provisions of the TRIPS that some Authors and Countries have hinged on to argue that disclosure of origin can be done under some articles of the TRIPS.

Carvalho points out that the requirements for patentability in 27 of the TRIPS agreement are novelty, inventiveness, and industrial applicability. A patent cannot be refused if it fulfills these requirements, and the disclosure requirement under the TRIPS is limited to Article 29. He also pointed out that under Article 62, it is not reasonable to impose new disclosure requirements.

Carvalho proposes several solutions to the conflict between the TRIPS and the disclosure agreement:

1. **Incorporate the requirement into the TRIPS Agreement:**

Carvalho's first proposal is to amend the TRIPS agreement to include the requirement to disclose to enforce protect the rights of developing countries. He writes that this would be the optimal solution in seeking to enforce the disclosure of Origin requirement. He argues, however, that it is improbable that the requirement would be incorporated into TRIPS either through an in-built agenda or new negotiation. His conclusion is based on his analysis of the debate on amending the provisions of the TRIPS Agreement.

He points out that the proposal to amend the TRIPS Agreement to incorporate a disclosure of origin requirement was first raised as item 8 of the communication submitted by the Indian Delegation before the WTO[305]. The Indian Delegation, in its communication, pointed out that there were contradictions between the TRIPS and the CBD that would make implementation of the disclosure of origin through TRIPS impossible. They outlined the contradictions as follows:

i) First the TRIPS agreement makes no provision for disclosure of the origin of biological or genetic resources. The TRIPS agreement also fails to address disclosure of the origin of Indigenous or traditional knowledge used in the biotechnological field.

ii) The second contradiction is the TRIPS does not make provision for prior informed consent of the source of the origin country.

The Indian Delegation proposed that TRIPS be amended to include an obligation for patent applicants to execute a "transfer of information agreement for any traditional or indigenous knowledge already in the public domain. This would aid benefit-sharing as provided in the CBD. Although Columbia and Malaysia supported the proposal by the Indian delegation, it was refuted by the US.[306]

Two years later, on December 1-2, 1999, the TRIPS council began a review of Article 27.3(b)[307]. The Indian Delegation proposed during this review that implementation of the CBD'S regulation on bioprospecting should be done through the TRIPS Agreement. This could be achieved by amending Article 29 on the conditions for patentability to mandate patent applicants to mention the source of origin of the biological or genetic material used in the invention.

[305] The relationship between the TRIPS Agreement and the Convention on Biodiversity, WTO Doc WT/CTE/W/65 7, 12-14 and 16. September 29, 1997.

[306] At the CTE Meeting of November 24-25, 1997.

[307] Council for the Trade-related Aspects of Intellectual property rights, Minutes of Meeting, WTO Doc.IP/C/M/21, 110-18. January 22, 1999.

India's proposal was not examined at the meeting. The committee's plan was a review of Article 27.3(b) and not Article 29.[308] The US submitted its comments on the Indian proposal on October 29, 1999.[309] The paper proposed enforcing the disclosure of origin requirement through a contract between the developed country and the donor or source of genetic material.

At the TRIPS Council meeting a month later, November 20-22, 1999, the proposal to reconcile Article 29 of the TRIPS Agreement with Article 15 of the CBD was not resolved. While the European communities supported the US argument, developing countries like Kenya and South Africa supported the Indian proposal[310].

The WTO members[311] proposed to the general council that the next round of negotiations at the third ministerial conference in Seattle should adopt the requirement for the amendment of Article 29 of the TRIPS. This proposal was never negotiated or adopted.

On the basis of this history, Nuno Carvalho concluded that amending the TRIPS Agreement is a probable future solution, but the chances of a consensus agreement seem highly unlikely. Carvalho argues that enforcing the disclosure of origin requirement under national laws without an amendment of the TRIPS Agreement creates a contradiction between the CBD and the TRIPS. He, therefore, proposes what he calls a possible solution.

---

[308] WTO Doc. IP/C/M/24 . August 17, 1997.

[309] WTO Doc.IP/C/W/162.

[310] Nuno Carvalho, "Requiring Disclosure of Origin of Genetic Resources and Prior Informed consent in Patent Applications without infringing the TRIPS Agreement: The problem and the solution". 2000. 2:1 WUJP.

[311] Ibid.

2. Introducing the disclosure requirement under the fraudulent procurement doctrine:

Carvalho's second solution is to change the focus of the argument from patentability to enforceability of Patent rights. In order to do so, he recommends introducing the disclosure requirement under the fraudulent procurement doctrine. The fraudulent procurement doctrine is a US common law principle. It was first established in *Walker Process Equipment Inc. V. Food Machinery and Chemical Corp*.[312]

The fraudulent procurement doctrine requires the patent applicant to provide complete information about the invention in their application.

The information provided should give the examiners sufficient information to determine whether the substantive conditions of patentability have been met. Patent application that fails to provide information on the source of origin would not affect whether or not a patent should be granted. The sanction should not be enforceable as a requirement for patentability. The patent applicant, however, has the option of correcting the misrepresentation made in the application and obtaining the prior informed consent that should have been sought.

Carvalho argues that Patents affect public interests; he makes this argument by linking biotechnology products with environmental policies. The Supreme Court has stated that public policy places inventors' rights within a constitutional frame[313]. In S*inclair & Carroll co. V. Interchemical Corp,*[314] the Supreme Court held that inventors' rights are subject to public policy.

This is in line with Art. 8(1) of TRIPS. Carvalho also argues that disclosing the origin of a condition of patentability conflicts with the TRIPS. The Court can, however, sanction an applicant's failure to disclose the source of origin to enable benefit sharing. The deliberate concealment of information is deemed fraudulent. Any attempt to enforce such patent rights would be deemed an abuse of rights.

---

[312] 382 US 172. 1965.

[313] U.S CONST. Art 1 & 8, cl 8:)

[314] 325 US. 327, 330-32 (1945).

Carvalho also suggests that the fraudulent procurement principle can be enforceable at a multilateral level through the WIPO framework. The concept developed in WIPO could then be incorporated into the text of TRIPS through multilateral trade-related negotiations, which would allow developing countries to access the WTO's dispute resolution mechanisms.

The proposal by Nuno Carvalho thus attempts to re-imagine how disclosure of origin can be enforced through the TRIPS without first amending the provision on patentability. He emphasizes that one of the challenges developed countries have with the proposal to amend the TRIPS is the proposed sanctions for failure to disclose.

As laudable as Nuno Carvalho's proposal is, there are challenges to applying his proposal. First, Nuno Carvalho does not expound on what "enforcement of Patent rights means?"

The cases referred to in his work - *Walker Process Equipment Inc. V. Food Machinery and Chemical Corp*[315] *and SCM Corp v. Radio Corp of America*[316] - seem to point to enforcement when an infringement occurs. Under this model, a patent owner would go to court to enforce their right; or a plaintiff might sue a patent owner for fraudulently obtaining a patent.

Developing countries proposed disclosure of origin to reduce misappropriation of genetic materials through patents. If the court could only enforce the sanction for non-disclosure, the objective of deterring misappropriation may be defeated. The court in *SCM Corp v. Radio Corp of America*[317] pointed out a thin line between "unclean hands" and "fraud." Unclean hands could result in courts declining to enforce the patent, while fraud might invalidate the patent. The court, however, does not explain or examine instances where an action can be called unclean hands, or where the line is between unclean hands and fraud. This question seems to be subjective, determined on a case-to-case basis.

---

[315] 325 US. 327, 330-32 (1945).

[316] 318 F. Supp. 433 (S.D.N.Y. 1970).

[317] 407 F.2d 166 (2d Cir. 1969).

Carvalho argued that where there is deliberate concealment of information that affects public policy, any attempt to enforce such rights would be deemed an abuse of rights

Carvalho's recommendation still circles back to enforcement through a multilateral treaty, specifically the TRIPS. The challenge of enforcement of disclosure of Origin has been a lack of consensus among the different countries.

Since the Carvalho article was published in 2001, there have been proposals before other Intellectual property bodies[318] recommending different approaches to regulating bioresources' patents.

None of these proposals have been adopted, nor has there been any consensus on any proposal to regulate the patenting of human genetic materials. The challenge is not the patent proposal but the power structures within the patent system. This work will build on Carvalho's attempt to re-imagine bio-prospecting regulation. Carvalho, in his work, argued that his proposal could only be applied to biotechnological patents from non-human genetic materials. He had also argued that issues concerning the use of genetic materials could affect public policy. He makes this argument by linking biotechnology products with environmental guidelines.

Public policy has been defined as an "unruly horse"[319] because it has no clear definition and can be interpreted differently in several contexts. One of the reasons for canvasing that mandatory disclosure of origin is enforced through the TRIPS is to ensure harmonization. This work will propose re-imagining regulating bioprospecting by expanding the regulation to include human genetic materials. The misappropriation of human genetic materials in bioprospecting is primarily through patents and, often, includes misrepresentation or inappropriate use outside the terms of consent.

The hedges around IP law must be expanded to address abuse of power within the existing IP structure. The following subsection will examine the new constitutional Architecture of Intellectual property to analyze the possibility of enforcement through the TRIPS.

---

[318] The standing committee of the WIPO.

[319] Burrough, J., Richardson v. Mellish (1824), 2 Bing. 252; quoted by Lord Bramwell in Mogul Steamship Co.;. McGregor, Gow and others, 66 L. T. Rep. 6.

5.2 REIMAGINING THE REGULATION OF BIOPROSPECTING THROUGH NEW CONSTITUTIONALISM THEORY.

This work would adopt the new constitutional theory to describe this alternative method. As noted earlier in this thesis, constitutionalism of intellectual property begins with a progressive integration of intellectual property with fundamental rights.[320]The constitutionalism of Intellectual property aims to identify, address and categorize the problems arising from trans-border nation-states issues.[321] The constitutional IP discourse recognizes that nation-states cannot create exclusive constitutional norms.

The broad aspects of intellectual property make a new constitutional discourse. Constitutional discourses based on nation-state or regional laws do not cover the broadening transformation of Intellectual property.

In re-imaging the regulation of bioprospecting, this work will propose an alternative debate on the TRIPS Amendment. This will examine how TRIPS can be used to enforce disclosure of the source of origin. This work will achieve these first through an analysis of the TRIPS Agreement's history and the proposed alternative's current application. Secondly, it will analyze how the proposed option can be strategically applied to regulating bioprospecting through the TRIPS Agreement.

First is an analysis of the history of the TRIPS Agreement. Disputes and lack of consensus on the TRIPS provisions started during the negotiation of the TRIPS provisions at the talks of the General Agreement on Tariffs and Trade (GATT).[322] The substance of IP rights was a debate between developed and developing countries on whether the TRIPS Agreement should exist.

---

[320] Upendra Baxi, The future of human rights. Oxford University Press, 2008. 234 and 253-58.

[321] Gawin W. Anderson. Beyond Constitutionalism and, Beyond the state. Journal of law and society. 2012. 39(3). 359.

[322] Christophe Geiger and Luc De Saunettes-Barbero. The Revitalization of the object and purpose of the TRIPS Agreement. The plain packaging Reports and the Awakening of the TRIPS Flexibility clauses. In Jonathan Griffiths and Tuomas Myilly (ed) in Global Intellectual property protection and New constitutionalism. Oxford University Press. (New York, 2021).

The US-led developed countries pushed for the negotiations while developing countries like Brazil initially opposed the negotiation.[323]The Ministerial Declaration of Punta del Este in 1986 finally reached an agreement that negotiations should relate to issues concerning trade in goods.[324]

The talks were limited to aspects of IP rights that impeded international trade, and the negotiation did not include cases of harmonization of IP rights.

Developed countries negotiated for harmonization of IP rights to impose legal protection internationally.[325] The objective of the US was to push for rights beneficial to its economic development. At the time of these negotiations, the effect of these laws on other aspects of society was not as well-known as they are today.[326] The US and European Union presented two proposals in the negotiation group which called for the development of the scope and exercise of Trade-related rights.[327]

In response, developing countries led by Argentina and Brazil[328] argued that the IP Architecture proposed through these rights might not fit their current level of development.[329] Developing countries recognized that they are less likely to create as many innovations as developed countries and proposed rights that could allow access and the spread of knowledge.[330]

---

[323] Catherine Field, 'Negotiating for the United States' and Piragibe Dos Santos Tarrago 'Negotiating for Brazil' in Watal and Anthony Taubman (eds), The making of the TRIPS Agreement (WTO 2018, 130-31, 212-213).

[324] Ministerial Declaration on the Uruguay Round. 20 September 1986. 7-8.

[325] Catherine Field, 'Negotiating for the United States' and Piragibe Dos Santos Tarrago 'Negotiating for Brazil' in Watal and Anthony Taubman (eds), The making of the TRIPS Agreement (WTO 2018, 132).

[326] William Cornish and Kathleen Liddell. The Origins and structure of the TRIPS Agreement. In Ullrich et al (eds) TRIPS Plus 20. From Trade Rules to Market principles. (Springer 2016). 194.

[327] Draft agreement on trade-related aspects of IPR (29 March 1990. MTN.GNG/NGII/W/68; Draft Agreement on trade-related aspects of IPR. 11 May 1990 MTN.GNG/NGII/W/70.

[328] Communications from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, and Uruguay. 14 May 1990. MTN.GNG/NGII/W/II.

[329] Christopher Geiger, The social Function of intellectual property Rights in Methods and perspectives in intellectual property Graeme B, Din woodie (ed), (Edward Elgar, 2013). 153.

[330] Christopher Geiger. Exploring the flexibilities of the TRIPS Agreement provisions on limitations and Exceptions in Annette Kur and Vytautas Mizaras (eds), The Structure of intellectual property law- can one size fit all? (Edward Elgar 2011) 287.

Developing countries suggested that the agreement should be flexible and allow States to determine policies in the domain. The consensus was made through Art 7 and 8 to regulate the exercise of the sovereign States through fixed objectives and principles for national legislation.

Article 7 provides that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and a balance of rights and obligations.

Article 8 provides, on the other hand, that:

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
>
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.

While these two provisions may seem different, their history and role show that they are necessary for understanding and enforcing the TRIPS Agreement.[331] The challenge with applying Articles 7 and 8 of the TRIPS is their broad scope capable of numerous interpretations. The WTO dispute settlement body was reluctant to refer to Articles 7 and 8 in resolving issues of State's obligations under the TRIPS.

[331] Christopher Geiger, The social Function of intellectual property Rights in Methods and perspectives in intellectual property Graeme B, Din woodie (ed), (Edward Elgar, 2013). 153.

One example of where these articles could have applied but were sidelined is found in the Panel report of Canada: Patent protection of pharmaceutical products.[332] The Panel had to decide the legality of exceptions to pharmaceutical patents considering Article 30 of the TRIPS Agreement. Canada relied on Articles 7 and 8 in its argument for the government to have the flexibility to adjust patent rights to balance with other national policies.

The European communities countered this argument by stating that balancing the goals provided in Articles 7 and 8 were done during the TRIPS provisions negotiation. The WTO Panel agreed with this view, concluding that Articles 7 and 8 were reflected in the provisions of the TRIPS Agreement and could not be argued separated.

In the Panel Report of the United States - Section 211 Omnibus Appropriations Act of 1998, The diversion towards 'good faith,'[333] the panel was called upon to interpret the term "Good Faith" in the light of TRIPS Articles 7 and 8. The task before the panel was to analyze whether Article 7 required States to express good faith in exercising their rights under the Treaty. The panel remained neutral, taking the position that ensuring a balance of rights and obligations under Article 7 was not about regulating interstate transactions and relations.

Secondly, the current application, of Articles 7 and 8 was established in the Australia Plain Packaging reports.[334] In this case, the WTO panel finally addressed the question of how to interpret articles 7 and 8 of the TRIPS. The issue before the Panel for dispute settlement was the interpretation of the term "*Justifiably"* in Article 20 TRIPS. The facts of the case are summarized below.

[332] 17 March 2000. WT/DS114/R.

[333] WT/DS/76/R.

[334] Australia: certain measures concerning Trademarks, Geographical indications, and other plain packaging Requirement Applicable to Tobacco products and packaging. 28 June 2018. WT/DS435/R, WT/DS441/R, WT/DS458/R, and WT/DS467/R.

Australia introduced the Tobacco plain packaging regulations (TPP) in 2010. The Regulation allowed Tobacco companies to print just the brand name in small, standardized fonts. The regulation aimed to reduce smoking by making tobacco packaging unattractive. Countries like Cuba, Indonesia, and the Dominican Republic challenged the Tobacco plain packaging regulation contrary to the TRIPS provisions, specifically Article 20. Article 20 of the TRIPS provides that:

> The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

The plaintiffs, led by the Dominican Republic, argued that the purpose of Article 20 of TRIPS was to protect trademarks and enable them to fulfill the function of distinguishing goods and services. The word "unjustifiably" should therefore be interpreted in this light. Australia countered this position by arguing that unjustifiably should be interpreted as meaning the interruption of the function of trademarks where there are no policy considerations at stake.

The panel applied Articles 7 and 8 and stated that the pursuit of public policy should be balanced with the interest of trademark owners in protection. The panel concluded that Article 20 reflected this balance and that WTO members may adopt measures to protect societal interests that affect such use.

The interpretation Articles 8 and 9 of the Panel in the Australian plain packaging case will be used to creatively by-pass some of the political arguments against the enforcement of the disclosure requirement under the TRIPS.

In applying the concept of re-imaging, this work will be strategically apply the use the interpretation of Articles 7 and 8 to the interpretation of some provisions of the TRIPS Agreement. Articles 7 and 8 of the TRIPS have a decisive role in evaluating balancing the rights of inventors with other social norms like human rights and social justice. New social, economic, and technological issues require balancing the interests of society with the rights of the IP owner.

For instance, the member states to the TRIPS Agreement agreed on two declarations to systematically apply Articles 7 and 8 to the issues of ethics and public health at the WTO 4th Ministerial conference[335].

While IP rights under TRIPS protect inventors, they must be balanced with other societal needs. The TRIPS Agreement does not explicitly mention fundamental rights or ethics. These can, however, be inferred through Articles 7 and 8. Christophe Geiger et al.[336] believe that Articles 7 and 8 can be used as horizontal interpretation clauses that allow fundamental rights to be introduced in the interpretation of TRIPS. The reports on Australia-Plain packaging could be a pilot of this approach. He posits that Articles 7 and 8 could solve conflicts between the TRIPS agreement and other ethical and human rights concerns. This work agrees with the argument of Christophe Geiger et al.[337] that Articles 7 and 8 could provide leeway for infusing ethics into intellectual property laws.

This work recommends that one of the ways this can be achieved is the amend TRIPS to define biotechnological patents as including human and non-human genetic materials. Disclosure of source of origin, which includes evidence of prior informed consent and benefit-sharing, should be included as a requirement for patenting biotechnological patents.

---

[335] Ministerial Declaration, 14 November 2001. WT/MIN(01)/DEC/1 Para 19.

[336] The Revitalization of the object and purpose of the TRIPS Agreement. The plain packaging Reports and the reawakening of the TRIPS Flexibility clauses. In Jonathan Griffiths and Tuomas Myilly (ed) in global Intellectual Property protection and New constitutionalism. Oxford University Press. (New York; 2021).

[337] The Revitalization of the object and purpose of the TRIPS Agreement. The plain packaging Reports and the reawakening of the TRIPS Flexibility clauses. In Jonathan Griffiths and Tuomas Myilly (ed) in global Intellectual Property protection and New constitutionalism. Oxford University Press. (New York; 2021).

This work also recommends that a proposal for the amendment of the TRIPS Agreement should be made based on Articles 7 and 8. Like in the Australia Plain Packaging case, developing countries that have suffered the loss of benefits or had their human genetic materials misappropriated through patents should compile specific instances of these misappropriations. These cases of misappropriations should be brought before the TRIPS Council to interpret whether the provisions of the TRIPS Agreement address the challenge of misappropriation of genetic human and non-human materials.

The specific Articles to be interpreted have been formerly interpreted to make provision for the enforcement of disclosure of the source of origin.

Some Authors and developed countries have argued that specific TRIPS provisions could be interpreted as including the duty to disclose the source of origin and what to disclose.[338] The relevant sections are Article 27.1, Article 29, and Article 62. Article 27.1 of the TRIPS Agreement provides that:

> *Patents shall be available for any inventions provided they are new, involve an inventive step, and are capable of industrial application.*

This section lists the minimum requirements for patentability as Novelty, inventive step, and industrial application. Where a State includes these requirements in its patent law, it is sufficient to qualify an invention for patentability.

Article 29 of the TRIPS Agreement provides:

i) Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor of the filing date or, where priority is claimed, at the priority date of the application.

[338] Gurdial Singh Nijar, "The Nagoya Protocol on Access and benefit sharing of genetic resources: Analysis and implementation options for developing countries. (2011) Online: Center of excellence for biodiversity. <https://southcentre.int>

ii) Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Carvalho opines that Article 29 makes disclosure and how to disclose optional for WTO members. Subsection 2 requires that applicants provide information on foreign patent applications and similar grants are also optional.

Article 29 is therefore not an appropriate framework for enforcing the disclosure of source of origin requirement. The provisions of Article 29 refer to the disclosure of prior art and not the source of genetic resources. The US argues that the TRIPS agreement has provided what it deems necessary to disclose. They further argued that disclosure of the source of origin is not necessary for an expert skilled in the art to replicate or use the invention. Biotechnological invention requires knowledge of the genetic materials to be "used," or where disclosure of the source of origin may be relevant for practical exploitation of the invention.

The US also argued in its statement before the WTO Committee on Trade and Environment that where the source of origin is unique, it must be disclosed under Article 29 of the TRIPS Agreement.[339] Carvalho gives an example of where disclosure may be necessary for his work. An example is where an extract from a plant could be obtained from more than one geographical area. It may be necessary to disclose if the extract from one location is more effective than the others.

The agreement does not require disclosure of sources where such knowledge is not necessary for the practical use of the invention. Article 62 of the TRIPS Agreement deals with the conditions applicants who are members of the WTO must meet under the law. Article 62 provides that:

> (1) Members may require compliance with reasonable procedures and formalities as a condition of the acquisition and maintenance of the intellectual property rights provided under sections 2 through 6 of Part II. Such procedures and formalities shall be consistent with the provisions of this agreement.

[339] WTO Doc. IP/C/W/162. Oct 29, 1999.

> (2) Where the acquisition of an intellectual property right is subject to the right being granted or registered, members shall ensure that the procedures for grant or registration, subject to the compliance with the substantive conditions for the acquisition of the right, permit granting or registration of the request within the reasonable time to avoid unwarranted curtailment of the period of protection.

Carvalho argued that Article 62 applies to intellectual property rights requiring the fulfillment of certain administrative procedures. Trademarks, geographical indications, industrial designs, and layouts - designs of integrated circuits. In applying these to a patent application, reasonable procedures aid the administration or office in determining whether the requirements for patentability have been met.

The interpretations of these Articles are subjective at best and capable of numerous interpretations. As such, these Articles should be brought before the WTO Council for interpretation on whether they address the challenge of misappropriating human genetic materials through patents. Developing countries should also request that the WTO Council interpret the actions of patenting human genetic materials outside the terms of consent in line with Articles 8 and 9. Lastly, developing countries should also request for an interpretation of Article 71.1 in line with Articles 7 and 8, where there is a need to balance the economic rights of developed countries with the obligation to disclose the source of Origin.

The drafters of the TRIPS foresaw that the TRIPS would need to be re-evaluated in the future to account for new or foreseeable issues not addressed during the negotiations. The arguments of developing countries should be that there is a gap in the TRIPS Agreement that needs to be addressed through an amendment. The provision for re-evaluation is set out in Article 71 of the TRIPS.

Article 71(1). The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date and at identical intervals after that. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

(2) Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action under paragraph 6 of Article X of the WTO Agreement based on a consensus proposal from the Council for TRIPS.

The proposal for the TRIPS Amendment should be made based on the rulings of the WTO council and the interpretations of Articles 27.1, 29, 62 and 71.1 of the made by the Council.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

In the 1980s, as research and the creation of inventions from genetic materials increased in developed countries, bioprospecting in developing countries also increased. Developed countries accessed and used biodiverse resources without consent or compensation. This led to protests by developing countries against these actions they call biopiracy. A proposal was put forth under the Convention on biodiversity to regulate bioprospecting. This proposal required signatories to the convention on biological diversity to seek informed consent and reach benefit-sharing agreements before access to genetic materials would be granted.

The CBD, however, has some significant limitations, two of which concern this work. First, CBD does not apply to the bioprospecting of human genetic materials. Second, the CBD does not address the issue of misappropriation through patents.

There have been several attempts to address these challenges. First, Countries tried to regulate the patenting of inventions from human and non-human genetic materials through the implementation of a disclosure of source of origin requirement, under which patent applicants must disclose in his patent application that he had obtained prior informed consent and reached a benefit sharing agreement.

Implementing the disclosure of the source of origin requirement on-a-country by a country basis resulted in several challenges, including lack of harmonization and the problem of patents.

i) Lack of Harmonization

Different countries have different approaches with respect to the disclosure of source of origin requirement. While some countries required voluntary disclosure, others made disclosure mandatory. There was also a lack of harmonization on what to disclose. While some countries required just a disclosure of the country which is the source of origin, others required disclosure of proof of informed consent and a Benefit-sharing agreement.

Some countries specified that the disclosure of the source of origin applied to genetic materials, while others specified that it is used for genetic human and non-human materials. This work concludes that in order to address the problem of misappropriation and curb incidences of bioprospecting, it is necessary to have a law that harmonizes the approach of States.

ii)The Problem of Patents

The features of Patent makes it territorial. This means patents are only enforceable based on the territory's laws or international laws to which the country is a signatory. Most developing countries adopted the proposal for disclosure of source of origin within their patent laws, while developed countries did not amend their patent laws to include this requirement. For disclosure of the source of origin to be effectively applied, it must be harmonized and introduced into the patent laws of both developed and developing countries.

iii) The need to extend the debate on disclosure of source of origin to human genetic materials

The disclosure of the source of origin and debates on its implementation does not apply to the patenting of inventions from human genetic materials.

This research proposed re-imagining the regulation of bioprospecting through the TRIPS Agreement. First, the current debates on regulating bioprospecting were analyzed using the critical IP theory. Secondly, this work builds on Nuno Carvalho's proposal on re-engineering the TRIPS amendment proposal debates. This work proposed re-imagining the regulation of bioprospecting using the *new constitutionalism* theory.

6.2 FINDINGS

1. Bioprospecting also occurs in human genetic materials.

2. There are no laws to regulate the bioprospecting of human genetic materials.

3. Misappropriation of human genetic materials occurs mainly through patents. Non-human genetic materials can also be misappropriated through patents. International laws to regulate bioprospecting and the debates on regulating the patenting of genetic materials have focused on just non-human genetic materials.

4. Medical ethics and international law does not regulate the patenting of human genetic materials.

6.3 RECOMMENDATIONS

1. The definition of bioprospecting should include human genetic materials.

2. The TRIPS Agreement should be amended to include a provision defining biotechnological patents and imposing a disclosure requirement for inventions using human genetic materials. The source of origin requirement should mandate disclosure of informed consent to commercialize through patent and agreement on benefit sharing.

3. Enforcing the amendment of the TRIPS Agreement using Articles 7 and 8. Articles 7 and 8 could be creatively used to bypass some of the political arguments against amending the TRIPS Agreement and create a new focus in the debates.

4. Countries that suffered specific losses through patent-based misappropriation should bring a collective claim before the WTO council. The claim should be for an interpretation of whether Articles 27, 29 and 62 require disclosure of source of origin and compliance with informed consent and benefit sharing agreement. The claimant should rely on the precedent of The Australian Plain packaging case and should ask the WTO council to interpret Articles 27, 29 and 62 in light of Articles 7 and 8 of the TRIPS Agreement.

6.4 AREAS FOR FUTURE RESEARCH

One area of future research relates to the potential impact of recognizing property rights in human genetic materials on the future use of collected genetic materials, on available patents, and on future patents. There is also a need to research the possibility of establishing property rights in genetic information in human genetic materials, along with the cultural implications that this might have for Indigenous people.

REFERENCES

BOOKS

A Krattiger, RT Mahoney, L Nelsen, Davis, *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices,* (USA: MIHR: Oxford, PIPRA, 2007) Online: <www.ipHandbook.org>.

Daniel Gervais, "The TRIPS Agreement- Drafting History and Analysis," 4th Ed. (London: Sweet and Maxwell, 2012) 237-248.

David Kairys (ed), *The Politics of Law: A Progressive Critique.* 641, 655.3rd Ed. (New York: Pantheon Books, 1988).

Dawn Watkins, Mandy Burton, ed *Research Methods in law,* (London: Routledge, 2018).

Lely Glowka, *A guide to designing legal frameworks to determine access to Genetic resources.* (Switzerland: Gland, Cambridge and Bonn: IUCN, 1998) 4.

Irene Calboli, Lila Montagnani, Handbook *on Intellectual property research,* (UK: Edward Elgar Press, Forthcoming, 2018) Online: <https://ssrn.com/abstract=3219966>

Joanna Gibson, *Patenting Lives*, (New York: Routledge, 2016)

Konrad Zweigert, Hein Kotz, *An introduction to comparative law*. 3rd edn (Germany: Trans. Tony weir, 1998), 32-47. First Published in die Rechtsvergleichung (Vol I, 1971) 27-48.

Kur and Levin, *Intellectual property rights in a fair world Trade System: Proposals for Reform of TRIPS.* (UK: Edward Elgar, 2011)

Martha Chouchena Rojas, Manuel Ruiz Muller, David Vivas, and Sebastian Winkler, *Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD,* (Switzerland: IUCN, Gland, and Cambridge, 2005).

Matthew Y, H Wong, *Comparative Hong Kong Politics* (Palgrave: Macmillan, 2017).

Mills, Oliver, *Biotechnological Inventions: Moral Restraints and Patent law,* (London: Routledge, 2016).

Tuomas Mylly, Jonathan Griffiths, *Global Intellectual Property Protection and New Constitutionalism* (United Kingdom: Oxford University Press, 2021).

Upendra Baxi, *The future of Human Rights*. 3rd edn, (United Kingdom: Oxford University Press,

2008). 234, 253-258.

ARTICLES

AJ Park, "Disclosure of origin of genetic resources and traditional knowledge in the patent regime", (2019) LEXOLOGY. Online:<https://www.ajpark.com/insights/disclosure-of-origin-requirements-in-new-zealand-patents-regime>

B M, Knoppers, "Population genetic and benefit-sharing" (2003) Community genetics. 1273.

B, R , Jeffers, "Human Biological materials in research: ethical issues and the role of stewardship in minimizing research and risks". (2001) 24(2) ANS Adv. Nurs Sci.32-46. Online:<DOI: 10.1097/00012272-200112000-00005>.

Beauchamp. T.L, "Informed consent: its history, meaning and present challenges" Cambridge quarterly of Healthcare Ethics. (2011) 20(4) 515-523.

Catherine Field, 'Negotiating for the United States' and Piragibe Dos Santos Tarrago 'Negotiating for Brazil' in Watal and Anthony Taubman (eds), The making of the TRIPS Agreement (WTO 2018, 132).

Chandra Nath Saha, Sanjib Bhattacharya, "Intellectual property rights: An overview and implications in pharmaceutical industry", (2011) 2(2) J. Adv Pharm Technol Res. 88-93. Online:< https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/pdf/JAPTR-2-88.pdf>

Chapman, A. R, "Human Rights perspective on intellectual property, scientific progress and access to the benefits of science." (2007) Intellectual Property and Human Rights, WIPO Publication 763 (E).

Chennells R, S, "Introduction. In: Equitable Access to Human Biological Resources in Developing Countries". (United Kingdom: Springer, Cham, 2016) Online:<https://doi.org/10.1007/978-3-319-19725-8_1>.

Christophe Geiger, Luc De Saunettes-Barbero, "The Revitalization of the object and purpose of the TRIPS Agreement. The plain packaging Reports and the Awakening of the TRIPS Flexibility clauses" in *Global Intellectual property protection and New constitutionalism*. Jonathan Griffiths and Tuomas Myilly (ed) (New York: Oxford University Press, 2021).

Clayton E. W, Barbara J. E, James W. H and Rothstein M. A, "The law of genetic privacy: applications, implications, and limitations", Journal of law and the biosciences. (2019) 6(1). Online:<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6813935/>

Clint Genet, "HUGO Ethics committee statement on Benefit Sharing" (2000) 58: 364-366. Online:<http://www.blackwell-synergy.com/doi/abs/10.1034/j.1399-0004.2000.580505.x>.

Collins F. S, Leslie F, "The Human Genome Project. Alcohol Health Research World", (1995) 19(3): 190-195. Online:<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875757/>.

Cory Craig, "Critical Copyright law and the Politics of IP" in *Research Handbook on Critical Legal Theory*, in Emilios Christodoulidis, Ruth Dukes, Marco Goldoni, (UK: Edward Elgar Publishing, 2019). Online: <https://digitalcommons.osgoode.yorku.ca/cgi/viewcontent.cgi?article=3715&context=scholarly_works>

Craig, Carys J, "Critical Copyright Law and the Politics of 'IP'" (2018), in *Research Handbook on Critical Legal Theory* Emilios Christodoulidis, Ruth Dukes & Marco Goldoni (eds), (United Kingdom:Edward Elgar Press, 2019), Online:<https://ssrn.com/abstract=3287377>.

Damodra A, "Traditional Knowledge, Intellectual Property rights and Biodiversity Conservation: Critical issues and key challenges". (2008)13(5) Journal of Intellectual property rights 509-513.

David J, Faye, "Bio-prospecting, Genetic patenting, and indigenous populations. Challenges under a structure commons", (2005) Journal of World intellectual property,401.

Dennis Patrick Leyden, Albert N. Link, "The Bahyl-Dole Act of 1980 in Public Sector Entrepreneurship: U.S Technology and Innovation Policy", (2015), Oxford University Press. Online:<DOI:10.1093/acprof:oso/9780199313853.003.0005>.

Dominic Keating, "Access to Genetic Resources and Equitable Benefit sharing through a new disclosure requirement in the Patent system: An issue in search of a Forum." (2005). 87 J Pat and Trademark office Soc'y 525-526.

Edwin, L, Cooper, " Bioprospecting: A CAM Frontier" (2005) Advance Access Publication.

Gawin W. Anderson, “Beyond Constitutionalism Beyond the state.” (2012) 39(3), Journal of law and society 359.

Geoffrey Samuel, “Comparative law and methodology,” in *Research Methods in law* Dawn Watkins and Mandy Burton ed. (London: Routledge, 2018).

Glowka L, “Towards a certification system for bioprospecting activities,” (2001) 41-45, Commissioned by the Swiss State Secretariat for Economic Affairs.

Greenfield DL, “Greenberg v. Miami Children 's Hospital: unjust enrichment and the patenting of human genetic material,” (2006) Ann Health Law. Summer;15(2):213-49, Online: <https://pubmed.ncbi.nlm.nih.gov/17554842/>

Gupta, V, Sengupta, M, Prakash, J, Tripathy, B, C, (2016). “An Introduction to Biotechnology. Basic and Applied Aspects of Biotechnology”, 1–21. Online: <https://doi.org/10.1007/978-981-10-0875-7_1>

Gurdial, Singh, Nijar, “The Nagoya Protocol on Access and benefit sharing of genetic resources: Analysis and implementation options for developing countries.” (2011) 7:343 Canterbury Law Review.

Helen Boussad, Aphrodite Smagadi, “The principle of Benefit Sharing in the Utilization of natural plants and human genetic resources: beyond the property and no-property rights paradigms,” (2006)17: 29-53, Journal International De Bioethique.

Hengyuan Liao, “Disclosure requirement of source of origin in Patent law: the Pros and Cons of the “layer” between patents ad genetic resources and traditional knowledge” (2021), 10(4) Journal of Civil and legal sources.

I, A, Oyemitan, “African Medicinal spices of Genus Piper” in Medicinal spices and Vegetables from Africa, Victor Kuete (ed.), Academic Press. (Cameroon: Academic Press, 2017) 581.

Jacques De Werra, “Fighting Against Biopiracy: Does the obligation to disclose in patent Applications truly help?” (2009), 42:1, Vanderbilt Journal of Transnational law. 143-179.Online:<https://www.archive-ouverte.unige.ch/unige:1480>.

Jonathan Carr, “Agreements that divide: TRIPS VS. CBD and proposes for mandatory disclosure of

source in Patent Applications," (2008), 18 J. Transnational L and POL'y 131.

Joshua D, Sarnoff, Carlos M, Correa, "Analysis of options for implementing disclosure of origin disclosure of origin requirements in intellectual property applications," (2005), (UNCTAD), Digital commons@American University Washington College of Law.

Julia Mahoney, "The market for Human Tissue," (2000) 86 VIR. L. REV. 163.

King Business and patent law, "What are the requirement for an invention to be patented? King Business and Patent law". Online:< https://jckinglaw.com/ip/patent-services/invention-patent-requirements/>

Klaus Hoeyer, "Informed Consent: The Politics of intent and Practice in Medical Research ethics," (2014) 43(1): Annual review of Anthropology, 347-362. Online:<https://10.1146/annurev-anthro-102313-030413>.

Lydia Makitubu, "Bioprospecting in an African context." (1998) 2: 5386 Science 41-42. Online:< https://www.science.org/doi/full/10.1126/science.282.5386.41>.

Mahendra Pratap, Singh Shekhawat, Manvendra Singh Shekhawat, Reneeta Pal, "The Doctrine of Disclsoure of Origin requirement" (2022), ii(iii) Indian Journal of Integrated research in law.

Marchant, G, E. "Genomics, Ethics, and Intellectual Property" in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* A Krattiger, RT Mahoney, L Nelsen, Davis, (USA: MIHR: Oxford, PIPRA, 2007) Online: <www.ipHandbook.org>.

Marcia S. F, Lucia S. Jose R. Goldim, Judith M. C. 2017. "Brazilian Legal and bioethical approach about donation for research and patents of Human Body parts" (2017) 8 J. Community Genet. 199-208.

Margret Chon, "Intellectual Property research and critical theories." in *Handbook on Intellectual property research* Irene Calboli, Lila Montagnani eds, (UK: Edward Elgar Press, Forthcoming, 2018) Online:< https://ssrn.com/abstract=3219966>.

Marianne Levin, "The pendulum keeps swinging-present discussions on and around the TRIPS Agreement" in *Intellectual property rights in a fair world Trade System: Proposals for Reform of TRIPS*, Kur and Levin. (UK: Edward Elgar, 2011). 236-237.

Marina L. Whelan, "What if any are the Ethical obligations of the U.S patent office? A close look at

the biological sampling of indigenous groups" (2006) 5:1 DTLR .

Matthew T, Latimer, "Patenting inventions arising from biological research", (2005) 6(1): 203 Genome Biology, online:<doi:10.1186/gb-2004-6-1-203>.

Matthew Y, H Wong, "Methods in Comparative Politics", in *Comparative Hong Kong Politics* (Palgrave: Macmillan, 2017).

Michalopoulos, C, "Special and differential treatment of developing countries in TRIPS", (2003) TRIPS issues Paper 2, Quaker United Nations Office: Geneva. Online: <http://www.quno.org/geneva/pdf/economic/issues/special-differential-treatment-in-TRIPS-English.pdf.2003>

Micheal Blakeney, "Proposals for disclosure of origin of Genetic resources in Patent applications", (2022), Queen Mary's Intellectual property Research institute. Online:<Researchgate.net/publication/237325587_proposals_for_the_disclosure_of_origin_of_Genetic_Resources_in_Patent_Applications>.

Micheal Blakeney, "Proposals for the disclosure of origin of Genetic resources in Patent applications", (2022), Queen Mary Intellectual Property Research institute. Online: <https://www.researchgate.net/publication/237325587_Proposals_for_the_disclosure_of_origin_of_Genetic_Resources_in_Patent_Applications>.

Monique K, Mansoura, Francis S, Collins, "Medical implications of the Genetic Revolution", (1998) 1 j. HEALTH CARE L., & POL'Y 329.

Nuno, Pires, Carvalho, "Requiring Disclosure of the disclosure of the Origin of Genetic Resources and Prior informed consent in Patent applications without infringing the TRIPS Agreement: The problem and the solution". (2002) 2 WASH. U. J . L & POL'Y 371.

Pablo Damian Colmegna, Njoseph Alvaro Gonzales Pariente, Magdalena Belen Rochi Monagas, Maria Florencia Garcia, Maria Paloma Espnosa Alonso, "Disclosure of the Origin of patented Genetic resources: Will a Plurilateral Agreement be a possible option?" (2018) International Economic law clinic.

Paul Katzenberger, Annette Kur, "TRIPS and Intellectual Property" in GATT *to TRIPS- The agreement of the Trade-Related Aspects of the intellectual property rights*, Friedrich-Karl,

Beier, Gerhard, Schridoer (eds)1996.

Perrault, Anne, Olivia, Maria Julia, "Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement On the Road to Hong Kong", (2005) Online: <ICTSD/CIEL/IDDRI/IUCN/QUNO .http://www.ciel.org/Publications/PIC_PerraultOliva_Apr05.pdf>.

Pierre- Christian Labeau, "Free, Prior, and informed consent in International law. Global" (June 2010), Online:<https://lexology.com/library/detail.aspx?g=7>.

Q, Renzong, "Human genome, and philosophy: What ethical challenge will human genome studies bring to the medical practices in the 21st century", (2001) 324 CR. Acad. Sci. Paris, sciences de la vie/ life sciences. 1102. Online:<https://www.semanticscholar.org/paper/Human-genome-and-philosophy%3A-what-ethical-challenge-Renzong/8d5516069d7d6f47546e58a9e435bc711af8d2bb>

Robert W, Gordon, "Some critical theories of Law and their critics", in *The Politics of Law: A Progressive Critique* David Kairys (ed). 641, 655.3rd Ed. (New York: Pantheon Books, 1988).

Roselind Lieb, "Population-Based study" in Encyclopedia of Behavioral Medicine Gellman M. D., Turner J.R. (eds), (New York: Springer, 2013) Online:<https://doi.org/10.1007/978-1-4419-1005-9_45>.

Roselind Lieb, 2013. "Population-Based study" in *Encyclopedia of Behavioral Medicine*. Gellman M. D., Turner J.R. (eds) (New York: Springer, 2013) Online:<https://doi.org/10.1007/978-1- 4419-1005-9_45>.

Safrin S, "Hyper-ownership in a time of biotechnological promise: The international conflict to control the building blocks of life" (2004) 98:4 American Journal of International Law, 641 – 685. Online: <https://doi.org/10.2307/3216691>

Samuel Loewenberg, "The Bayh-Dole Act: A model for promoting research translation?" (2008). Molecular Oncology. Online:< https://doi.org/10.1016/j.molonc.2008.12.004>.

Selim Louafi, Brendan Tobin, "User Measures to resolve potential conflicts between the WTO and the CBD", in Martha Chouchena Rojas, Manuel Ruiz Muller, David Vivas, Sebastian Winkler, *Disclosure Requirements: Ensuring mutual supportiveness between the WTO*

TRIPS Agreement and the CBD,(Switzerland: IUCN, Gland, and Cambridge, 2005).

Ten Have, H, Patrão, Neves, M, "Bio-prospecting" in *Dictionary of Global Bioethics*. (UK: Springer, Cham, 2021) Online:< https://doi.org/10.1007/978-3-030-54161-3_95>

Terry Hutchinson, "Doctrinal Research: researching the jury" in *Research Methods in law* Dawn Watkins and Mandy Burton ed. (London: Routledge, 2018).

Thomas A. Kursar, Catherina C. Caballero-George, Todd L. Capson, Luis Cubillia-Rios, William H. Gerwick, Mahabir P. Gupta, Alicia Ibanez, Roger G. Linington, Kerry L. McPhail, Eduardo Ortega-Barria, Luz I. Romero, Pablo N. Solis, and Phyllis D. Coley. "Securing Economic benefits and Promoting conservation through bioprospecting",(2006) 56:12. Bioscience 1005.

Timothy A, Wolfe, Benjamin, Zycher, "Biotechnological and Pharmaceutical Research and development investment under a patent-based Access and Benefit-sharing regime", 2 (2005).

Timothy Caulfield, Robert M. Cook- Deegan, F Scott Kieff and John P Walsh, "Evidence and anecdotes: An analysis of human gene patenting controversies". (2006) 24 1091-1094. Nature biotechnology.

Tony Howard, "The Legal Framework surrounding patents for living materials" in *Patenting Lives*, Joanna Gibson, (New York: Routledge, 2016)

Tuomas Mylly, Jonathan Griffiths, "The Transformation of Global Intellectual Property Protection" in *Global Intellectual Property Protection and New Constitutionalism* (United Kingdom: Oxford University Press, 2021).

Walter, V, Reid, "Bio-prospecting: A force for sustainable development." (1993) 27:9. Energy and Fuels Journals. Environmental sci. Technology. 1732.

William Cornish, Kathleen Liddell, "The Origins and structure of the TRIPS Agreement" In TRIPS Plus 20 from Trade Rules to Market principles. Ullrich H, R, Lamping, M, Drexl, J, (Berlin Heidelberg: Springer,2016). 194.

Zhengyuan Liao, "Disclosure requirement of source of origin in Patent law: the Pros and Cons of

the “layer” between patents ad genetic resources and traditional knowledge,” (2021) Journal of Civil and legal sources,10(4).