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From Biopiracy to Fair Benefit Sharing: Evaluating the Impact of IP and Genetic Resources Treaty with reference to Ahom Tribes of Assam

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Abstract
India is rich in biodiversity, flora and fauna. It is also rich in cultural diversity and many indigenous communities reside together. The tribal communities have rich culture, traditions and knowledge about bio reserves surrounding them as they are dependent on the biodiversity they are living with. This knowledge they received from forefathers is transferred from generation to generation. But if someone from outside the community tries to steal their knowledge and gain profit out of it without taking their consent which is known as biopiracy. After so many years of WIPO establishment there is a treaty dealing with Genetic Resources and Associated Traditional Knowledge, 2024. Are they really going to support the indigenous communities to protect and preserve their Traditional Knowledge? This research article will try to critically evaluate the Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, assessing its effectiveness in curbing biopiracy and promoting fair benefit-sharing mechanisms with reference to case study of Ahom Tribes of Assam.

Key Words: Traditional Medicinal Knowledge, Biopiracy, Intellectual Property Rights, Biodiversity

Introduction

The indigenous communities and mostly the developing countries are awaiting for a treaty which will speak expressly about curbing the biopiracy as well as promotion of fair benefit-sharing mechanisms. In the international platform there has been only noise or voices being heard about protection and promotion of traditional knowledge or traditional medicinal knowledge of the communities. Only discussions among the member countries are not enough steps to take for the protection and promotion of traditional knowledge. Now, this Treaty came as the teeth of the dog who was simply barking earlier to act actively towards the issue. Mostly, third world countries who are rich in bio reserves start celebrating the benefits of this treaty, but they have to look into the actual problems their indigenous communities are facing against biopiracy and non-sharing of benefits acquired from their knowledge. Biopiracy is like a disease which silently kills knowledge. Problems with most of the indigenous communities facing is to prove their traditional knowledge with written evidence as it has been passed from generation to generation orally. The big giant pharmaceutical companies usually take advantage of this flaw to escape from any kinds of penalty while using the knowledge of the communities without acknowledging them. They even succeed in getting Patent registration without properly disclosing the source of the knowledge.

If we speak about the Patent or other IPR then its basis is individual positive rights against the community rights. There is less possibility of clubbing both the community rights with these individual rights. But the Treaty incorporates IP, Genetic resources and TK together within its purview. They are trying to bring a mid-path solution to innovation and acknowledgement of source of knowledge within this which seems to be a great job of the drafters. But are there any

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real swords hanging upon the pharmaceutical industry if they don't comply with the rules and regulations of disclosing the source of the knowledge? Can any treaty or protocol prevent these giants from exploiting the traditional knowledge of the communities? Is the soft law enough to hold them accountable for this? Let's find out in this article.

TK Practitioners of Ahom tribe of Assam

The origin of this tribe is confused but mostly it is believed that they are the descendants of the *Shans* or *Tais* of *the South – East Asia*.[1] This is the descendant from a racial group, cognates to the Chinese and known among themselves as the *Tai*.[2] In the middle of the Seventh Century A.D., they formed the powerful kingdom of *Nanchao*.[3] They found their way into South- Eastern China on the one side and the Northern Shan states of Burma on the other. In 1229, *Tai* immigrants founded the Ahom Kingdom of Assam in the Brahmaputra valley.[4] Following the Course of the *Luhit*, and eastern tributaries of the Brahmaputra, after crossing the *Patkai* range found themselves at the extreme coast of the Brahmaputra Valley. The first *Shan* or *Thai* invaders consisted of 9,000 men, women and children. It is said that the *Ahoms* ruled over six hundred years and could resist the Mughal invasion several times. With this great historical significance, they have a different cultural tradition as compared with other tribes of Assam.[5]

The *Tai-Ahoms* have different types of food habits which they have tried to retain from their forefathers. They are "*Hurum*"[6] (a kind of puffed rice), "*Kumol saul*"[7] (rice softened by adding hot-boiled water), "*Leta*"[8] (butterfly cocoon), "*Hanj*"[9] (rice beer which contains one hundred

[1] Nagendra Nath Acharyya, "The History of Medieval Assam (A.D. 1228 to 1603)", Thesis submitted to the Degree of Doctor of Philosophy, University of London, 1957, P.45.

[2] Nagendra Nath Acharyya, "The History of Medieval Assam (A.D. 1228 to 1603)", Thesis submitted to the Degree of Doctor of Philosophy, University of London, 1957, P.45.

[3] Nagendra Nath Acharyya, "The History of Medieval Assam (A.D. 1228 to 1603)", Thesis submitted to the Degree of Doctor of Philosophy, University of London, 1957, P.45

[4] Hall D.G.E. Burma, London, 1950, p- 28 citated in Nagendra Nath Acharyya, "The History of Medieval Assam (A.D. 1228 to 1603)", Thesis submitted to the Degree of Doctor of Philosophy, University of London, 1957, P.45.

[5] Nagendra Nath Acharyya, "The History of Medieval Assam (A.D. 1228 to 1603)", Thesis submitted to the Degree of Doctor of Philosophy, University of London, 1957, P.49.

[6] Kironmoy Chetia, "Tradition and Faith of the Tai-Ahoms and Deoris of Assam", International Journal of Science and Research (IJSR) Volume 10 Issue 6, June 2021, P.310. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ijsr.net/archive/v10i6/SR21601120141.pdf accessed on 20th June, 2022.

[7] Kironmoy Chetia, "Tradition and Faith of the Tai-Ahoms and Deoris of Assam", International Journal of Science and Research (IJSR) Volume 10 Issue 6, June 2021, P.310. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ijsr.net/archive/v10i6/SR21601120141.pdf accessed on 20th June, 2022.

[8] Kironmoy Chetia, "Tradition and Faith of the Tai-Ahoms and Deoris of Assam", International Journal of Science and Research (IJSR) Volume 10 Issue 6, June 2021, P.310. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ijsr.net/archive/v10i6/SR21601120141.pdf accessed on 20th June, 2022.

[9] Kironmoy Chetia, "Tradition and Faith of the Tai-Ahoms and Deoris of Assam", International Journal of Science and Research (IJSR) Volume 10 Issue 6, June 2021, P.310. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ijsr.net/archive/v10i6/SR21601120141.pdf accessed on 20th June, 2022.

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medicinal plants as well), "*Amlori Parua*"[10] (ants) fried with duck's eggs and different dishes of Pork, Chicken and duck's meat. They mostly prefer boiled dishes like boiled pork with spinach leaves, Bamboo, cane, banana leaves used in the preparations and banana shoots form an important part of their food habits.[11]

The Ahom tribes starting from their food habits which includes both plants and insects and animals are dependent on the Natural Resources. On the same note, they are also widely dependent on the plants for the medicine preparation and treatments. During the *Ahoms* rulers' period they believed that if you include the medicinal plants and vegetables into your food habits then most of the diseases are cured automatically. Apart from this they even prepare a special kind of rice beer termed as "*Laopani*"[12], which is prepared using medicinal plants. These facts proved that the dependency of the Ahom tribes mostly on the natural resources makes them stand on the bar of having great knowledge about the various medicinal plants. This also proves that they are rich in traditional medicines and indigenous knowledge.[13]

Traditional Knowledge and Biopiracy:

The definition of "*Traditional knowledge"* is not defined in the international forum till now but it is described as "*knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations*"[14] Under this the term "*Tradition*" according to the General meaning means "*long established*" but according to the "*Elements of a Sui Generis System for the Protection of Traditional Knowledge"*[15] it is stated as "*the way in which the knowledge is created, preserved and disseminated*".[16] In short we can

[10] Kironmoy Chetia, "Tradition and Faith of the Tai-Ahoms and Deoris of Assam", International Journal of Science and Research (IJSR) Volume 10 Issue 6, June 2021, P.310. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ijsr.net/archive/v10i6/SR21601120141.pdf accessed on 20th June, 2022.

[11] Kironmoy Chetia, "Tradition and Faith of the Tai-Ahoms and Deoris of Assam", International Journal of Science and Research (IJSR) Volume 10 Issue 6, June 2021, P.310. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ijsr.net/archive/v10i6/SR21601120141.pdf accessed on 20th June, 2022.

[12] Pranjal Deka, "Traditional Medicine Among the Ahom Community of Assam, India", International Journal of Scientific & Technology Research Volume 9, Issue 03, March 2020, P. 6850, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/http://www.ijstr.org/final-print/mar2020/Traditional-Medicine-Among-The-Ahom-Community-Of-Assam-India.pdf Accessed on 22nd June, 2022.

[13] Pranjal Deka, "Traditional Medicine Among the Ahom Community of Assam, India", International Journal of Scientific & Technology Research Volume 9, Issue 03, March 2020, P. 6850, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/http://www.ijstr.org/final-print/mar2020/Traditional-Medicine-Among-The-Ahom-Community-Of-Assam-India.pdf Accessed on 22nd June, 2022.

[14] Glossary of key terms related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions Document prepared by the Secretariat of Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in the Fortieth Session at Geneva, held during June 17 to 21, 2019: The definition of Traditional knowledge further defined as "*Traditional knowledge, as a broad description of subject matter, generally includes the intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities (traditional knowledge in a general sense or lato sensu). In other words, traditional knowledge in a general sense embraces the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with traditional knowledge*".

[15] (WIPO/GRTKF/IC/4/8) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in the Fourth Session at Geneva, held from December 9 to 17, 2002.

[16] (WIPO/GRTKF/IC/4/8) Ibid No. 2

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state that traditional knowledge means continuing from generation to generation as a culture, tradition and practice by a community or group of people and they are immensely interested to preserve and carry forward it in the future as well. Traditional knowledge has two types one is Traditional Medicinal Knowledge (TMK) and other one is Traditional Cultural Expressions (TCE).

Traditional Medicinal Knowledge (TMK) defined by WHO as "*the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses.*"[17]Different forms of Traditional Medical Knowledge (TMK) are those forms of Traditional Knowledge associated with medicine that is handed down orally or by written material.[18] For example medicines prepared from bio-resources, folk medicines, folk healing and oral TMK. **Traditional Medicinal practitioners** or traditional healer can be defined as "*someone who is recognized by the community in which he lives as competent to provide health care by using vegetable, animal and mineral substances and certain other methods based on the social, cultural and religious backgrounds as well as the prevailing knowledge, attitudes and beliefs regarding physical, mental and social well-being and the causation of disease and disability in the community".* Traditional healers used different medicinal formulas from various natural substances (animal, mineral and vegetable). They have extensive knowledge on the use of plants and herbs for medicinal and nutritional purposes.[19]

After the beginning of the era of industrialization, the concept of commercial intellectual property rights started, and then gradually the international institutions started discussion and negotiations about the traditional knowledge and importance of indigenous knowledge and cultural expressions. A need is felt to respect, preserve and protect the knowledge, innovation and practices of the communities.[20] These are emphasized by the Convention of Biological Diversity. But before this convention the historical development of the protection of the traditional knowledge started after the Second World War where the indigenous people were recognized as "*peoples*"[21] for the first time. Further, the UN Charter (1945)[22] uplifted the need to recognize human rights and

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[17] WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine (WHO/EDM/TRM/2000.1), p. 1.

[18] Sungha Kim et.al., Development of A Template For The Classification of Traditional Medical Knowledge in Korea, 178 Journal of Ethnopharmacology (2016), Pp. 82–103.

[19] Rama Shankar, G. S. Lavekar, S. Deb, and B. K. Sharma, "Traditional healing practice and folk medicines used by Mishing community of North East India", Journal of Ayurveda Integrative Medicine 2012 Jul-Sep; 3(3): 124–129.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3487237/#:~:text=The%20traditional%20medical%20practitioner%20or,religious%20backgrounds%20as%20well%20as
doi: 10.4103/0975-9476.100171

[20] Natalie P Stoianoff, "A Governance Framework for Indigenous Ecological Knowledge Protection and Use", published in "New Directions for Law in Australia", ANU Press. (2017) accessed on 20th Jan 2020 at https://www.jstor.org/stable/j.ctt1ws7wbh.25

[21] Christopher Antons, "The International Debate about Traditional Knowledge and Approaches in the Asia – Pacific Region" in Christopher Antons (ed), Traditional knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia – Pacific Region (Wolters Kluwer 2009) 40 – 51.

[22] Charter of UN (adopted 24 October 1945) Preamble, Chapter 1.

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sovereignty of every man and people. Then the UN, UDHR emphasized on the principles of "*equality and non-discrimination for all human beings*."[23]

In 1952, the International Labour Organization (ILO), with other UN agencies, initiated the Andean Indian Programme for the development of South American native Indians. In 1957, the same agency adopted the "*Convention concerning the protection and the Integration of Indigenous and other Tribal and Semi – Tribal populations in Independent Countries*" that recognizes the right of ownership for the populations over their traditional territories.[24] But, this Convention has been replaced with the ILO Convention No. 169 i.e. The Convention Concerning Indigenous and Tribal Peoples in Independent Countries, as this convention recognized in its Preamble "*The aspirations of these peoples to exercise control over their own institutions, ways of life and economic development and to maintain and develop their identities, languages and religions, within the framework of the States in which they live*".

Even if this treaty does not mention explicitly TK and TCEs, there are some provisions that are relevant like Art 23(1) which states that the handicrafts, rural and community – based industries, and subsistence economy and traditional activities of the peoples concerned such as hunting, fishing, trapping and gathering, shall be recognized as important factors in the maintenance of their Cultures and in their economic self – reliance and development. Then in Art 13(1) "*governments shall respect the special importance for the Cultures and spiritual values of the peoples concerned of their relationship with the lands or territories*". In Art 15(1) "*The rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded. These rights include the rights of these peoples to participate in the use, management and conservation of these resources*." The two other international documents worth mentioning are the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the International Covenant on Civil and Political Rights (ICCPR) both adopted in 1966. There is one common article in these two treaties which states that "*all people may, for their own ends, freely dispose of their natural wealth and resources*." According to many scholars they believed that this provision could be relevant in the context of the recognition and protection of TK and indigenous resources in general.

In the development of the history of the concept of TK there is another movement that anthropologists and sociologists have termed "*indigenism*"[25] which is used to describe the term international movement that aspires to promote and protect the rights of the World's "*first peoples*".[26] In the global arena, the early forms of informal cooperation between traditional communities started in civil rights movements. In 1974, several delegations of indigenous people from different continents gathered in Guyana and they agreed on a definition of "*indigenous peoples*" and decided to create an informal international conference. In 1975 during a conference hosted in Canada in a Nootkia Indian band, the World Council of Indigenous People was established. In 1982, these issues became structurally part of the activity of the UN with the creation of the UN Working Group on Indigenous Populations within the frame of the UN Economic and Social Council. This is the biggest forum where the indigenous matters are dealt

[23] UDHR adopted 10th December 1948 UNGA Res 217 A (III) (UDHR) art 1 and 2.

[24] Adopted 26th June 1957 into force 2 nd June 1959 328 UNTS 247 (ILO Convention 107/1957).

[25] The Origin of Indigenism: Human Rights and the Politics of Identity (University of California Press 2003) and Jeffrey Sissons, First Peoples: Indigenous Cultures and Their Futures (Reaktion Books 2005)

[26] The Origin of Indigenism: Human Rights and the Politics of Identity (University of California Press 2003) and Jeffrey Sissons, First Peoples: Indigenous Cultures and Their Futures (Reaktion Books 2005)

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with and it is known as the "*Permanent United Nations Forum on Indigenous Issues*". These above stated conventions and international institutions didn't speak explicitly about the TK but it implicitly emphasized the existence of such a concept associated with the indigenous communities and which is explicitly taken up in the CBD. Hence, now this Treaty of Genetic Resources and TK speaks explicitly about the protection and promotion of TK from Bio pirates.

What is Biopiracy?

Biopiracy has emerged as a term to describe the ways by which the corporations from the developed world claim ownership of or otherwise take unfair advantage of or free ride on the genetic resources and traditional knowledge and technologies of developing countries.[27] Biopiracy means *the process of taking indigenous people's knowledge without paying any compensation*.[28] The dictionary meaning of the term 'bio-piracy' is the unethical or unlawful appropriation or commercial exploitation of biological materials (such as medicinal plant extracts) that are native to a particular country or territory without providing fair financial compensation to the people or government of that country or territory.[29] The term 'bio-piracy' was coined by the North American advocacy group, Action Group on Erosion, Technology and Concentration (ETC Group), formerly known as Rural Advancement Foundation International, to refer to the uncompensated commercial use of biological resources or associated TK from developing countries as well as the patenting by corporations of claimed inventions based on such resources or knowledge.[30] Biopiracy is found in three forms, varying by the extent to which they are piratical. They are Bioprospecting, Discovery of Unknown Properties in Known Plants and Organisms and Exploitation of Traditional Knowledge. The gravest among these three is the last one.

Let's understand the problem with the help of a case of Mexico. A fermented Mexican drink which was invented by the Mayan people many years ago with the name *Pozol*. This drink contains some health promoting antibacterial properties. Due to these features the *University of Minnesota* and a *Dutch Corporation* extracted bacillus subtilis from this drink to use it as a natural inhibitor of unwanted flora in foods and feeds. They have been granted patents but they didn't give any recognition to the Mayan people nor did they pay any compensation to them. This shows the clear exploitation of traditional knowledge. After this the community wanted the government to adopt anti-prospecting legislation to protect traditional knowledge.[31]

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[27] Dr. Md. Zafar Mahfooz Nomani and Dr. Faizanur Rahman, "Bio Piracy of Traditional Knowledge Related Geographical Indications: A Select Study of Some Indian Cases", Manupatra Intellectual Property Reports October 2016, PP 135-152, https://docs.manupatra.in/newsline/articles/Upload/EAF22E08-7444-40EA-A07C-CBCE1F6F6FCB.pdf

[28] John Reid, "Biopiracy: The Struggle for Traditional Knowledge Rights", *American Indian Law Review,* 77-98, Vol. 34, No. 1 (2009-2010).

[29] Meaning of 'bio-piracy' according to Merriam Webster Dictionary cited in Lisa P. Lukose, "*Bio-Piracy and IPR issues*",620 (Thomson Reuters, Legal, Gurgaon).

[30] See, Graham Dutfield, 'Bioprospecting: Legitimate Research' or 'Bio-Piracy'? In Lisa P. Lukose, "*Interface between Traditional Knowledge and Intellectual Property*" 92-93 (Lambert Academic Publishing, 2013), Cited in Lisa P. Lukose, "*Bio-Piracy and IPR issues*", 620 (Thomson Reuters, Legal, Gurgaon).

[31] See Marcia E. DeGeer, *Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge*, 9 NEW ENG. J. INT'L & COMP. L. ANN. 179, 180 (2003) ("Indigenous Peoples have been cultivating and improving their local plant life for centuries."); see also Sumathi Subbiah, "Reaping What They Sow: The Basmati Rice Controversy and

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It is believed that the term biopiracy has less legal, more social and ethical dimension of unauthorizedly using and misappropriation of the plant resources and its associated TK developed, cultivated and preserved by indigenous communities.[32] The work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has helped in the development of sets of draft provisions for the protection of traditional cultural expressions/folklore (TCEs) and for the protection of TK against misappropriation and misuse of TK.[33] The Biodiversity Bill has been contradicting all these obligations of these international instruments.

Biopiracy: Pre-CBD and Post CBD

The Scenario of the Pre- convention on Biodiversity is different for the biopiracy after the Convention of Biodiversity (CBD). The natural resources were regarded as a 'common heritage of mankind.' During the pre-Convention era the researcher could easily arrive at the field site, collect samples from nature very easily like plants, microbes, animals etc. But as these researchers started exploiting this freedom and missued the natural resources without giving proper justification or compensation to the parties responsible for its conservation and preservation then there was a requirement for the protection of these natural resources. There was unauthorised exploitation of the living resources and associated Traditional Knowledge (TK) as well. This gradually led to loss of control by the common people over their own land and resources and above all their own traditional knowledge was at stake. Then, the Convention on Biological Diversity (CBD) came into place.[34]

After the Convention on Biological Diversity came into place they tried to protect and preserve the natural resources and traditional knowledge of the communities. They mainly highlighted the importance of biodiversity conservation and carved out the necessity of a proper legal mechanism for the preservation of the same and the sharing of benefits arising out of its commercial exploitation by stressing the economic potential of the same. This convention focused on the judicious use and the responsibility of each and every world community which uses such resources as well as the associated TK for various purposes. Along with it the convention also provides due credits to the indigenous communities for conserving the natural resources with their associated traditional knowledge and they are dependent on these natural resources for their survival. Article 10 of CBD states that each contracting party should integrate consideration and sustainable use of biological diversity in order to protect and encourage customary use of biological resources in accordance with traditional cultural practices. Hence, in this post CBD regime, biopiracy is illegal as well as unethical as it amounts to cheating upon the indigenous people's knowledge which they have shared without knowing that they are being exploited by third parties or outsiders. These cheaters then earn huge profits due to commercialization of their traditional knowledge associated with biodiversity.

Strategies for Protecting Traditional Knowledge", 27 B.C. INT'L & COMP. L. REV. 529, 544 (2004) ("Traditional knowledge develops incrementally from generation to generation.").

[32] Lisa P. Lukose, "*Bio-Piracy and IPR issues*" 621 (Thomson Reuters, Legal, Gurgaon).

[33] Lisa P. Lukose, "*Bio-Piracy and IPR issues*" 621 (Thomson Reuters, Legal, Gurgaon).

[34] *Id.*

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Although these seem to be very simple, on the same note it is very difficult to prove and catch hold of these bio pirates. The IPR laws provide only defensive rights to the traditional knowledge right holder.

Talking about IPR and Patent Specifically:

Intellectual Property Rights are mostly called as child of developed countries who wanted to monopolize the market with private or individual rights over the intellectual creation. Among the conventional intellectual property rights, patent is considered one of the important forms of the IPR. As the traditional understanding of the Patent, provided for the inventions having novelty[35], inventive step[36] and non-obvious[37] elements which can be used for industrial use[38], mostly granted to inventors which invested money and time for preparation of new products or processes. As per *Giles Rich*[39], who articulated this core conception of patent law, suggesting that *"progress is most effectively promoted by protecting those who enrich the art as well as those who improve it."*[40]

Considering this expression of conceptual commitment to the centrality of ownership[41] as the predominant norm in intellectual property received, is the exact expression in the preamble of TRIPS. This holds as one of its primary claims, "***that intellectual property rights are private rights".***[42] "*The* ***institutions of the modern patent era reflect this norm of innovation through individualized ownership.***"[43]

If we study the various politics attached with the Patent, then one of the models of politics emphasizes and indicates state as the primary factor.[44] It states how states are formed based on

[35] The concept of novelty in intellectual Property jurisprudence lays down that only what is new at the time of the filing of the application for a patent is patentable. Elizabeth Verkey, "Law of Patents", Eastern Book Company, Lucknow, 2012, p. 27.

[36] Section 2 (1)(ja) Indian Patent Act: "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

[37] Elizabeth Verkey, "Law of Patents", Eastern Book Company, Lucknow, 2012, p. 27.

[38] Elizabeth Verkey, "Law of Patents", Eastern Book Company, Lucknow, 2012, p. 27.

[39] a noted patent jurist in the US and one of the primary authors of the Patent Act of 1952, Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013.

[40] Giles Rich, "Principles of Patentability," 42 J. Pat. & Trademark Off. Soc'y 75, 85 (1960). This conceptual map was by no means the dominant norm of the intellectual property system, from the 1890s until 1940s, as reflected in key provisions of the Berne and Paris Conventions, related to issues such as working requirements. See, e.g., Royal E. Montgomery, "The International Aspects of Patent Legislation," 31 J. Pol. Econ. 90,93 (1923) ("Perhaps the working clause - a requirement that the monopoly grant be worked within a specified numbers of years - is of first importance.") cited in Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013, p.3.

[41] The General rule is that an individual owns the patent rights to the subject -matter of which he is an inventor, even though he conceived it or reduced it to practice in the course of his employment. Elizabeth Verkey, "Law of Patents", Eastern Book Company, Lucknow, 2012, p. 276.

[42] Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013, p.3.

[43] Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013, p.3.

[44] Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013, p.14.

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rates of innovation, either decentralized innovation regimes or centralized innovation regimes.[45] Another model focused on that patent law is a relational approach to the development of legal structures within the international intellectual property regime.[46] This indicates the state relationship approach towards the development of legal structures for the international intellectual property regime. This international intellectual property regime leads to development of public international treaties which is responsible for the individualized ownership of rights under patent.[47] Hence, making the patent right an individualized ownership negating all scope of considering any kind of community ownership within that.

As per *Section 2(j)* of the Patent Act, 1970, it states specifically that the definition of the term invention means newness and usefulness either in the art, process, method or manner of manufacture, machine, apparatus or other article and improvement of any of them.[48] It clearly indicates that there needs to be something new at the same time it should be useful. In the case of *Raj Prakash* vs. *Mangat Ram Choudhary and others*[49], discussed about what is considered as invention by stating through these lines:

> "*Invention is to find out or discover something not found or discovered by any one before and it is not necessary that the invention should be anything complicated ……so long as it is something novel or new, would be an invention and the claims and the specifications have to be read in that light and a new invention may consist of a new combination of all integers so as to produce a new or important result or may consist of altogether new integers….*"[50]

Hence, for clearly defining or identifying an invention the key ingredient is something new, it may be even new combinations of integers. There is a very thin line difference between the invention

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[45] Compare Daniel Drezner, "State Structure, Technological Leadership and the Maintenance of Hegemony," 27 Rev. of Intern'l Stud. 4 (2001)(contending that the governance structure of nation-states is crucial for determining rates of national innovation) with Mark Zachary Taylor, "Political Decentralization and Technological Innovation) with Mark Zachary Taylor, "Political Decentralization and Technological Innovation: Testing the Innovative Advantage of Decentralised States,"27 Rev. of Intern'l Studies 231, 232 (2007) (contending that decentralized state structure does not enjoy an advantage within the context of national innovative policies). Recently, Zorina Khan has offered an innovative assessment of the State formation model that emphasizes the ideological function of the selected regulatory forms. See, e.g., B. Zorina Khan, The Democratization of Invention: Patents and Copyrights in American Economic Development, 1790-1920 (2005) (contending that the examination system of the United States led to more widespread economic innovation in the nineteenth century). This state formation model has been dominant within international relations and institutional economics. Cited in Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013, p.14

[46]Jordan J. Paust, "Nonstate Actor Participation in International Law and the Presence of Exclusion," 5 Va. J. of International Law 977, 985 (2011) (critique of classical international law model of international law) cited in Kali Murray, "A Politics of Patent Law Crafting the Participatory Patent Bargain", Routledge, New York, 2013, p.14

[47] This difficulty in ignoring non-state actors points to the anomalous nature of property rights in the international order, which is consequential to the extent that the patent right is classified as a property right. For instance, Article VII of the Outer Space Treaty permits avenues for claiming property in chattels, which has served to justify state regulation of international intellectual property in chattels. Article VII, in particular, refers to liability assessed to one state party if the launching of a registered space object causes damage to another state party; this requires the registration of these chattels. See Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and other Celestial Bodies, January 27, 1969, 610 UNTS 207. This treatment of property objects necessarily suggests the importance of articulating and recognizing the rights of property owners - and thus the subsequent recognition of them-in public international treaties.

[48] P.S. Narayana, Intellectual Property Law in India, 23 (Gogia Law Agency, Hyderabad, 2006).

[49] AIR 1978 Del. 1 citated in P.S. NARAYANA, supra note 37, at 23.

[50] P.S. NARAYANA, supra note 37, at 23.

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and not to be considered as an invention. An invention will not be considered as an invention which in effect is "*traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components or components*".[51] Therefore, even if the traditional knowledge has been used in the invention, then one needs to prove what new combination or new addition has been made to the existing knowledge. Simply, copying the traditional knowledge will not be considered as an invention.

On the same note the word '*Patent*' means monopoly right over invention.[52] Invention being the main ingredient of the Patent Right it is very much required that the inventor must be able to show that he has invented something new which doesn't fall within any of the ingredients of non-patentability. Patents are very important for the economic and social development of any nation and ignorance or delay in proper patent protection regime can be an issue of great concern for the entire country.[53] An inventor owns a property right in his invention. This is a natural right. What the patent system does is to guarantee a limited term of protection in return for the inventor's agreement to disclose details of his invention and ultimately, to abandon his property right in it. Inventors are offered a stronger and more effective property right than under their natural right on condition that they will lose all rights in the invention when the patent expires.[54] Therefore, each inventor is required to register his invention as Patent Right by which the inventor can at least enjoy the exclusive right for a certain period and take the benefits of it.

Challenges faced by the traditional practitioners in the Registration Process of Patent:

Before we discuss the registration process of Patent, we need to understand what an invention actually is. "*Invention*" means a new product or process involving an inventive step and capable of industrial application.[55] This invention can be registered as patent if it is having something new as compared with the prior art or has not been anticipated by the prior art.[56] As per the literal interpretation of section 2(1)(j)[57], the pharmaceutical inventions are considered to be inventions; if prepared as inventive products and/or processes for making pharmaceutical compounds are considered to be inventions under the said clause.[58] By only showcasing: 1) Use of compounds in the treatment of particular disorders and 2) A product or a substance (which is known) for the treatment of a new disease (which is nothing but a use/application claim) will not be considered

[51] Section 3(p) of the Patent Act, 1970 citated in P.S. NARAYANA, supra note 37, at 26.

[52] Feroz Ali Khader, The Law of Patents- With A Special Focus on Pharmaceuticals In India, 1 (Lexis Nexis, New Delhi, 2007).

[53] V.K. Ahuja & Archa Vashishtha (Ed.), Intellectual Property Rights Contemporary Developments,552 (Thomson Reuters South Asian Private Limited ed. al., ed.2020).

[54] Feroz Ali Khader, The Law of Patents- With A Special Focus on Pharmaceuticals in India, 1 (Lexis Nexis, New Delhi, 2007).

[55] Section 2(1)(j) of the Indian Patent Act.

[56] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[57] 2. Definitions and interpretation. — (1) In this Act, unless the context otherwise requires, — (j)"invention" means a new product or process involving an inventive step and capable of industrial application;

[58] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

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as an invention.[59] In *Fumapharm AG* Vs. *the Controller of Patents & Designs*,[60] Hon'ble Intellectual Property Appellate Board (IPAB) rejected such application. There have been objections raised on two heads, firstly the claims are not allowable under *section 2(1)(j)* as that claims neither relate to product nor to process also the compounds claimed to be invented were known. Due to lack of novelty this has been rejected by the Controller.[61]

On this similar note, if a traditional practitioner comes forward for filling their traditional medicinal knowledge as a patent, they need to scientifically prove the uniqueness of pharmaceutical compounds, which is not possible for them to prove, as this knowledge is culturally transferred. This is the first and main challenge faced by the traditional practitioners.[62] This is the main challenge faced by the Ahom Tribes of Assam where those practitioners who wanted to file their formulations were facing challenges in proving their formulations scientifically. Even if they prove it, they will face the challenge of reverse engineering but their patent will be taken away from them. These major issues are not addressed under the Treaty of Intellectual Property, Genetic Resources and Traditional knowledge.

An application needs to be filed for registering the patent. For this the application needs to be filed in the appropriate manner as provided by the provisions:

1. Prior Art Search:

The first step for registration of a patent is the prior art search by the examiner. The Examiner should design/frame a comprehensive search strategy by combining various search parameters including keywords, IPC, compound searches, etc. and thorough search should be carried out in patent as well as non-patent databases.[63]

Another challenge for the traditional practitioner of Ahom tribes is to file for registration of patent is this prior art search. When the traditional medicines are themselves part of the prior art then how can they clear this prior art search. In order to clear this step, they need to actually undergo some kind of experiments through which they can develop a new product out of their own knowledge.

2. The Assessment of Novelty:

Under the Assessment of Novelty, if we speak about the documents required to prove the novelty there should be different documents required to be shown for different embodiments unless such

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[59] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[60] OA/6/2009/PT/KOL and Miscellaneous Petition No. 34/2011 in OA/6/2009/PT/KOL, ORDER (No. 73 of 2013) 2

[61] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf,

[62] From the survey conducted by the researcher upon Ahom Tribes of Assam.

[63] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf, p.9.

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combination has specifically been suggested or essentially linked to one another.[64] If anyone is using Markush formula[65] covers innumerable compounds and if some of the compounds fall within one prior art and certain other compounds fall within another prior art, in such cases all these prior art documents need to be shown.[66] For the traditional practitioners it's very difficult to prove the existence of their traditional knowledge as mostly they practice it and transfer this knowledge from generation to generation orally. Hence, there is no scope for them to showcase their knowledge through documents. Therefore, it becomes challenging for them to show the novelty element in their medicinal product even though it is present in it.

Next important element is priority date, as per *section 2(1)(w)*[67] of the Act, means such publication must be before the date of priority of the claim under consideration.[68] The prior art document must be enabling i.e. there should be a clear and unmistakable direction for the invention in the prior art.[69]This aspect is not possible to prove under the traditional medicines as they themselves are part of the prior art. These aspects are not discussed or taken up under the Treaty which would have clarified the confusion of inclusion of Traditional knowledge under the prior art.

3. Determination of novelty[70]:

[64] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[65] Often broad ("generic") patent claims are drafted covering a family of a large number (sometimes thousands or millions) of possible compounds. The so-called 'Markush claims' refer to a chemical structure with plurality of functionally equivalent chemical groups in one or more parts of the compound. The Markush claims are drafted to obtain a wide scope of protection encompassing a large number of compounds whose properties might not have been tested, but only theoretically inferred from the equivalence with other compounds within the claim. Quite often the Markush claims generate confusions regarding the novelty, non-obviousness and industrial applicability of a group of compounds covered within the said Markush formula. Also, the Markush claims may invoke the questions of sufficiency and plurality of distinct group of inventions surrounding such claims. Cited under Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[66] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[67] Section (1)(w) "priority date" has the meaning assigned to it by section 11; Section 11: Priority dates of claims of a complete specification. If one files the complete specification on a priority date then that date will be considered for the convention countries filling as well, this will provide advantage to the inventor as no one can claim that invention's novelty between the first and second filings.

[68] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[69] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[70] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014

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For determining the novelty, the inventor must show clearly with chemical compounds how his invention of product or process is novel as compared with the prior art. If we take an example of the patent application disclosing about the chemical components of it as follows[71]:

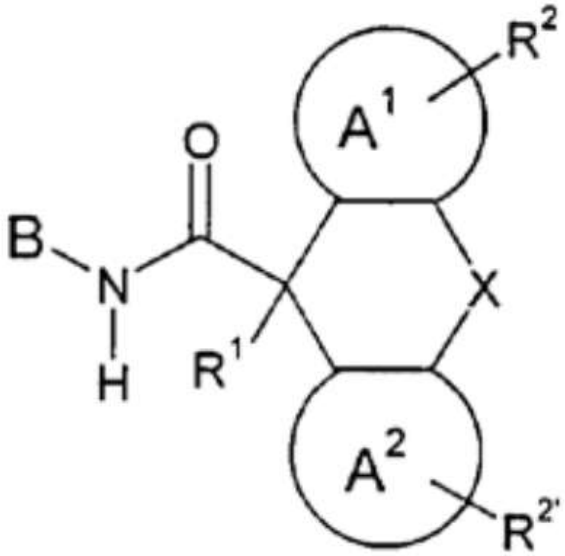

Diagram 1: Showing Prior Art

In the above diagram, O, B, N and H signify Oxygen, Boron, Nitrogen and Hydrogen molecules respectively.
R1 signifies hydrogen or lower alkyl, R2, R2' signify, independently from each other, hydrogen, lower alkyl, lower alkoxy, halogen or trifluoromethyl

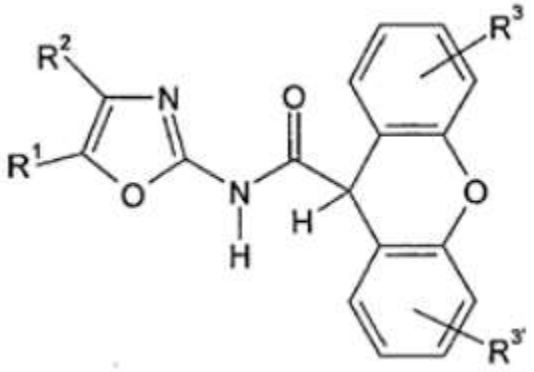

Diagram 2: Showing the Invention

https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[71] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014
https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

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In the above diagram, here, one of R1 and R2 signifies trifluoromethyl, and the other one signifies hydrogen
R3, R3' signify, independently from each other, hydrogen or halogen.

Difference between Diagram I and Diagram II. Diagram I involves compounds where one of R1 and R2 signifies trifluoromethyl, while the other signifies hydrogen, with specific variations in R3 and R3'. Diagram II, on the other hand, includes compounds where both R1 and R2 signify hydrogen, with variations in R3 and R3'. The differences in the chemical structure of the compounds in Formula I and Formula II impact their pharmaceutical applications and potential utility.

In the case of the traditional medicinal knowledge, the traditional practitioners combine various plants, herbs together into a certain proportion, add it with other food items and then give it to the patients. This knowledge comes out of practice not by scientific experiments about the compounds or novelty proved within it. Hence, it's very difficult as they don't have any access to any organization which they can help out to identify the chemical compounds of their traditional medicines. Even if they can show somehow, it's difficult to prove it is different from the prior art.

4. Product-by-process claims:

A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se, regardless of its method of production.[72] In a product-by-process claim, by using only process terms, the applicant seeks rights to a product, not a process.[73] In product-by-process claims, the applicant has to show that the product defined in process terms, is not anticipated or rendered obvious by any prior art product.[74] In other words the product must qualify for novelty and inventive steps irrespective of the novelty or inventive step of the process.[75]

In re Thorpe,[76] in this case it is a claim for a novolac color developer. The process of making the developer was allowed. The inventive process was an addition of metal oxide and carboxylic acid as a separate ingredient as compared with the prior art of expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not

[72] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[73] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[74] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[75] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[76] 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

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directly added, but is instead produced in-situ does not change the end product.[77] However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim.[78]

If we speak about the traditional medicinal knowledge proceeding with the patent registration, even after facing so many difficulties, somehow the traditional practitioner tries to register for the product patent but it is infringed by the process patent. For example, one of the traditional practitioners wants to file a patent registration for his traditional medicine on the disorder of jaundice. With the help of National Institute of Pharmaceutical Education and Research, Guwahati (NIPER), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, he was able to successfully conduct the scientific experiments about the chemical composition of his medicine and then came up with the invented product as medicine for patent registration. But he faced the challenges of filling his application for registration due to fear of reverse engineering as anyone can get that product as well as restrict him to get exclusive rights over it. Therefore, it is advisable that they register the process as well for better protection.

5. Assessment of Inventive Step:

An invention should possess an inventive step in order to be eligible for patent protection. As per the section 2(1)(j)(a) of Patents Act, an invention will have inventive step if the invention is (a) technically advanced as compared to existing knowledge or (b) having economic significance or (c) both, and that makes the invention not obvious to a person skilled in the art. Inventive step is determined vis-à-vis any matter published in any document anywhere in the world or any use before the priority date of the claim. Unlike the novelty, mosaicking of prior art documents is permissible in the context of inventive steps. In the context of traditional medicines, as it lacks novelty, similarly inventive steps in it. Again, if it is part of the prior art then it will also come under the definition of obviousness.

In the case of *Biswanath Prasad Radhey Shyam* vs *Hindustan Metal Industries,*[79]Hon'ble Supreme Court observed on inventive step as: The expression "*does not involve any inventive step*" used in Section 26(1) (a) of the Act and its equivalent word "*obvious*", have acquired special significance in the terminology of Patent Law. The '*obviousness*' has to be strictly and objectively judged.

Method for objectively analyzing the inventive step[80]:

a) Identify the inventive concept of the claim in question

b) Identify the "person skilled in the art",

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[77] *Amgen Inc. v. F. Hoffmann-La Roche Ltd.,* 580 F.3d 1340, 1370 n 14, 92 USPQ2d 1289, 1312, n 14 (Fed. Cir. 2009). See also *Purdue Pharma v. Epic Pharma,* 811 F.3d 1345, 117 USPQ2d 1733 (Fed. Cir. 2016). "a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim").

[78] The United States Patent and Trademark Office an agency of the Department of Commerce https://www.uspto.gov/web/offices/pac/mpep/s2113.html

[79] (AIR 1982 SC 1444)

[80] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

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c) Identify the relevant common general knowledge of the person skilled in the art at the priority date;
d) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim;
e) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?

As per the above objectivity of analyzing the inventive step, as it's difficult for the inventor to prove the element of novelty, inventive step and non-obviousness, in the same note its difficult for the traditional healers to prove their traditional medicines unique as the standard three elements required as per the Patent Law. Even if there is actually involvement of the innovative element or methods or process but it's difficult to prove scientifically.

6. Industrial applicability[81]:

As we know, traditional medicinal knowledge is a cultural and traditional practice. It associates the communities' interest and identity. It also has an association of the faith of God and spirituality along with the knowledge about biodiversity. There is no connection of commercialization of the traditional medicines associated with it. Even no private rights or individual rights can be claimed over it. Hence, thinking about the patent registration of the traditional medicines and then to think about industrial applicability is like poles apart. As per Section 2(1) (ac)[82] of the Act, the expression "*capable of industrial application*", in relation to an invention, means that the invention is capable of being made or used in an industry.
Although, there can be one element which can easily be shown is the usefulness of the invented product. The traditional medicinal knowledge has been able to cure many patients with its traditional practice and knowledge about the medicinal plants. So, this can be shown as evidence to prove the usefulness of the product. As stated under the Section 64 (1) (g)[83] the Act provides that a patent is liable to be revoked if the invention is not useful. To be patentable an invention must be useful and capable of industrial application. The specification should disclose the usefulness and industrial applicability of an invention in a distinct and credible manner unless the usefulness and industrial applicability of the invention is already established, either in explicit or in implicit manner. The patent specification must disclose a practical application and industrial use for the claimed invention wherein a concrete benefit must be derivable directly from the description coupled with common general knowledge. Mere speculative use or vague and

[81] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[82] Section 2. Definitions and interpretation - (ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;

[83] Section 64. Revocation of patents.—(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say— (g) that the invention, so far as claimed in any claim of the complete specification, is not useful;

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speculative indication of possible objective will not suffice.[84] Even if to show traditional medicinal products of the industrial applicability in conventional manner is challenging for the traditional practitioners but if they can show that they have access to market outside of their community and locality by various means, then even this element of difficulty can be removed. Like, for example in Munnar Kerala, they have created tourists' spots (Natural Garden) where they will display the medicinal plants in their bioreserve and along with that they will have a showroom (shop or outlet) from where the tourists can buy the products directly from these outlets. This way there will be marketing of their products as well.

7. Sufficiency of description, clarity and support of the claims:

Description, clarity and specification are one of the essential elements in the process of filing a Patent. Usually, an inventor describes the invention or its operation backed by the scientific explanation documentation. According to Section 10 (4) (a) and (b)[85] of the Act, the complete specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed and it should also disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection. As per Section 10(c)[86], every complete specification should end with a claim or a set of claims defining the scope of invention. Section 10(5)[87] prescribes that the claims should be clear, succinct and fairly based on the description. Also, the claims must relate to a group of inventions linked so as to form a single inventive concept. This specification is a biggest challenge for the traditional practitioners to show as they need to specify lots of things which are not clear to them, also as they mostly practice orally, they lack the support of documentary evidence to show their practice of the knowledge from a longer period.

Specifications:

Two kinds of Specifications:

(A) Provisional Specification and Complete Specification[88]:

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[84] Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs and Trademarks October 2014 https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

[85] Section 10. Contents of specifications. — (1) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates. (4) Every complete specification shall— (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection;

[86] Section10. Contents of specifications. — (1) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates. (4) Every complete specification shall (c) end with a claim or claims defining the scope of the invention for which protection is claimed;

[87] Section10. Contents of specifications. — (1) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates. (4) Every complete specification shall— (5) The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.

[88] Section 9. Provisional and complete specifications. — (1) Where an application for a patent (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) is accompanied by a provisional specification, a complete specification shall be filed within twelve months from the date of filing of the

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A patent specification is a unilateral statement by the patentee[89], in words of his own choosing, that informs what he claims to be the essential features of the new product or process for which the letters patent grants him a monopoly.[90] This provisional specification helps in the determination of priority of patents. The object of filling a provisional specification is more manifest in cases where there are similar inventions which give rise to competing applications. Where two or more persons develop similar concepts and make competing applications for patents for the same invention, in different parts of the world, the priority of the co-pending applications is determined on a 'first-o-file' basis. The application which is filed first in time before the appropriate scrutinizing authority will be accorded precedence over the later application. The provisional specification should describe the true nature of invention, and such description should be the same as that claimed in the complete specification.[91] Where only a provisional specification is filed at the first instance along with the application, the complete specification shall be filed within 15 months from the date of filling of the applications.[92]

The 15 month time period granted for filling the complete specification after the provisional specifications has been filed allows the applicant to develop, improve and perfect the invention.[93] In the case of *Glaxo Group Limited's Application*[94], an issue arose as to whether a claim to a process of reacting a steroid, of a certain general formula in which a number of radicals were identified, with a phosphoric acid compound under specified conditions was fairly based on a provisional specification which referred to the reaction, but described the group of steroids in general terms. It was held by the hearing officer that the monopoly sought by the claim to the general formula with identified radicals was more restricted in its scope than the invention set out

application, and if the complete specification is not so filed, the application shall be deemed to be abandoned. (2) Where two or more applications in the name of the same applicant are accompanied by provisional specifications in respect of inventions which are cognate or of which one is a modification of another and the Controller is of opinion that the whole of such inventions are such as to constitute a single invention and may properly be included in one patent, he may allow one complete specification to be filed in respect of all such provisional specifications. Provided that the period of time specified under sub-section (1) shall be reckoned from the date of filing of the earliest provisional specification. (3) Where an application for a patent (not being a convention application or an application filed under the Patent Cooperation Treaty designating India) is accompanied by a specification purporting to be a complete specification, the Controller may, if the applicant be requests at any time within twelve months from the date of filing of the application, direct that such specification shall be treated, for the purposes of this Act, as a provisional specification and proceed with the application accordingly. (4) Where a complete specification has been filed in pursuance of an application for a patent accompanied by a provisional specification or by a specification treated by virtue of a direction under sub-section (3) as a provisional specification, the Controller may, if the applicant so requests at any time before grant of patent, cancel the provisional specification and post-date the application to the date of filing of the complete specification.

[89] Section 2 (p) "patentee" means the person for the time being entered on the register as the grantee or proprietor of the patent;

[90] Catnic Components Ltd v Hill & Smith Ltd [1981] FSR 60, (1982) RPC 183, pp 242-243.

[91] Nuttall v. Hargreaves [1892] 1 Ch 23.

[92] Section 9(1) of the Patents Act 1970 states that the complete specification shall be filed within 12 months, but if the applicant makes a request in the prescribed manner the time may be extended to 15 months.

[93] Feroz Ali Khader, "The Law of Patents-with a special focus on Pharmaceuticals in India", LexisNexis Butterworths Wadhwa, Nagpur, P.112.

[94] [1968] FSR 503

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in general terms in the provisional specification, and the claim ought therefore to be allowed the priority date of the provisional.[95]

(B) Complete Specification:

A complete specification should satisfy the requirements stipulated under the Patent Act. It shall begin with a title that sufficiently indicates the subject matter of the invention,[96] fully and particularly describe the invention,[97] disclose the best method of performing the invention,[98] disclose the best method of performing the invention,[99] end with the claim defining the scope of the invention, and be accompanied by an abstract.[100] The object and purpose of filling a complete specification is to enable a reasonably well-informed artisan dealing with the subject-matter with which he is familiar (person skilled in the art) to make the thing, so as to make it available for the public at the end of the term of the Patent. In keeping with this important objective, the decisions of the courts involving patents will usually include a reproduction of the relevant claims or a brief summary of the specification.[101]

The main contents of a complete specification and its accompaniments include:

(1) Title;
(2) Abstract;
(3) Description of invention;
(4) Claims;
(5) Drawings;
(6) Models or Samples[102]

In order to convert the traditional medicine into the conventional pharmaceutical drugs, the main challenges faced by the traditional practitioners is to prove the test of novelty, uniqueness and non-obviousness. As this traditional knowledge is already mentioned or available under the public documents it is challenging to show the provisional or complete specification of claims. Nowadays, there has been the creation of a traditional knowledge digital library where information about most of the traditional knowledge is mentioned.

Apart from the challenges faced for trying to register traditional medicine as a patent, there are lots of other challenges faced by the traditional practitioners. Like, most of the traditional practitioners are not aware about the Intellectual Property Rights. National Institute of Pharmaceutical Education and Research, Guwahati (NIPER)[103], Department of Pharmaceuticals, Ministry of

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[95] Feroz Ali Khader, "The Law of Patents-with a special focus on Pharmaceuticals in India", LexisNexis Butterworths Wadhwa, Nagpur, P.113.

[96] S. 10(1)

[97] S.10(4)(a)

[98] *Van der Lely NY* v *Ruston's Engineering Co Ltd* (1993) RPC 45, P 56(CA) where it was held that 'best' means best in practice and not theory. It was also held that as the claims pertained to a product and not a process, the best method of performing the invention did not require the applicant to disclose the best method of using the invention.

[99] S. 10(4)(d).

[100] S. 10(2) and (3).

[101] *Valensi* v. *British Radio Corpn Ltd* (1973) RPC 337, [1972] FSR 273 (CA).

[102] Feroz Ali Khader, "The Law of Patents-with a special focus on Pharmaceuticals in India", LexisNexis Butterworths Wadhwa, Nagpur, P.112.

[103] https://niperguwahati.ac.in/

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Chemicals and Fertilizers, Government of India, working with the traditional healer, for the last few years. They have connections with various traditional healers in different states also. They provide training and conduct various awareness programs for the traditional healers so that they become aware about the Intellectual property rights and can come forward for getting some kind of recognition for their practice. They help the traditional healers for mainstreaming their formulations. They have connected with many traditional healers and some of the formulations they have chosen as batch wise like First Batch, Second Batch and tried to validate their formulations on the efficacy and toxicity. So, after getting the results if it is non-toxic and having good efficacy through *invivo*[104] and *invitro*[105] study. The analysis of compounds they use to help them to file for regulatory certificates from AYUSH[106] and AYUSH will give them the regulatory Certificates and they can commercialize their product. So, they also work to help them for Patent filing and they have collaborations with Astic also so that they can help for the Patent Filing of traditional healers formulations.[107]

As per this organization, the most important and difficult thing is patenting the formulation. If it is formulations which are depicted in that traditional manuals or the folklore then it will not be considered as new information and then it won't be considered as the patent filing. Also, if it is a new plant used then it will be difficult to get the regulatory certificates then they need lot of valedictions for this and even if they can apply for the patent the main problem is that it is very easy to reverse engineering or just make a slight change in the formulations and to have a new Patent. To prevent this, they suggest the traditional practitioners go for the process patent. This way they prepared to get the perfect formulations with consistent stability. In addition, they give some additional information so that their application becomes strong and they get the patent. Presently, they are working with 9 traditional healers with their formulations for treating Malaria, Diabetes and Hepatitis. They are working in between *invivo* studies and *invigo* and get them regulatory certificates from AYUSH.[108]

The WIPO Treaty on Intellectual Property Rights, Genetic Resources and Associated Traditional Knowledge

The WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge came into existence in 2024. It was adopted in Geneva on May 24, 2024. This treaty has introduced a mandatory patent disclosure requirement which states that the patent applications if they use any kind of genetic resources then the associated traditional knowledge and source of the country/place of the indigenous communities or local communities needs to be disclosed who provided the knowledge for the claimed invention. Almost 39 countries are signatories to this treaty.

The main objective of this Treaty is to *enhance the efficacy, transparency and quality of the patent system with regard to genetic resources and traditional knowledge associated with genetic*

[104] In vivo is Latin for "within the living." It refers to work that's performed in a whole, living organism.

[105] In vitro is Latin for "within the glass." When something is performed in vitro, it happens outside of a living organism.

[106] The Ministry of AYUSH (Ayurveda, Yoga, Unani, Siddhi, Homeopathy) https://ayush.gov.in/

[107] Interview conducted by the researcher with the officer in charge of the Incubation Centre, NIPER

[108] Interview conducted by the researcher with the officer in charge of the Incubation Center, NIPER

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resources and prevent parents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and associated TK.[109]

Key Provisions of the Treaty:

1. Mandatory Disclosure Requirements:

As per the Article 3 of the treaty it clearly states that the patent applicants need to disclose either the country of origin of the genetic resources or if it is not known by the applicant then at least the source of information as per Article 3.1. (b).[110] This mandatory disclosure will help the indigenous communities to get recognition of their knowledge used in Patent applications. Again under Article 3.2. it is mentioned that when any of the indigenous communities has provided traditional knowledge to the Patent applicant then they should disclose it within their application.[111] As per Article 3.3.,[112] it asks the patent applicant to provide a declaration that whatever information provided by them is true and correct to the best of their knowledge. Under Article 3.4.,[113] it is the obligation of the contracting parties to provide guidance to the patent applicant that even if they fail to disclose the source of information or minimum information then they are allowed to rectify it later during the process of registration. This provision gives an upper hand to the contracting parties to take an active part in pressurizing the patent applicant to disclose the source of information. The most significant part of the provision is mentioned under Article 3.6[114] of the treaty where it states that the contracting parties will be obliged to disclose the information provided by the Patent applicant and if there is any confidential information needs to be maintained. In case if some of the indigenous groups or families want to keep their information confidential then it should be respected.

These mandatory disclosure requirements will also help in curbing biopiracy. If they can compel the patent applicants to reveal the origins of associated traditional knowledge and genetic resources then it will reduce the misappropriation which will ensure that patent examiners will have necessary information to assess the novelty or inventiveness of applications.

If we consider the case of Ahom Tribes of Assam's traditional knowledge which is orally transmitted from generation to generation, if their knowledge is taken by any patent applicants and not disclosed in their application, then they wouldn't be recognize nor they will be able to use their own traditional knowledge due to exclusive rights of the patent holders. Also, this community of people who are practicing this knowledge are mostly illiterate and innocent to work smartly and

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[109] Summary of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (2024) https://www.wipo.int/treaties/en/ip/gratk/summary_gratk.html accessed on 06th March 2025.

[110] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[111] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[112] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[113] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[114] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

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not to disclose it to any third person without prior consent of benefit sharing. Therefore, safeguarding the practice of knowledge of this community from third parties who are going to file for patents without taking prior consent of benefit sharing should be prevented. Hence, it's very much necessary to make mandatory disclosure of information by the patent applicant.

Sanctions and Remedies:

Under this treaty they have even introduced sanctions and remedies under Article 5[115] for not complying with the disclosure clause of Article 3[116] by the Patent applicant. They have considered the non-disclosure of the information by mistake can be rectified again but if there is fraudulent intent to not disclose the information then there is no exemption of levying sanctions and remedies. This provision of imposing sanctions on non-disclosure of information transforms the treaty from soft law to hard law, ensuring that wrongdoers face consequences rather than allowing the law to remain a mere spectator, ineffective without enforcement.

As per Goss's explanatory notes to the text states that the rationale for not revoking a patent solely on the ground of non-disclosure was to ensure legal certainty for patents. Furthermore, the provision aimed to enable benefit-sharing without guaranteeing it, as it does not revoke the foundation of benefit-sharing—the commercial patent. Described as a compromise between pragmatism and theory, the sanctions and remedies provision fail to integrate the fair and equitable benefit-sharing principle of the CBD within the treaty itself. By leaving the duty to provide remedies to national discretion and not establishing a cohesive framework between the CBD and IP law, the treaty misses another crucial opportunity. Without an international obligation to compensate traditional knowledge holders, the WIPO treaty remains largely symbolic, representing a lost chance to create a mutually reinforcing relationship between intellectual property and biodiversity conservation.[117]

Establishment of Information Systems:

Under Article 6 this treaty proposes the creation of information systems to make traditional knowledge accessible to patent office's globally. Under Article 6.1.[118], it states that the member countries should create a database in consultation with their indigenous communities and under Article 6.2.[119] It states further that all the database information must be accessible by the Offices for the purpose of search and examination of Patent which will make it easy for the Registration

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[115] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[116] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[117] Kriti Sharma, "Missed opportunities: WIPO Treaty falls short of protecting Traditional Knowledge", CIL Dialogues an International Law Blog https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge accessed 07th March 2025.

[118] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[119] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

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officers to identify the source of information used for Patent[120] and no patent will be granted without any disclosure of source. This initiative seeks to prevent the erroneous granting of patents on existing traditional knowledge and to respect the intellectual contributions of Indigenous Peoples and local communities.

Some scholars believe that the treaty encourages member states to voluntarily establish "information systems" or national databases of traditional knowledge (TK) in consultation with their Indigenous Peoples and Local Communities (IPLCs) (Article 6).[121] These databases would serve as repositories of TK, accessible to patent examiners worldwide, to prevent the wrongful granting of patents and the misappropriation of TK.[122] As India has set up a very good example by setting up India's Traditional Knowledge Digital Library, which was created in response to unjustly granted patents on the medicinal properties of neem and turmeric.[123] These kinds of databases function as a form of defensive protection within intellectual property law, primarily aimed at preventing third parties from claiming ownership over TK.[124] They help safeguard TK from misuse by blocking patents on "inventions" that fail to acknowledge the longstanding knowledge, originality, and creativity of TK holders.[125]

Promotion of Fair Benefit-sharing mechanisms:

The treaty lays the ground for fair benefit-sharing arrangements by recognizing the rights of Indigenous peoples and local communities over their genetic resources and traditional knowledge. This will ensure these communities to receive appropriate compensation, recognition of their rights over their knowledge they possess from time immoral. As in the case of Ahom Tribes of Assam, they are practicing in remote villages and due to their oral transferring of rights they are not yet recognized under the traditional knowledge database of AYUSH. Hence, this treaty will help them to get recognition of their traditional knowledge and also if someone is utilizing their traditional knowledge then they can make agreements for fair benefit sharing of profits on their knowledge used by them.

Criticism:

Although this treaty speaks about the recognition of traditional knowledge but still it has many criticisms as follows:

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[120] World Intellectual Property Organization (WIPO) TRT/GRATK/001 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge https://www.wipo.int/wipolex/en/text/592504 accessed on 07th March 2025.

[121] Kriti Sharma, "Missed opportunities: WIPO Treaty falls short of protecting Traditional Knowledge", CIL Dialogues an International Law Blog https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge accessed 07th March 2025.

[122] Kriti Sharma, "Missed opportunities: WIPO Treaty falls short of protecting Traditional Knowledge", CIL Dialogues an International Law Blog https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge accessed 07th March 2025.

[123] Kriti Sharma, "Missed opportunities: WIPO Treaty falls short of protecting Traditional Knowledge", CIL Dialogues an International Law Blog https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge accessed 07th March 2025.

[124] Kriti Sharma, "Missed opportunities: WIPO Treaty falls short of protecting Traditional Knowledge", CIL Dialogues an International Law Blog https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge accessed 07th March 2025.

[125] Kriti Sharma, "Missed opportunities: WIPO Treaty falls short of protecting Traditional Knowledge", CIL Dialogues an International Law Blog https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge accessed 07th March 2025.

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As this treaty came after twenty-five years of long discussion and it is the hope for many indigenous communities. But still, many scholars believe that it has not serve the purpose it should have done for the indigenous communities. Like, under the treaty they have made Government as the custodian of genetic resources. If, government become the custodian of genetic resources and there is no representation from the indigenous communities then it's like phrase "*Fine words butter no parsnips*". It's like talking about rights of the indigenous communities without allowing them to be part of the panel for decision making about their genetic resources and knowledge associated with them. *As Peter Yu writes:*

> *"Indigenous Peoples may fear that a more relaxed three-step test will invite abuse in those contracting states that are reluctant to strengthen the protection of genetic resources and associated TK. For instance, these states could introduce broad limitations and exceptions to undermine the hard-fought obligations in the finalized instrument, including provisions that "run counter [to] indigenous peoples' right to self-determination and the principle of [free, prior, and informed consent]." To close these loopholes, Indigenous Peoples therefore prefer a more restrictive three-step test—at times even tighter than the one found in the TRIPS Agreement and other international trade and intellectual property agreements."*[126]

Another flaw in this treaty is that this treaty has given flexibility to the international disclosure obligations to the government to deicide the rules need to be applied in their respective countries for implementation of necessary disclosure rules mention in this treaty. If the power or flexibility is given to the government then there is high chance possibility of manipulation. Treaty being the soft law will not suffice the purpose for formation of this treaty. If we compare the TRIPS Agreement then there are no exceptions to the disclosure requirements in TRIPS Article 29, which requires patent applicants "to disclose the invention in a manner sufficiently clear and complete" for the invention to be used by others.[127] There appears to be sufficient flexibility in Article 29 to allow inhibiting public disclosure of patent information, as evidenced by the case of secret patents in the U.S. and Japan.[128] Similarly, if we speak about Convention on Biological Diversity (CBD) there are no explicit exceptions to the Convention on Biological Diversity's requirement that "*access to genetic resources shall be subject to prior informed consent*" (Art. 15(5)) and that "*legislative, administrative or policy measures, as appropriate*," be taken "*with the aim of sharing*

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[126] Sean Flynn, "*Limitations and Exceptions in the WIPO Instrument on Genetic Resources and Associated Traditional Knowledge Resources and Associated Traditional Knowled",* American University Washington College of Law American University Washington College of Law Digital Commons @ American University Washington College of Digital Commons @ American University Washington College of Law https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1129&context=research accessed on 13th March, 2025.

[127] Sean Flynn, "*Limitations and Exceptions in the WIPO Instrument on Genetic Resources and Associated Traditional Knowledge Resources and Associated Traditional Knowled",* American University Washington College of Law American University Washington College of Law Digital Commons @ American University Washington College of Digital Commons @ American University Washington College of Law https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1129&context=research accessed on 13th March, 2025.

[128] Sean Flynn, "*Limitations and Exceptions in the WIPO Instrument on Genetic Resources and Associated Traditional Knowledge Resources and Associated Traditional Knowled",* American University Washington College of Law American University Washington College of Law Digital Commons @ American University Washington College of Digital Commons @ American University Washington College of Law https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1129&context=research accessed on 13th March, 2025.

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in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources." Whereas the convention includes broad affirmation about government flexibility in implementation of Article 15(1). Similarly, under the Nagoya Protocol Article 17 state has the authority to determine what is appropriate and necessary. "There are no exceptions to the duty in Article 17 of the Nagoya Protocol, requiring "measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources."[129]Hence, the drafters of this treaty should have observed the consequences of giving exceptions or flexibility to the obligations and should have restricted it for better implementation of the treaty.

Conclusion:

The concept of biopiracy and fair benefit-sharing are like a relationship between problem and solution. Biopiracy is the problem and fair benefit sharing is the solution for the traditional medicinal knowledge practitioners. It's still a challenge for the indigenous communities like Ahom Tribes of Assam to first identify that they could be exploited as they are the most innocent people on the earth who can be exploited by outsiders for their own benefits. As the practitioners would easily disclose their knowledge to any outsiders without knowing the repercussions of sharing their knowledge. They should be made aware about their rights and they should be recognised that they are practising a great thing which has commercial benefits as well. They should come together to make one group to discuss and be in a position to sign any agreement for fair benefit sharing of the knowledge they possessed if used by any third parties. This is something very much important before we speak about disclosure of the source of TK for filling any IP registration. If we don't recognise the importance of the indigenous communities possessing such knowledge then it's no use making an international treaty to only state the disclosure of sources. Once we give recognition then we can speak about giving acknowledgement by the third party using the knowledge of the indigenous communities.

The Treaty on IP, Genetic Resources and Traditional Knowledge seems to be good on the fact that it's the first Treaty to deal directly with Traditional Knowledge. The treaty displays strengths like transparency as well as fairness by asking the Patent applicant to disclose the source of traditional knowledge and genetic resources used for Patent registration filling. In order to reduce the risk of legal disputes related to biopiracy and unauthorised use of traditional knowledge the treaty provides with clear guidelines to researchers, companies and policymakers. This treaty integrates biodiversity conservation with intellectual property systems, sustainable use of genetic resources. The indigenous communities have faced historically many exploitation and loss of control over their genetic resources. By mandating informed consent and benefit sharing, this treaty tried to protect the community's interests.

But more than the strength there are limitations as well. One of the major demerits of this treaty is that it lacks strong enforcement mechanisms. Countries will be facing challenges in ensuring compliance, particularly when domestic laws do not align with provisions. Those developed

[129] Sean Flynn, "*Limitations and Exceptions in the WIPO Instrument on Genetic Resources and Associated Traditional Knowledge Resources and Associated Traditional Knowled",* American University Washington College of Law American University Washington College of Law Digital Commons @ American University Washington College of Digital Commons @ American University Washington College of Law https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1129&context=research accessed on 13th March, 2025.

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countries who have a strong Patent protection will have issues due to mandatory disclosure of sources insisted by the Treaty, especially countries like the US and EU. Some believe that this requirement adds bureaucratic barriers for inventors. The main concern of this treaty is how effectively it could be implemented even though it has highlighted the principle of equitable benefit-sharing. Based on many past agreements we can derive this conclusion that due to lack of proper enforcement this fair compensation has been a challenge for the communities. Many biotechnology and pharmaceutical companies along with developed nations have generally resisted similar measures by stating that this will stifle innovation. They try to create a lobby against the treaty's implementation and try to make weaker versions of national legislation. Major terms used by the treaty like "associated traditional knowledge" and "prior informed consent" might be interpreted differently across the legal systems, leading to inconsistencies for implementation.

There should be a strong treaty which will first recognise the Traditional Knowledge of the communities and then provide a strong implementation of the rules stated by the treaty. Even though the Treaty is a soft law but should have strong recommendations for the domestic law to implement it. Then, we can say that there is a law which is dealing with the protection of the Traditional knowledge of the communities. Like Ahom tribes of Assam many other communities are still facing problems of gradual decline of traditional practitioners due to less commercial benefits and less emphasis on recognition of their practice. Hence, it's very much important to first recognise the indigenous communities practising traditional knowledge then provide them with adequate knowledge about how to come in consent for written agreements on benefit sharing and prior informed consent.