



INTERNATIONAL LAW  
JOURNAL

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**WHITE BLACK  
LEGAL LAW  
JOURNAL**  
**ISSN: 2581-  
8503**

*Peer - Reviewed & Refereed Journal*

The Law Journal strives to provide a platform for discussion of International as well as National Developments in the Field of Law.

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal provided dedicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

# **NAVIGATING THE LEGAL LANDSCAPE: TRADITIONAL KNOWLEDGE AND PATENT RIGHTS IN 21ST CENTURY**

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## **Abstract**

There are a huge number of indigenous communities in India being the custodians of Traditional Knowledge (TK) having their unique culture passed on from one generation to another. However, owing to an overexploitation of their TK majorly by pharmaceutical industries, they are facing a looming threat of extinction. This paper analyses the implications of commercializing TK by big Corporates and Pharmaceutical companies in recent times. This certainly calls for a need to attain a balance between commercial interests of Corporations spending huge sums on Research and Development on TK for making a remedy and rights of indigenous communities. Additionally, providing Patent Rights to corporations for Traditional Knowledge can also be counterproductive since it would provide monopoly rights to the detriment of general public. This paper involves a critical analysis of statutory and legal protection afforded to the indigenous communities under the Patents Act, 1970, Biological Diversity Act, 2002, Access and Benefit Sharing Regulations, 2014 in consonance with cultural rights and Directive Principles of State Policy provided under the Indian Constitution. The key issue of appropriation of TK by the Pharmaceutical Companies for their own commercial gains without obtaining due consent of the Indigenous Tribes and unfair compensation shall also be focused on. In order to ensure an inclusive development wherein the tripartite interests of the community, companies and the indigenous tribes are effectively met, there are certain measures which can be adopted such as prioritizing public health, establishing a stringent criteria for Patent eligibility and equitable sharing of benefits.

**Keywords:** Access and Benefit Sharing, indigenous communities, Patent Law, public health, Traditional Knowledge



## **Introduction**

India is a diverse nation, boasting a rich tapestry of over 500 Indigenous Communities, each with its distinct culture. However, these communities are currently grappling with the imminent threat of extinction. One of the primary challenges they face is the widespread exploitation of their Traditional Knowledge, particularly in the realm of traditional remedies. This article endeavors to scrutinize the issues arising from the utilization of such Traditional Knowledge. Additionally, it aims to explore the delicate balance that must be struck between the commercial interests of companies investing substantial resources in researching and transforming traditional remedies into marketable medicines by providing them Patent rights, and the inherent right of self-determination guaranteed to Indigenous Communities under Article 21 of the Indian Constitution.

### **Traditional Knowledge and impending issues**

In very simple terms, Traditional Knowledge (hereinafter denoted as TK) is the awareness, experience, expertise, knowledge and applications that are established, continued, performed and passed on from generation to generation within a region or community, often forming a part of its cultural, social or spiritual identity.<sup>1</sup> Traditional Knowledge includes within its purview agricultural, scientific, technical, ecological and medicinal knowledge as well as biodiversity-related knowledge.<sup>2</sup>

There are two prominent issues emerging in the context of Traditional Knowledge in the current times:

- a) The first concern revolves around Pharmaceutical Companies and researchers attempting to exploit Traditional Knowledge owned by local communities for industrial or commercial gain, often seeking patents. This raises ethical concerns as it involves the unfair appropriation of knowledge held by local communities, creating monopolies for patent owners through intellectual property (IP) protection.
- b) The second major issue pertains to access and benefit sharing, necessitating fair compensation for local communities when their Traditional Knowledge is commercially utilized.

Moreover, Traditional Knowledge, deeply rooted in time-honored practices, cannot be patented in its original form under the Patents Act, 1970<sup>3</sup>, due to a lack of novelty or inventive step, even though it

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<sup>1</sup> Suchi Rai, Traditional Knowledge and Scope of Patent Protection, Mondaq, 30<sup>th</sup> January 2018 accessed 13<sup>th</sup> December 2023, available at: [Traditional Knowledge And Scope For Patent Protection - Patent - India \(mondaq.com\)](https://www.mondaq.com/india/patent/511111)

<sup>2</sup> Traditional Knowledge, World Intellectual Property Organization (WIPO), available at: [Traditional Knowledge \(wipo.int\)](https://www.wipo.int)

<sup>3</sup> The Patents Act, No 39 of 1970



may have industrial applications according to Section 2(1)(j)<sup>4</sup> of the Patents Act, 1970.

Various laws, both within the country and at the global level, have been introduced to address these issues and safeguard the interests of both companies and Indigenous Communities. These legal frameworks aim to strike a balance between promoting innovation by conferring Patent Rights and protecting the rights and well-being of local communities.

### **Protection under Indian Laws**

Under Section 3(p)<sup>5</sup> of the Patents Act, 1970 nothing is an invention, which is a Traditional Knowledge or which is an aggregation or duplication of known properties of traditionally known component or components. Hence, it is not only the TK but also the use of any of its unique components or parts thereof that can't be patented. Further, even the Government of India recognizes Traditional Knowledge. It has taken an initiative in the form of TKDL (Traditional Knowledge Digital Library), where it has transcribed around 35,000 formulations used in the Ayurvedic system and converted these into patent applications so that these are preserved but only after taking consent of concerned communities.<sup>6</sup> Indigenous communities, already facing vulnerability in terms of their overall existence, bear the brunt of climate change and the imperative to safeguard natural resources. Typically inhabiting designated reserve forests or areas, these communities experience encroachment that amounts to trespassing, a direct violation of Section 8(j)<sup>7</sup> of the Convention on Biological Diversity. This section explicitly mandates each contracting party, in accordance with its national legislation, to preserve, respect, and maintain the knowledge, innovations, and practices of indigenous communities. It also underscores the importance of ensuring the sustainable use of biological resources and promoting equitable sharing of benefits. The same has been accommodated under domestic legislation of India under Sections 2(g)<sup>8</sup> read with Section 6(2)<sup>9</sup> of the Biological Diversity Act, 2002.

The Indian Constitution further aims at protecting the overall interests of the indigenous communities.

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<sup>4</sup> The Patents Act, Sec 2(1)(j), No 39 of 1970

<sup>5</sup> The Patents Act, Sec 3(p), No 39 of 1970

<sup>6</sup> Dr. VK Gupta, Protecting India's Traditional Knowledge, WIPO Magazine, 1<sup>st</sup> June 2011, accessed 16<sup>th</sup> December, 2023 available at: [Protecting India's Traditional Knowledge \(wipo.int\)](https://www.wipo.int/presscenter/2011/01/protecting-india-traditional-knowledge)

<sup>7</sup> Convention on Biological Diversity, Sec 8(j), 2002

<sup>8</sup> Biological Diversity Act, 2002 Sec 2(g), No 18 of 2003

<sup>9</sup> Biological Diversity Act, 2002 Sec 6(2), No 18 of 2003

There are certain cultural rights guaranteed to minority communities under Article 29(1)<sup>10</sup> of the Indian Constitution. Traditional Knowledge, in most cases being an inherent part of the culture of Indigenous Tribes, shall be preserved as a part of the rights of Indigenous communities.

At the same time, it has been provided in the Directive Principles of State Policy that the state has a duty to protect the forests, wildlife and environment of the country under Article 48A<sup>11</sup> of the Constitution and the same has also been defined as a duty of citizens under Article 51(A)(g)<sup>12</sup>. Yet, DPSPs and Fundamental Duties are not enforceable and impose non-binding obligations. However, in the case of *Re Kerala Education Bill*<sup>13</sup>, the Court held that DPSPs are to be read along with the Fundamental Rights and the latter has to be interpreted in light of the former. Considering the same, the right to self determination guaranteed under Article 21<sup>14</sup> of the indigenous communities has to be interpreted in the lines of duty upon State and citizens of India to protect forests and wildlife which are an integral part of the natural environment of such communities and compulsorily enforced.

Conversely, citizens bear the responsibility to foster and cultivate scientific temper and humanism, as has been stated under Article 51(A)(h) of the Indian Constitution. This obligation entails conducting research on indigenous communities and their environments, which may not have been fully explored, to unveil potential remedies and conditions beneficial to the broader public. This is particularly evident in the realm of Traditional Knowledge, as exemplified by the distinctive case of the Kani Tribe<sup>15</sup>, contributing significantly to the enhancement of overall public health.

The inherent challenge lies in striking a delicate balance among three essential components: the well-being of indigenous communities, the commercial interests of corporations by conferring Patent Rights, and the broader societal interests.

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<sup>10</sup> India Const, Art 29

<sup>11</sup> India Const, Art 48A

<sup>12</sup> India Const, Art 51(A)(g)

<sup>13</sup> Re Kerala Education Bill (1959) 1 SCR 995

<sup>14</sup> India Const, Art 21

<sup>15</sup> Rv Anuradha, Sharing With The Kanis A Case Study From Kerala, India, Convention On Biological Diversity, accessed 15<sup>th</sup> December, 2023 Available At: <https://www.cbd.int/financial/bensharing/india-kanis.pdf>

## **Access and Benefit Sharing**

One of the most effective approaches to achieving a balanced framework is to ensure the equitable sharing of benefits derived from the Traditional Knowledge of Indigenous Communities, with their prior informed consent, when utilized commercially by any Corporation or Individual.

The application of the Doctrine of Access and Benefit Sharing becomes imperative when Traditional Knowledge has been acquired by a third party without the prior informed consent of the indigenous community. According to this doctrine, any profit gained from the commercial use of Traditional Knowledge must be shared fairly and equitably with the traditional community. A landmark case illustrating this principle involved the Kani Tribe.<sup>16</sup>

The Kani Tribe possessed a unique traditional plant, Arogya Pacha or evergreen health, previously unknown to the outside world. This plant, known for its non-steroidal nature and fatigue-combating properties, was researched by scientists. The Tropical Botanic Garden and Research Institute's (TBGRI) Product Development Division developed a pharmaceutical drug called Jeevani, incorporating the remedy Arogya Pacha. In a significant ruling, the court mandated that 50% of the benefits arising from the Jeevani drug be shared with the Kani Tribe, setting a precedent for the validity of access and benefit sharing. It's worth noting that there is an exception to this rule, as it does not apply to Vaidis and Hakims under the Access and Benefit Sharing Regulations, 2014.<sup>17</sup>

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization<sup>18</sup>, under the Convention on Biological Diversity, focuses on protecting the interests of Traditional communities, ensuring the conservation of bio-resources, and promoting the equitable sharing of benefits from commercial use of TK or any Bio-Resources. This international convention led to the introduction of Access and Benefit Sharing (ABS) Regulations<sup>19</sup> in India in

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<sup>16</sup> Ibid

<sup>17</sup> Regulation 17, Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations – 2014, available at: [https://kbb.karnataka.gov.in/storage/pdf-files/notification%20Eng/ABS-Regulations-2014-Notification\(1\).pdf](https://kbb.karnataka.gov.in/storage/pdf-files/notification%20Eng/ABS-Regulations-2014-Notification(1).pdf)

<sup>18</sup> Nagoya Protocol On Access To Genetic Resources And The Fair And Equitable Sharing Of Benefits Arising From Their Utilization To The Convention On Biological Diversity, available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

<sup>19</sup> Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations – 2014, available at: [https://kbb.karnataka.gov.in/storage/pdf-files/notification%20Eng/ABS-Regulations-2014-Notification\(1\).pdf](https://kbb.karnataka.gov.in/storage/pdf-files/notification%20Eng/ABS-Regulations-2014-Notification(1).pdf)

2014. The essence of these conventions lies in safeguarding the interests of local indigenous communities in the face of excessive innovation and resource overexploitation.

### **Extent of protection granted to TK**

While it is an accepted fact that certain resources found in nature or any remedy made out of it can't be patented owing to prior use, there is protection provided to these resources in certain forms, to protect the research carried out on TK. For example, Turmeric in its very form can't be patented as had also been observed in Turmeric Patent case where the application for patenting Turmeric filed by USA was rejected since it had been in use in India since the very beginning and its use was also found in traditional Sanskrit, Hindi and Urdu Texts.<sup>20</sup> However, through a search on Google Patents, it can be determined that Turmeric Oil, Turmeric Powder, etc have been and can be granted patents. It can be granted for both the end product i.e., the Turmeric Oil as well as the overall process of making it. In 2009, Product as well as Process Patent had been granted to San Ei Gen FFI Inc for Turmeric Dye compound as well as the preparation process.<sup>21</sup> This is more than explanatory to signify that any efficacious modification made to a natural element with involvement of an inventive step shall be entitled to Patent protection. Further, in Phillipines patent had been granted to a powder made out of Curry Leaves even though these are found in almost each and every household in India.<sup>22</sup>

While applying this to Traditional Knowledge, when a Company spends huge sums of money just to research upon the TK of any indigenous community and uses it as a base for developing a product which is an efficacious modification, they shall be provided Patent Rights over it. In the case of *Novartis AG v. Union of India*<sup>23</sup>, the Court held that invention is synonymous to a new product but the new product may not necessarily mean something altogether or wholly unfamiliar. It may mean something different from previous invention or in addition to another or others of same kind. This case hence reasserts that a modification made to TK shall be patentable.

Moreover, a corporation investing substantial amounts in research and development possesses the right to secure a reasonable return on their investments by obtaining Patent Rights. This grants them

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<sup>20</sup> Hariharan, Basmati, Turmeric and Neem- Patenting and Related issues- Case Studies, 2 Law Rev. Gov't L.C. 185 (2002-2003)

<sup>21</sup> Patent No JP5448511B2, Turmeric dye composition and preparation method thereof

<sup>22</sup> Patent No PH2202005018, Curry leaves powder

<sup>23</sup> Novartis AG v. Union of India (2013) 13 SCR 148 (India)



the ability to prevent others from entering the market with similar developments. However, a critical challenge lies in determining the threshold or extent to which such exclusive rights can be granted. In hindsight, a solution to this is rooted in the acknowledgment that the invention or end product may not have been feasible without the incorporation of Traditional Knowledge or Remedies.

## **Way Forward**

There is a need to resort to certain measures or strengthen the existing measures for enhancing the protection of TK and at the same time giving due consideration to Commercial interests of the Corporations. Enhancing the equilibrium among the interests of Corporations, general society, and Indigenous communities can be achieved through the following measures:

- A) Patent Rights should be granted only when a Corporation substantiates that the product involves an inventive step or a substantial modification of Traditional Knowledge (TK). When defining efficacious modification, it is crucial to consider that it must result in a genuinely new product brought before the general public through comprehensive research efforts.
  
- B) The utilization of TK should be permitted in the interest of public health with certain restrictions. Following Bentham's theory of Utilitarianism, the focus shall be towards ensuring 'greater good for greater number,'<sup>24</sup> especially with respect to public health in the modern context. In other words, general public interest should supersede the interests of Indigenous Communities. In essence, any remedy from an indigenous community, with prior informed consent and equitable benefit sharing, should be eligible for patenting if it proves to be beneficial to the general public. However, this should not be the only factor to be taken into consideration.
  
- C) Access and Benefit Sharing with the Indigenous/Traditional community should extend over the entire period during which the product developed from TK is sold in the market. Such benefit sharing should not take the form of a lump sum payment. Prior informed consent should also involve determination of the form and manner in which gains are shared with indigenous communities, without imposing unilateral conditions favoring dominant Corporations.

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<sup>24</sup> Henry R West, Brian Duignan, Utilitarianism, Britannica.com accessed 19.12.2023, available at: <https://www.britannica.com/topic/utilitarianism-philosophy>

- D) Protection of the Commercial Interests of the Corporation should be granted on a case-by-case basis. Expenditures incurred in resource procurement and research and development should result in a product that significantly improves upon the original/Traditional remedy. If not, regardless of expenditure, no protection should be afforded.
- E) Extraction of natural resources unique to an indigenous or traditional community by a Corporation for product development may deplete resources. Therefore, corporations should be obligated to establish and cultivate vegetation at an alternate location, i.e., ex-situ vegetation, to mitigate the environmental impact.

### **Conclusion**

Normalizing the acts of extraction of TK and other natural resources unique to Traditional communities can lead to depletion and an overexploitation of resources. At the same time, the commercial interests of corporations involved in the research shall also be taken into consideration along with the overall public health. In conclusion, the imperative to safeguard Traditional Knowledge and natural resources demands a delicate balance between commercial interests in form of Patent Right, public health, and the preservation of resources. The establishment of robust regulations for patent grants is a crucial step in this direction. As we navigate the path of inclusive development, the role of Patent Rights becomes increasingly significant, holding the potential to foster harmony between corporate pursuits and the sustainable use of Traditional Knowledge. While initial measures have been implemented to curb overexploitation, the true impact of Patent Rights in achieving equilibrium awaits further exploration and evaluation in the unfolding future.