

CLEA (INDIA ROUND) MOOTING COMPETITION – 2019

**CSI COLLEGE FOR LEGAL STUDIES, KOTTAYAM, KERALA
12-13th JANUARY, 2019**

**TO SELECT INDIAN TEAM TO REPRESENT INDIA IN CLEA MOOTING -
ZAMBIA, APRIL-2019**

This moot problem is solely authored for the purpose of CLEA (India Round) Moot - 2019 to be held on 12-13 January, 2019 at CSI College for Legal Studies, Kanakkary, Kottayam, Kerala to select Indian team to represent India in CLEA Moot-2019 to be held at Zambia in April 2019. This Problem is authored by Dr. Lisa P Lukose, Associate Professor, GGSIPU/CLEA (South Asia) Mooting Coordinator and D.r Kavitha Chalakkal, Assistant Director (Research) Commonwealth Institute of Justice Education and Research (CIJER), Lloyd Law College, Greater Noida. The copyright in the moot problem vests exclusively with CLEA (South Asia) and the same shall not be used by any Institution, Organization, University or College without the written permission from CLEA (South Asia).

MOOT PROBLEM

1. Bio-piracy, protection of traditional knowledge and other related IPR issues are selected as the topics for CLEA (India Round) Moot- 2019 competition as these are very important issues in Countries like India with a notable indigenous population and centuries of knowledge transferred through generations.
2. Traditional knowledge as a legal discipline is not a separate and distinct area of substantive law. Rather, it cuts across a broad range of issues under national and international IPR, Environmental and biodiversity laws.
3. Thus, the substantive areas of law relevant to the moot problem are IPR laws, environmental laws and biodiversity laws.

I General Information

1. Kehuar Community, Novum Industries Pvt Ltd, *Jaiiv Sanskruti Avagat* and all other entities and circumstances in this moot problem are fictional.
2. It is not possible to provide all of the information that one would have access to in reality in the context of a scenario of this nature. Competitors should not extrapolate upon the information that has been provided unless absolutely necessary and any such extrapolation must be reasonable and not intended to secure an unfair advantage.
3. Judges will not entertain any submissions that are not directly related to the legal issues relevant to the moot problem.
4. The relevant facts to be relied upon are those listed in the Agreed Facts only.

AGREED FACTS

I

The eco-social culture of the Kehuar Community in Mahagir mountain range has generated a powerful heritage of Kehamani knowledge, which includes the knowledge of plant and genetic resources that has extraordinary medical and commercial value. Mahagir mountain range is a wet evergreen forest consisting of 120 endemic plant species and is one of the recognised ecologically fragile bio-diversity areas of the State of the Democratic Republic of Toqoi. Toqoi, though a developing country is rich ecologically and culturally; in biodiversity it is one of the richest in the world being one among the major countries abounding in biodiversity.

The Democratic Republic of Toqoi, as stated earlier, is a developing country. This range is also designated to be protected as a representative ecosystem and the natural/cultural sceneries by the Ministry of Forest and Environment of the State of Toqoi. The Kehuars is a parochial-indigenous community and refrains from any external outreach or mainstreaming activities. The community firmly believes in traditional ethno medicines and treatment methods. The members

of the community share their ethno medicinal knowledge only through oral traditions. A council of elder community members lead by a hereditary Chief decides the treatment which involves the use of any traditional medicine. The traditional medicines are being prepared by Kehuaras from the medicinal plants which they conserve, nurture and preserve for centuries. One of the key traditional medicines the community use is a combination of (i) *Strychnos nux-vomica* also known as nux vomica; (ii) *Rauwolfia serpentina* also known as snakeroot and (iii) *Limonia Acidissima* also known as elephant apple, for curing blood pressure related heart diseases. All three species are endemic to the region where the State of Toqoi is geographically located and are listed in the endangered plant species list of the State of Toqoi. The concoction is prepared using various parts of the plants, by indigenous methods, which involves boiling the plant parts in milk, fermenting and cooling processes. The concoction needs to be consumed by the patient immediately as the toxic properties of the plant parts will be active after 2 hours of its preparation. In the past, during the period between 1990-2005, three MNCs have tried to develop relation with Kehauras and attempted for carrying out certain bio-prospecting to get some lead information relating to Kehauras ethnobotanical knowledge and practices. However, Kehauras have neither revealed the secret formula of their concoction nor any knowledge relating to their plants and its various uses.

II

In 2005, two young members of the Kehaur community, Ms. Arikara Hopo and Mr. Bannock Hopo, joined the Toqoi Institute of Environment and Bio Diversity studies (TIEBS) to pursue their higher education. TIEBS has some international collaborations with foreign universities for students' and faculty exchange programmes. Ms. Arikara Hopo and Mr. Bannock Hopo after completing their post graduation from TIEBS, later got admission in a prestigious research programme of Inter University Centre for Bio-diversity and Ethno Medicine (IUCBEM). As a part of an academic exchange programme, "the Adsila-Ojibwe Scholarship" between the Toqoi University and the Mayford University of State of Parsinia, Ms Arikara and Mr Bannock were sent to the State of Parsinia, in 2010 for a period of two years with a fully

funded fellowship. However, as per the TOR of the fellowship, their status would remain as a bonafide students of TIEBS. The State of Parsinia is a developed nation and is one of the leading industrialised countries.

The Adsila-Ojibwe Scholarship is one of the ‘Skill Parsinia’ efforts of the Ojibwe Industries Inc. (OII), at the Mayford University and the company - OII completely sponsors the scholarship. The Ojibwe Industries Inc. is a bio-agro multinational company, with its registered headquarters in Parsinia, and has interests in varied corporate sectors like crop science; horticulture, consumer health; pharmaceuticals; ethnobotany, animal health, animal husbandry, and other business services. OII has its own specialised R&D wing; the company has more than 100 patent applications pending in multiple jurisdictions relating to various medicinal preparations and processes. As per the TOR of the scholarship, the ownership of any intellectual property created during the scholarship period will exclusively vest with the OII., although the individual will be recognised as the inventor/creator as per the law. This mandatory term was also agreed in the Memorandum of Association between the IUCBEM, Toqoi University and the Mayford University.

As part of their academic activities and the terms of the Adsila-Ojibwe Scholarship, Ms Arikara and Mr Bannock were required to complete a project in the field of medicine. Ms Arikara and Mr Bannock worked on the scientific aspects of bio-ethnic medicine concoction of their indigenous community, which involved the use of *Strychnos nux-vomica*, *Rauwolfia serpentina* and *Limonia Acidissima*. However, instead of indigenous method of boiling, fermenting and cooling method, they used advanced biochemical distilling method and included tools like genomics, proteomics, and bioinformatics in the process. The biological pathways, such as gene and protein expression, modulation and regulation and cell signalling were also applied by them and they created a drug- *Rausilux*, which is an anticoagulant to be used for Deep Vein Thrombosis (DVT) and helps in preventing blood clots after a stroke or pulmonary embolism, which also makes it a life saving drug. Due to these pharmaceutical processes, the shelf life of the drug increased to 6 months compared to the requirement of immediate

consumption of the concoction in its traditional use. The biogenetic materials of the plants were gathered from *ex situ* collections in three countries where these plants do not exist naturally. These three countries are members of CBD. The Ojibwe Inc. successfully completed the FDA requirements of the State of Parsinia, which also involved a multi-phase clinical trials process. OII applied for patent for the drug *Rausilux* in 2015 in Parsinia. Parsinia Patent and Trademark Office (PPTO) granted patent for the drug *Rausilux* in February, 2018 to OII. It was an unopposed patent.

III

Jaiv Sanskruti Avagat (JSA) is a non-profit organisation based in the State of Toqoi and the organisation focuses mainly on the documentation and protection of traditional knowledge, especially that of the indigenous communities in Toqoi. They are in the process of preparing a traditional knowledge library. JSA became aware of the patent grant for *Rausilux* immediately after its grant by PPTO in 2018 and has accused Ojibwe (OII) of bio-piracy and misappropriation of the traditional knowledge of Kehuar Community. JSA, representing the Kehuar Community, decided to file a post-grant review at the Patent Trial and Appeal Board of Parsinia. The State of Parsinia's process for post grant review of patent is akin to that of USPTO model.

IV

The State of Toqoi is a party to the United Nations Convention on Biological Diversity (CBD) and has enacted the National Biodiversity Act, which sets the regulation of biological resources in any commercial processes, and its transportation and uses in other countries. The authority appointed under the Act grants the permits and licences for the same. However, the State of Parsinia is not a member to CBD. Both Toqoi and Parsinia are parties to the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement) and have completed their transition period and compliance obligations.

V

The Patent Trial and Appeal Board (PTAB) of Parsinia has listed the JSA'S application for post grant review on 12th January, 2019. The State of Taqoi has authorised JSA to represent the State in this matter before the PTAB.

Applicants must prepare Memorials and Arguments in line with the Competition Rules setting out arguments in relation to:

- a. How the patenting of *Rausilux* amounts to bio-piracy and misappropriation of traditional knowledge of Kehaur Community? and
- b. Can the granted patent for *Rausilux* can be revoked on the basis of anticipation and prior-art?

Respondents must prepare Memorials and Arguments in line with the Competition Rules setting out arguments in relation to:

- a. How the patenting of *Rausilux* will not amount to bio-piracy and misappropriation of traditional knowledge of Kehaur Community? and
- b. Why can't the granted patent for *Rausilux* be revoked on the basis of anticipation and prior-art?
