

## Traditional Medicines and the Requirement of Patentability: Do They Have a Technical Character?-the European Approach

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**Abstract.** When we consider the ways that local people can exercise their intellectual property rights through patent law, it will be necessary for these people to meet the requirements of patentability. Chief among such requirements is whether their inventions (traditional medicines) have a technical character. This requirement is particularly controversial for innovations that contain natural substances such as traditional medicines because the way though which knowledge and creations are produced and developed in indigenous societies differs from that of non-indigenous societies. This article deals with the question whether such medicines can be considered as technical invention. The method to address this topic is a comparative one, describing traditional medicines and biotechnology inventions. Finally, the compatibility between this requirement and such medicines will be studied. It will be observed that although the characteristics of such inventions do not make them less innovative than technology-based creations, the current patent norms do not fit the indigenous inventions.

**Keywords:** technical character, traditional medicines, biotech inventions, product of nature.

### 1. Introduction

Over the recent decade, there have been increasing attention to, and debate concerning the protection of indigenous people' medicinal knowledge by patent law in both academic and political forma. The controversial issue at the heart of them has been whether folk remedies are patentable invention under the rigid requirements necessitated by patent laws. An important requirement for patentability is the technical character.

An invention must have 'a technical character' to be patentable.<sup>1</sup> when an invention have a technical character, that means the invention does not fall within the scope of the exceptions to patentable subject matters.<sup>2</sup> It also proves that the invention is capable to have Inventive step and Industrial application. When assessing Inventive step, non-technical characters of the invention are not taken into account.<sup>3</sup> And technical character is required to support that the invention can be made or used in any kind of industry to be considered as susceptible of industrial application.<sup>4</sup>

The presence of technical character is accessed on the basis of two different classifications of inventions. Where the physical features or 'the core of the invention' is technical, it will already imply the existence of a technical character.<sup>5</sup> A clear example of such kind of inventions can be seen in inventions that are related to nanotechnology and mechanical engineering. On the other hand, in cases where the invention is non-technical in nature, a technical character can be exhibited by the use of technical means such as an industrial process for technical purposes.<sup>6</sup> Therefore, when an invention contains, is performed or makes use of some sort of technology, it will be regarded as 'a technical invention'.<sup>7</sup>

One of the upshots of such requirement is that the natural substances cannot be patented.<sup>8</sup> A naturally-occurring material, often called a 'product of nature', is neither technical in nature nor produced through a technical process. Also, as it is self-evident from the name, such substances are created wholly by nature 'unassisted by man'.<sup>9</sup> So, they lack the necessary degree of human intervention for the resulting product to be called an invention.

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The requirement that the invention must involve the sort of a technical contribution will have a significant effect on traditional medicines which are concerned with naturally occurring substances. In order to study whether traditional medicines are regarded as a technical invention, in the next three titles, I first provide a brief description of the nature of indigenous medicines, and then examine how situation is with the biotechnological inventions to satisfy this requirement. The necessity of the study of the biotechnological inventions comes from the fact that the both two inventions involve natural substances as the starting point. Finally, the application of this requirement to ethnobiological medicines will be discussed.

## 2. The nature of traditional medicines

According to the incrementally enormous intellectual efforts evolved for producing each remedy, local people identify the precise uses of the local herbs to cure particular illnesses. Through their long-standing observations, they also find the exact means of preparations, the specific dosages and the required conditions for the best results.<sup>10</sup> Ethnomedicines 'are crude plant materials, such as leaves, flowers, fruits, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.'<sup>11</sup> Powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials are prepared by steeping, brewing, boiling, grinding or heating herbal materials in beverages, honey or tea or in other materials.<sup>12</sup> Plant materials may be used fresh or dried. Unlike the modern pharmaceuticals, traditional remedies are not isolated and purified and they are derives from the natural forms of plants. They are made manually, and no chemical process has been used for their production.

According to the traditional practice, indigenous people's medicinal treatment is based on single-herb or multiple-herb prescription.<sup>13</sup> Such substances may be unknown or quite unique in the relevant community and do not exist elsewhere. The shaman of the tribe is usually the one who is responsible for providing medicines for afflicted people. He has observed different symptoms that are prevalent in the local group and applied various plant compounds to cure such illnesses. By recording the uses of different plants for different diseases over many years, he has learnt the best dosages and modes of preparations for many types of treatments.<sup>14</sup> He has also found that what specific parts of the plants contain the desired substances for medicinal purposes.

## 3. Lessons from biotechnological inventions

The advent of biotechnological inventions has had and continues to have profound impacts on the patent law. One of the most controversial issues in relation to these inventions was the use of natural substances in producing biotech products such as genetically modified organisms. After a long time challenging debates over the patentability of such invention, it seems that this matter is now well settled by adopting the Biotechnology Directive in Europe.

Article 3 (2) of the Directive provides that 'biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.'<sup>15</sup> This article indicates that human intervention is necessary to obtain patent protection for inventions that are concerned with biological materials. In the similar vein, it provides that natural substances may be the subject matters of a patent when the inventor use any means of a technical process in characterizing, isolating and purifying the concerned natural substance.

The case *Howard Florey/Relaxin* provides a real example of such inventions. The patentee had developed a process for obtaining the synthetic form of the gene coding for the unexpected second form of human relaxin (H2-relaxin and the DNA encoding it) which had been produced through the cloning technology. Opponents challenged the patent arguing that the claimed invention was a substance freely occurring in nature. However, the EPO's opposition division refused this argument and held that if the substance freely occurring in nature is newly isolated and characterized, then it is patentable invention.<sup>16</sup>

The way that the courts treat biotech inventions teaches us that although a gene in its natural state inside the cells of a living organism is not patentable, anyone who isolates and purifies the gene can obtain a patent on that gene when other requirements are met. Indeed, substances found in nature are being used in many biotech inventions. But, biotech researchers use new scientific technologies such as genetic engineering or

synthetic biology to alter and isolate the substance from its surroundings such that the resulted invention cannot be called a product of nature. In fact, due to the substantial alteration of the essential nature of the substances made as a result of synthetical isolation and purification in the laboratories, they turn to artificial products that do not occur in nature in their new forms.

#### **4. Application to traditional medicines**

The application of the ban on patenting inventions that are devoid of technical character to traditional medicines would challenge many of ethnomedicines that are made through traditional ways. In particular, traditional medicines are not technical in nature. They are different raw species of herbs found or natured in wild habitats whose curing properties have been identified by local people. Also, they are not produced through a technical process. Indigenous people use plants in its natural state. They produce traditional medicines though simple and conventional methods such as drying, boiling, powdering or brewing. These methods are not technical. They cannot also change the essential nature of the plant substantially and turn traditional medicines to technical inventions.

In order to examine whether a natural substance is eligible to be patentable, the natural material has to be sufficiently transformed to the point that the resultant product is substantially different from what had been previously occurring in nature.<sup>17</sup> Admittedly, even if indigenous people have improved traditional medicines in many ways over the centuries, slight modifications and minimal alterations to medicines could not render them patentable because still the active substance of the substance exists in the medicine as it does in the nature.

Thus, while ‘the requirement of technical character is inherent to the notion invention’<sup>18</sup>, traditional medicines are neither regarded as technical in nature nor concerned with a form of technical process. This would exclude most of traditional medicines from the patentable subject matters because of the lack of the technical-character requirement. When a product, despite of all human interventions, falls into the category of non technical inventions, it is not patentable subject matter.

This situation has led to a tragedy for indigenous people. While traditional people cannot patent their valuable medicines, traditional knowledge-based medicines produced by western pharmaceutical companies may well lead to a patentable invention where they isolate, purify, and then alter the plants’ active substances in a way that it does not occur in nature. Here, even though their modern-formed medicines perform the same function as the traditional medicines do for indigenous people, the access to modern theologies and substantial legal resources that pharmaceutical corporations possess and indigenous communities lack further enables these firms to meet the technical-character requirement.<sup>19</sup> No recognition or compensation is due to the communities who identify the beneficial uses of the local herbs and keep them for the centuries.<sup>20</sup> Thus, the western scientific research is valued over the traditional people’ knowledge.<sup>21</sup>

A U.S. patent on ‘use of turmeric in wound healing’<sup>22</sup> is a notable example of such discriminative formulation of laws. Turmeric is an herbal substance developed from the plant *Curcuma longa* of the ginger family that sprouts in India and Pakistan. This herb has been used for its curative effects on the treatment of various sprains and inflammatory conditions in India for hundreds of years. Indigenous group in India extract a yellow powder from turmeric through boiling and apply it on affected parts of body.

Local people could not obtain a patent for medicinal uses of turmeric because it would fail the technical-character requirement as the medicine was produces though manual and simple processes such as boiling and powdering. However, a patent has been granted for the use of turmeric in wound healing to two scientists Hari Har P. Cohly and Suman K. Das from the University of Mississippi Medical Center. Here, while the idea about such remedy and its medicinal properties derived from Indian who have used it for centuries, scientists isolated and synthesized the active agent of turmeric in the laboratory and the derivative of turmeric was deem patentable by United States Patent and Trademark Office because the laboratory-synthesized form of turmeric is not regarded as technically a product of nature.

#### **5. Conclusion**

This paper examines whether indigenous people can meet one of the most significant requirements for patentability, technical-character requirement. It was observed that the current law’s preference for

protecting only purified and isolated substances of the nature excludes from patentability indigenous medicines that consist of raw and minimally altered plant materials.

This opposition further influences two other patent requirements, inventive step and industrial application. The inventive step requires that the invention must involve not only inventive but also a technical contribution. While traditional medicines present inventive advances in many cases, however, they have not made a technical contribution to the known art. Also, traditional medicines would fail to be capable to be made or used in any kind of industry, because they are neither technical in nature nor produced through a technical process.

Following the line of lessons both in biotechnology and biopiracy, it seems that as the patent laws are being modified to better accommodate modern technology-based or newly-identified inventions in all the time<sup>23</sup>, ethnomedicines can be also redefined as products of human inventiveness, rather than as unpatentable ‘manifestation of nature’<sup>24</sup> or a ‘handiwork of nature’<sup>25</sup>.

Indeed, the definition of intellectual property provided by article 2 of the WIPO Convention casts a broad net and specifically includes language designed to extend protection beyond the listed categories of intellectual property, to all the kinds of ‘intellectual activity in the industrial, scientific, literary or artistic fields.’<sup>26</sup> In this way, countries can also extend the patent protection to traditional medicines to include them in the scope of patentable subject matters by removing the technical-character requirement for ethnopharmaceuticals.

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