

# **Position Paper**

## **THE CHEMICAL INDUSTRY COMMENTS ON THE LEGAL PROTECTION OF TRADITIONAL KNOWLEDGE & ACCESS TO GENETIC RESOURCES - PATENTING**

**Adopted in November 2000 and up-dated  
July 2002**



## EXECUTIVE SUMMARY

Cefic represents the chemical industry in Europe which includes about 40,000 large, small or medium companies, that account for about 30 % of the world's chemical production.

This paper represents the contribution of the chemical industry in the debate regarding the legal protection of traditional knowledge. Cefic is of the opinion it is time to address this matter. In doing so, it is necessary to ensure that the relevant issues are identified and properly dealt with to provide adequate and effective responses to the concerns raised and needs identified.

Against this background, Cefic believes that the WIPO (World Intellectual Property Organization) is the appropriate intellectual property world-wide body to deal with this issue.

The following issues are detailed in this paper: the definition of traditional knowledge, the creation of inventories, the clarification of its protection rights with other intellectual property, and the creation of a sui generis system.

Access to genetic resources is also dealt with in this paper. In many instances, companies are at a loss as to how access to genetic resources should be obtained in a specific country. Therefore, the chemical industry encourages the countries having signed the UN Convention on Biological Diversity to define and implement access conditions.

Finally, this paper includes a section on patents related to genetic resources, in which two items are detailed: the voluntary indication of the origin of material in patent requests and prior informed consent.

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## A. INTRODUCTION

This paper is intended to contribute to the debate surrounding the issue of the Intellectual Property (IP) legal protection of traditional knowledge.

Although traditional knowledge has existed for a long time, discussion on how it could be protected has accelerated recently, in particular since the entry into force of the CBD (the United Nations Convention on Biological Diversity) which formally recognises this concept in its Article 8 j, and the signature of the TRIPs (Trade Related Aspects of Intellectual Property rights) Agreement.

The question is also debated as some NGOs and local communities have accused industry of appropriating traditional knowledge and of bio-piracy when patenting inventions related to genetic resources from developing countries.

***The chemical industry believes it is time to address the issue of traditional knowledge and the protection thereof. In doing so, it is necessary to ensure that the relevant issues are identified and properly dealt with to provide adequate and effective responses to the concerns raised and needs identified.***

Traditional knowledge is a key issue in the global debate to define future trends of intellectual property rights regarding genetic resources, the environment and development.

At the moment many points have still to be explored. It is necessary to list related facts, build up expertise, compare with other IP systems already existing, and then only define suitable solutions.

***Against this background, Cefic believes that the WIPO (World Intellectual Property Organization) is the appropriate IP world-wide body to deal with this issue, and appreciates the first step made in the right direction by the publication of its recent report including detailed fact findings from all over the world.***

The chemical industry believes that in this debate, a number of notions should be dealt with separately, namely -traditional knowledge and the protection thereof, -access to genetic resources, and -the patenting of inventions based on genetic resources. These topics are developed below.

## B. TRADITIONAL KNOWLEDGE

***Cefic supports the creation of a system for the protection of traditional knowledge. Many steps are needed to achieve this important aim, such as :***

- 1. Definition of the notion of traditional knowledge***
- 2. Creation of inventories of traditional knowledge***
- 3. Clarification of the relationship between the protection of traditional knowledge and current IP right systems***

## **1. Definition of the notion of traditional knowledge :**

***Traditional knowledge is a concept that is not easy to define. Nevertheless, once a consensus has been reached within WIPO on what should be the scope of the term “traditional knowledge”, then inventories of traditional knowledge should be established. The chemical industry supports any progress to find such a consensus and to create those inventories.***

Traditional knowledge is generally expressed in the communities and encompasses expressions of folklore, religion (e.g. sacred places, plants, animals), crafts (e.g. development of technologies for producing textiles, food), agriculture (e.g. management of ecosystems, development of plants and animals with specific properties), and medicines (e.g. herbal products).

In defining what constitutes traditional knowledge, the following categories should be considered:

- knowledge about the use of genetic resources e.g. in agriculture, food, medicines;
- traditions in respect of the use of genetic resources and the environment;
- art and handicrafts. The present paper does not address this latter category, which the chemical industry believes that other industry sectors are better placed to comment on.

## **2. Creation of inventories of traditional knowledge :**

***In this process, the chemical industry believes that it is necessary to create inventories of traditional knowledge in order:***

- To “fixate” the memory and present day use of all kinds of knowledge and know how belonging to the different indigenous people and local communities in all regions of the world and relating to all fields of technologies. This will both assist in conserving this knowledge for future generations and provide a background on which further innovations may be documented.
- Determine the part of the traditional knowledge in the public domain and list it together with the indication of how and when it was communicated, if available.
- In preparing such inventories, care should be taken to determine the extent to which the traditional knowledge was communicated to other groups or not (with or without a secrecy provision).
- It is important that in those inventories a distinction is made between the traditional knowledge having a technological character and that of a basically artistic character.

To achieve this aim, it is proposed that the WIPO –in co-operation with its contracting states and interested circles- should proceed to define the format of such inventories, who should establish and manage such inventories, the conditions under which the content of the inventories is to be made available to the general public, and to companies. In this case, this could generate economic and other benefits for indigenous people possessing this traditional knowledge.

### **3. Clarification of the relationship between the protection of traditional knowledge and current IP rights systems :**

***The chemical industry believes that traditional knowledge would be best protected by a sui generis right to be created. However, there may be circumstances where protection through existing IP systems is possible and preferable.***

This could be the case when traditional knowledge relates to a technology that could be protected either as a trade secret, know-how, a patent, or geographical indication (or copyright for those of an artistic nature).

To do so, some notions have to be analysed with regard to traditional knowledge, such as:

- identification of the inventor, creator of the traditional knowledge,
- identification of the owner having the right to the traditional knowledge,
- term of protection,
- collective inventorship for a group of people, such as a tribe, or a local community,
- farmer's rights.

***Cefic is of the opinion that such possibilities have to be explored as a first step, before starting to develop work on a new sui generis right. This analysis and possible adaptations of the current IP systems, should not end up putting unnecessary pressure on IP systems as for example patent systems and lead to a weakening of such systems.***

### **C. CREATION OF A SUI GENERIS SYSTEM FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE**

***The chemical industry fully supports the creation of a sui generis system to protect traditional knowledge that could not be protected through existing IP systems. To achieve this aim and provide for a manageable system, Cefic believes that the following points are essential:***

- The protection of traditional knowledge has to be registered and rights conferred be granted for a limited period after registration (with the possibility to renew the period, under certain circumstances).
- The scope of protection granted to traditional knowledge rights must be construed narrowly if the right is provided by registration only.
- The right should be granted not only to an "identified person" or legal entities but also to a local community or a tribe, but in such a case with a designated representative.
- The right should, in principle, also cover traditional knowledge that is in the public domain (as defined for patent law), but adapting the scope of protection to ensure that, whoever used this knowledge in the past, this will not be disturbed by the newly created sui generis right (prior user right according to patent law).
- In addition, when creating such a new right, other notions such as the burden of proof, scope of the right and enforcement have to be defined in a manner consistent with existing IP right systems.

***Against this background, the chemical industry strongly favours the negotiation of an international instrument on this new right, at WIPO. Once created, its principles ought to be enshrined in the TRIPs Agreement. Indeed, such a process will facilitate the global approach to this important issue and ensure consistency between national laws.***

#### D. ACCESS TO GENETIC RESOURCES

Since the entry into force of the CBD, the Contracting States are required to respect the principles laid down in the CBD, in particular under Article 15, when they give access to genetic resources.

Some countries have created national legislation to regulate the conditions for obtaining access to genetic resources, others have proposed legislation which is pending but the vast majority have not yet addressed this issue in their legislation, leaving a void which creates a great degree of uncertainty and confusion for companies.

***The situation means that very often companies are at a loss as to how access to genetic resources should be obtained in a specific country, since there is no focal point for enquiry and, when existing, national laws are sometimes unclear and very often the matter is not regulated at all.***

***Therefore, the chemical industry urges all CBD Contracting Parties (including developed countries) to define and implement access conditions (e.g. through legislation), in accordance with Article 15 of the CBD.***

In order to support and promote the objectives of the CBD and facilitate the decision-making of companies in respect of access to genetic material, Cefic suggests that the implementation texts should specifically:

- create conditions to facilitate access to genetic resources for environmentally sound uses and not impose restrictions that run counter to the objectives of the CBD,
- specify any mandatory requirements set by the country for obtaining mutually agreed terms and prior informed consent, or the clear and unambiguous indication that such conditions are not mandatory in the country,
- provide rules setting out minimum requirements in respect of the sharing, in a fair and equitable way, of the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources and any other conditions to obtain mutual agreement,
- designate a responsible contact point in each country where companies could address their requests.

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| <b>E. PATENTS RELATED TO GENETIC RESOURCES</b> |
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The question of the patentability of genetic resources has already been debated at length. In this context, Cefic regrets that in Article 27.3 (b) of the TRIPs concerning the patenting of plants and animals this has been rendered optional.

At EU level, the Community has filled this gap in Directive 98/44/EC of 6 July 1998, on the legal protection of biotechnological inventions. Recital (29) of the Directive mentions that *“Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;”*.

***Cefic encourages countries to follow this approach and have unambiguous legislation put in place to allow patentability of plants and animals, including with a reference to the 1991 UPOV Convention as being the sole sui generis system for plant varieties.***

***In this debate, two items are of major importance:***

1. ***The voluntary indication of the origin of material in patent requests***
2. ***Prior informed consent***

**1. The voluntary indication of the origin of material in patent requests**

At EU level, this issue was also dealt with in Directive 98/44. Recital (27) provides that *“Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;”*.

***The chemical industry fully subscribes to this approach: any indication as described above should not be included in patent law as a condition, but should be made on a voluntary basis.***

***Therefore, Cefic strongly encourages its Members to indicate the source (i.e. the country) of biological material, in patent requests, when possible, on a voluntary basis (together with the mention that this indication is made without prejudice of the rights conferred by the patent).***

There are many reasons to justify why such an indication should not be made a condition in the patent procedure. First of all, it is totally “foreign” to patent law (it has no link with the novelty requirement, inventiveness, or the utility of the invention).

In addition, in practice, it will be extremely difficult, if not impossible in some cases, to be managed by patent offices, since they are not equipped to judge whether in a particular patent application an indication of origin is correct, and whether the patent applicant lawfully obtained that biological material. This may raise many ancillary questions:

- Patents involve private parties (whether people, or companies), while access involves the countries themselves.
- Some patent requests filed today are based on material that was obtained before the CBD entered into force. Thus, the indication may not always be possible. The same applies to requests based on some materials obtained from “collections” made decades ago and which can still be used.

- Some countries are not yet signatories of the CBD (e.g. the USA). As a consequence, when material is obtained via those countries, it is not always possible each time to obtain the information on the source as well.

## **2. Prior informed consent :**

In more recent years, some NGOs, developing countries and local communities have requested that proof of prior informed consent be made a requirement for obtaining a patent.

***In this context, if each CBD Contracting Party had a clear implementing legislation in place, it would facilitate the work of companies. This is fully supported by the chemical industry.***

***Nevertheless, similarly to the question of the indication of origin, prior informed consent is totally foreign to patent law, as applying before the invention is made. Therefore, this should not be made a requirement of patentability. Also, as for the indication of origin, patent offices are not equipped to check whether the consent reported was lawfully made and truthfully reported.***

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| <b>APPENDIX – ARTICLES 8 (j) AND 15 OF THE UNITED NATIONS CONVENTION ON BIOLOGICAL DIVERSITY</b> |
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*Article 8. In-situ Conservation*

*Each Contracting Party shall, as far as possible and as appropriate:*

*(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;*

*Article 15. Access to Genetic Resources*

- 1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.*
- 2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.*
- 3. For the purpose of this Convention, the generic resources being provided by a Contracting Party, as referred to in this Article and Article 16 and 19, are only those that are provided by the Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the Convention.*
- 4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.*
- 5. Access to genetic resources shall be subject to prior consent of the Contracting Party providing such resources, unless otherwise determined by that Party.*
- 6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.*
- 7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Article 16 and 19 and, where necessary, through the financial mechanism established by Article 20 and 21 with the aim of sharing 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 with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.*