

## Disclosure of the origin of genetic resources, including compliance with the provisions relating to prior informed consent and sharing of the benefits

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André BOURGOUIN  
VP Corporate Intellectual Property  
IPSEN – SCRAS  
Paris  
France

- The pharmaceutical industry is in agreement with the aims pursued by the Convention on Biological Diversity (CBD), in particular recognition of the sovereignty of states with respect to national genetic resources and fair and equitable sharing of the benefits derived from their use. It is fully prepared to cooperate with countries which own genetic resources within this framework.
- The first point to be noted is that the pharmaceutical industry is highly dependent on intellectual property and on patents in particular. Even its opponents recognize that the considerable investments (up to 1 billion dollars) and time frames (of the order of 10 years) required for research and development in the pharmaceutical field can be undertaken only if temporary exclusive rights provided by patents are granted with reasonable certainty to the enterprise carrying out this research.
- Consequently an invention, whatever it be, and in particular an invention requiring significant investment and very long development periods therefore has no prospect of being **exploited** unless it benefits from reliable patent protection.
- Certainly, other sectors of activity which may also be involved in the use of genetic resources and, first and foremost, companies active in the field of **non-prescription medicaments containing plant extracts** are less dependent on research and therefore have less recourse to the patents system and are less reliant on it than the pharmaceutical industry. This is also the case with cosmetics.
- Obtaining and possibly defending patents by its very nature involves legal risk. Any initiative that creates additional **uncertainty** discourages investment in a field where a particular risk would exist, above all if there are alternatives to investment in this field.

- Therefore, an effective and fair system of patent protection is one of the best means of stimulating innovation in the field of genetic resources and increasing its value. As indicated above, an invention which does not benefit from reliable patent protection has every chance of not being developed. A system which introduces additional risks of invalidation even in cases of good faith will tend to be avoided by those involved in the field. Moreover, the invalidation of a patent would in practice render the realization of a benefit, and thus any sharing in this benefit, difficult or impossible.
- Paragraph 19 of the Doha Ministerial Declaration instructed the TRIPS [Trade-Related Aspects of Intellectual Property Rights] Council to examine in particular the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), and in particular the compatibility between the two agreements, it being understood that one of the CBD's objectives is fair sharing of the benefits resulting from the use of genetic resources.
- In this respect, the introduction of an obligation to declare the source of genetic resources and possibly of traditional knowledge would probably lead people not to become involved in the type of research covered by these measures. The discussions which have been taking place for a number of years around this subject and the uncertainties which they have caused may have already led certain enterprises to defer or abandon their involvement in the field of genetic resources.
- The more binding the newly created obligations and the more disadvantageous or even punitive the penalties resulting from their non-observance, the greater will be this disincentive. In particular, this would probably be the case if the disclosure obligations were established as an additional condition of patentability with invalidation of the patent as a possible penalty.
- This problem is illustrated by the most restrictive proposals put forward by certain developing countries which provide for the amendment of the **TRIPS Agreement** so as to make possible the invalidation or revocation of the patent if the patent proprietor has not identified the **country of origin** of the genetic resources, has not provided the **evidence of prior informed consent** and of a **fair and equitable sharing of the benefits** obtained by the use of these resources.
- The fulfilling of these obligations would in practice encounter major obstacles. Determination of the country of origin can in particular be difficult and a biological product can for example have its origin in several countries. Moreover, the terms and concepts used often lack clarity, for example the difference between origin and source can be difficult to determine in practice. The problem becomes practically insoluble in the case of the transmission of materials for transformation or improvement etc.

- Amendment of the TRIPS Agreements does not appear to be the solution to the problem posed, as it can be maintained that there is no incompatibility between the CBD and these agreements.  
In fact, the CBD does not require any disclosure within the framework of patents and *a fortiori* does not oblige countries to amend their patent laws. The CBD asks the Parties to make access to genetic resources subject to prior informed consent and to encourage the fair and equitable sharing of the benefits resulting from the use of the genetic resources.
- Other proposals such as the Swiss memorandum appear more balanced.
- Switzerland proposes to amend the PCT Regulations so as to give the PCT Member States the **possibility** of requiring applicants, at the time of the entry of the international application into the national phase of the PCT procedure or **after**, during the international phase, to declare the **source** of the genetic resources when an invention uses such resources. When an international application does not contain the declaration required upon entry into the **national** phase, each state can provide for the application procedure to be suspended until the applicant has satisfied the obligation to supply the required declaration.
- In practice, according to the Swiss proposal, a new subparagraph would be added to Rule 51a.1 of the PCT Regulations. This text would provide that the national legislation which can be applied by the designated office can, in accordance with Article 27, require the applicant to declare the source of a determined genetic resource to which the inventor has had access. If this source is not known, he will have to state this.
- A similar provision would relate to traditional knowledge.
- The PLT refers to the provisions of the PCT, in particular to its Regulations. Therefore, the proposed new Rule would apply equally to the PLT. The contracting Parties of the PLT would then have the right to provide for a declaration **obligation** in their national laws. On the basis of the PLT the national law on patents could provide that the validity of a granted patent is called into question if the source is not declared or is wrongly declared, and that this results from a “**fraudulent intent**”.
- This provision could be a source of difficulties, as the determination of a fraudulent intent can be subjective and can in any case give rise to a dispute with an uncertain outcome. As indicated above, any attempt to link the validity of the patents in this field with the fulfilling of a disclosure obligation is a source of uncertainty.
- The European Union has also proposed a provision which would make it obligatory to disclose the country of origin or, if it is unknown, the source of the genetic resources used in the invention, the penalties for non-observance of these provisions being **outside patent law**.
- While certain of the provisions envisaged would introduce uncertainty as regards the validity of patents based on bioprospecting, an uncertainty

which would discourage those involved in the field from following this research path, it is not at all certain that they would help the countries concerned regulate and control the use of their genetic resources as the patents system can at best affect only a limited fraction of the prospecting activities.

- Research programmes based on “bioprospecting” are difficult and do not seem to be particularly numerous at present. In this regard, certain important research programmes already implemented do not seem to have produced results which can be exploited at present. Due to the existence of more modern research means, in particular the chemical synthesis of new compounds, this type of research, which succeeded in gaining acceptance before the signing of the CBD, is tending to be abandoned by a number of companies.
- In the past it is certain that a certain number of medicaments were derived from biological materials. However it does not seem that many pharmaceutical products recently introduced onto the market or in the process of development originate from a “bioprospecting” activity. The most recent medicaments are rather based on products (proteins or monoclonal antibodies) which in many cases are of **human** origin..
- In this respect, it is absolutely clear that any provision adopted within the framework of the CBD cannot affect products of **human** origin.
- In spite of certain declarations it seems that the magnitude of the problem of possible biological piracy seems limited. Companies which have been involved in this field for several years and before 1993 in particular had for the most part complied with the law in force at the time. It is not clear whether acts of biopiracy which are sometimes reported are in fact committed by pharmaceutical companies.
- In any case, organizations bringing together enterprises involved in this type of research have now established very detailed codes of conduct to be observed in the case of “bioprospecting” activities. This is in particular the case with the guidelines proposed by the “BIO” organization in the US.
- Industrialized countries such as Germany or Norway have already started to adapt their national laws to the requirements of the CBD in the matter of access and fair sharing. These laws do **not** provide for penalties within the framework of the **patents system**.
- Countries such as the Andean states which are party to the Cartagena Agreement, Brazil or India have already established national regulations covering access to genetic resources.
- The Bonn Directive gives indications of what national legislation could be in this field.
- **Above all, contractual provisions would make it possible to fulfil the obligation for prior informed consent and sharing of benefits. These**

**provisions can offer various solutions suited to different situations, allowing financial or non-financial compensation.**

- In the case of a dispute, the contractual nature of the relationships thus created allows the use of the civil or criminal legal provisions and a choice of the laws or competent jurisdictions.
- It is in particular possible to use international courts to resolve differences such as the WIPO **arbitration** centre or the ICC. This solution is very well suited to the case where a developing country is party to the dispute.
- Another of the advantages of this type of contract is to generally provide an initial payment (up-front payment) which allows the party dealing with the pharmaceutical company to receive compensation **immediately** whereas any royalties based on the use of a medicament derived from genetic resources are uncertain and remote in terms of time.
- A certain number of pharmaceutical companies have concluded such agreements. The agreement concluded by Merck with INBio, that of Novartis with BIOAMAZONIA and the agreements concluded directly by Shaman Pharmaceuticals with indigenous tribes can be mentioned. The NCI has drawn up standard agreements under the terms of which it is the proprietor of the patent rights and licenses them to the pharmaceutical companies concerned. The contract concluded by Diversa can also be mentioned.
- The contractual provisions make it possible to ensure that any penalty for non-observance of disclosure conditions is outside the patents field and tends to compensate for damage and not to punish any offenders who may have acted in good faith.

## **Conclusions:**

- **The pharmaceutical industry is in agreement with the aims pursued by the CBD and is fully prepared to cooperate with countries which own genetic resources within this framework.**
- **It must be borne in mind that the pharmaceutical industry is highly dependent on intellectual property and in particular on patents, which is not the case with all the enterprises operating within the framework of the CBD.**
- **Any initiative that creates additional uncertainty as to the value of the patents discourages investment in a field where there would be a particular risk.**
- **An effective and fair system of patent protection is one of the best means of stimulating innovation in the field of genetic resources and increasing its value.**
- **The introduction of an obligation to declare the source of genetic resources would lead people not to become involved in the type of research covered by these measures.**
- **The establishment of disclosure obligations as an additional condition of patentability is an extreme solution, of which the pharmaceutical industry disapproves.**
- **Moreover, it is not at all certain that these provisions would help the countries concerned to regulate and control the use of their genetic resources.**
- **Contractual solutions are more likely to satisfy the needs of the different parties.**
- **They make it possible to satisfy the obligation for prior informed consent and sharing in the benefits.**
- **They offer various solutions which are suited to different situations, making it possible to provide for financial or non-financial compensation, and in particular an up front payment.**
- **In the event of a dispute, contractual relationships allow the use of appropriate civil or criminal legal provisions and in particular that of international courts to resolve differences such as the WIPO arbitration centre or ICC.**
- **Any penalty for non-observance of disclosure conditions could only be outside the patents field.**