DISCLOSURE OF ORIGIN IN IPR APPLICATIONS: OPTIONS AND PERSPECTIVES

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IF NECESSARY, PLEASE USE ADDITIONAL SHEETS TO EXPAND ON YOUR ANSWERS.

1. Has your organisation been, or is it currently, involved in debates within your country, or your members' countries, regarding the introduction of disclosure requirements into patent legislation? Please give details of your involvement and any impressions of the national debates (e.g. what position you advocated, who else was involved in the debate, quality of consultation, main areas of controversy…).

This Federation has commented, on a number of occasions, on proposals for mandatory disclosure of the geographical origins of biological materials, in particular micro-organisms and other genetic resources. The comments have been submitted to the head of the UK Patent Office and other officials responsible for IPR policy and negotiation, and have concerned proposals emanating from the committees and councils of (1) WIPO (World Intellectual Property Organisation), particularly in relation to the proposed Substantive Patent Law Treaty (SPLT) and the existing Patent Cooperation Treaty (PCT); (2) WTO – TRIPS (World Trade Organisation – Agreement on Trade Related Aspects of Intellectual Property); and (3) the European Commission.

The comments we have made cannot be said to constitute a "debate". As far as we are aware, there has been no formal consultation by the UK government and our comments on disclosure requirements were not made in response to any request. We have not received any reply or reaction to them. We have not been directly informed of the position adopted by UK representatives at meetings, although we can deduce it from the paper on disclosure submitted by the European Commission, apparently acting on behalf of the EU member states, to WIPO on 16 December 2004.

In brief, the Federation is opposed to mandatory disclosure requirements in patent applications that are not concerned with ensuring that the invention covered by the application is sufficiently described (i.e., the description is such that the invention

can be reproduced by a person skilled in the art to which the invention relates). Our members fully accept the obligations arising under the Convention on Biodiversity, but these should not be used as an excuse for introducing unnecessary and unclear disclosure requirements, unrelated to explaining the nature of the invention, into patent law. There should be no sanctions under patent law for failure to disclose geographical origin of genetic materials. The reasons for this position will be outlined below.

Needless to say, we agree that it is sensible practice for patent applicants to provide as much information as is reasonably possible about any unusual biological material referred to in a patent application, including its geographic origin, but this should not be **mandatory,** except in the unlikely circumstance that the information is necessary for the sufficient disclosure of the invention.

Requirements to provide the license numbers of extraction permits and to prove that there has been permission to use the genetic material should have no place in patent law, which should be concerned with the adequate disclosure of inventions. Remedies for illegal or unlicensed activities should be found outside the patent system.

2. Has your organisation been, or is it currently, involved in debates at the EU or international level relating to disclosure requirements? Please give details of your involvement and any impressions of the debate.

In addition to submitting comments to UK policy makers and negotiators, as indicated above, the Federation has also submitted views directly to the International Bureau of WIPO, to the European Commission and to the European Employers' Federation (UNICE). Members have responded to a Swedish Board of Trade questionnaire concerning disclosure requirements.

It is difficult to get impressions of the debates in the various fora at second hand. In WIPO, there appears to be deadlock in SPLT negotiations on several issues, including that of mandatory disclosure of geographical origin. The European Commission, in proposals which this Federation does not support, proposes a mandatory requirement for disclosure of country of origin or source of genetic resources, failure to comply being penalised by no further processing of the patent application. Sanctions for incorrect information should be found outside patent law. The proposal seems to be an attempt to compromise between those developing countries proposing extensive mandatory disclosure, covering permit numbers and benefit sharing arrangements, with punitive sanctions for non disclosure, and those opposed to mandatory requirements. In PCT negotiations there seems to be a trend (which the Federation does not support) towards

introducing a mandatory requirement that has to be met as a formal matter at the application stage, but that does not have an automatic invalidating effect on the patent if the information is subsequently found to be in error. As regards WTO – TRIPS, the position appears to mirror that in WIPO. We are aware also that WIPO is cooperating with the Conference of the Parties to the Convention on Biological Diversity, but that there are differences of opinion as to whether any adjustments are needed in WIPO treaties to meet obligations under this Convention. This Federation considers that no adjustments are needed.

3. What advantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. improving transparency of the patent system; supporting mechanisms to facilitate fair and equitable access and benefit sharing in relation to genetic resources; *et al.*). Please expand.

We do not identify any advantages. It is not clear how disclosure of the geographical origin of biological material might improve the "transparency of the patent system". The transparency of patents depends on ease of access (search systems) and sufficiency of technical disclosure Benefit sharing in relation to genetic resources, as called for by the Convention on Biodiversity, should not be dealt with under patent law.

It seems that the proposals for origin disclosure in patent applications have been made following allegations that there is a significant amount of "bio-piracy". There is little evidence in support of such allegations and industry does not accept that there is a significant problem. If however, there is a problem, it will not be solved by introducing unreasonable requirements into the patent system. The proper way to manage access to and use of biological resources is to create national mechanisms that directly regulate these activities and to use contractual arrangements to determine equitable benefit sharing.

4. What disadvantages can you identify, or do you foresee, in implementing disclosure requirements within your country? (e.g. practicality and feasibility of implementation, *et al.*) If so, what measures do you think could be taken to alleviate these problems?

- The requirements would address a non-patent issue; i.e., whether a genetic resource has been acquired lawfully. This is a matter for other laws and regulations and cannot be dealt with successfully through patent law.
- There will often be serious difficulties in assessing whether a disclosure requirement applies in respect of a given biological material, what is meant by the "origin" of the material, whether that origin must be traced back to an *in situ* source and how direct should be the connection between the material and the invention. *[An annex to this reply, prepared by one of our members, gives*

examples of possible situations that may have to be considered]

- Many biotechnological inventions make use of genetic materials that are known and available. Identification of origin may be impossible and/or irrelevant.
- Genetic material may have been lawfully obtained without the origin or source being known; for example from a depository. It may have been obtained from raw materials exported in the general course of trade (e.g., timber) from a number of possible sources.
- The geographical origin of a genetic resource may be anonymous, as when it is taken from a culture created from material from several sources and/or after many reproductions.
- It will not be clear in many circumstances what is meant by an invention being based on or derived from a genetic resource. Many inventions are based on earlier inventions, though may not depend on the same genetic material.
- The additional bureaucracy, investigative work in trying to trace origin and uncertainty about the detail expected in unclear situations will lead to loss of confidence in and deterioration in the value of the patent system.
- A refusal to grant a patent if information about the origin of genetic material is not given will not prevent the further use of the material in development work. Inventions that are refused patent protection are liable to be freely exploited by copyists, leading to situations quite contrary to the intentions of those seeking to control the dissemination of the genetic material.
- A refusal to grant a patent because of no or erroneous origin disclosure would be a particularly pointless sanction, since that would stifle the commercial value of the invention and thus the value of any shared benefit in it.
- The aim in patent law should be to simplify and harmonise formal requirements in patent applications, not to add unreasonable ones with which it may be impossible to comply.
- Origin disclosure requirements in patents will have very limited value in helping countries to monitor the use being made of genetic resources, since very few uses result in inventions that are the subject of patent applications. For example, it is usual to screen many thousands of samples before arriving at a commercially useful invention. Many non patented or non patentable applications may be developed. Furthermore, many uses may be kept secret.
- The commercial value of a patent will not be clear until many years after the making of the first application for it. It is thus most unlikely that disclosure of geographical origin in the application will provide an effective means of gaining access to the benefits derived from the genetic material. Contractual arrangements

established when granted access to the material will be a much more effective tool for keeping check on future benefits.

- Disclosure requirements serve little purpose in relation to the patents of those companies (the vast majority) that have obtained the appropriate consents, since those consents will already be a matter of record in the countries concerned. If on the other hand national laws on the obtaining of consents have been breached, it seems unlikely that the companies involved will draw attention to this by providing detailed information about geographical origin.

The problems cannot be "alleviated" through adjustment of patent law.

5. What measures, if any, do you think should be taken at the European level in relation to disclosure requirements? Please explain your reasoning.

No measure should be taken beyond that in recital 27 of Directive 98/44/EC of the European Parliament and Council on the legal protection of biotechnological inventions. This recital declares that information on geographical origin should be provided **where appropriate** and **if known**; and that this is **without prejudice** to the processing of patent applications or the validity of the resulting patent rights.

6. What measures, if any, do think should be taken at the international level in relation to disclosure requirements?

None

7. Do you think any other measures should be taken at the European or international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing? Please expand.

As discussed above, it should be a matter for each national (non patent) law to set a framework for regulating the extraction of biological materials, and for each country to establish if necessary appropriate contractual arrangements for the sharing of benefits, in the light of the relative contribution and effort of the country involved and the company making use of the extracted materials. Each situation is different and it should be recognised that without the efforts of the companies involved, there will be no inventions and no commercial benefits.

FOLLOW-UP ACTIVITIES

8. In order to gain a more in-depth understanding of this issue, we will be carrying out additional interviews following this questionnaire survey. Would you be willing to discuss these questions further with us? If so, please ensure you have provided full contact details above, and let us know if you will be unavailable for any long periods between now and September 2005.

Yes

9. Please indicate whether you wish your views to remain anonymous.

No

FINAL NOTE: These answers do not particularly concern disclosure requirements relating to the origin and use of "traditional knowledge". We consider that there should be no special disclosure requirements in patent law concerning such knowledge.

It seems to us that there are difficult problems (which are under consideration in WIPO) in defining what is meant by traditional knowledge, as distinct from other knowledge in the public domain, that would justify a need for origin disclosure. Does traditional knowledge differ in kind, for example, from technical knowledge or craft skills passed down from one generation to the next, e.g., from the industrial revolution in the UK? There would be an outcry if efforts were made to give special protection to this knowledge, unless it had always been passed on in strict confidence and had never entered the public domain

Annex to Response

Scenario 1

1. Company A is informed that rubbing a bruise with a leaf from the XYZ tree in Brazil alleviates bruising. It obtains the seeds (with appropriate consents) and grows sufficient quantities to enable it to extract and purifies the oils which it sells. It patents the purified oils, their use and the process of extraction and purification. Would the disclosure requirement apply?
2. Company A is informed that rubbing a bruise with a leaf from the XYZ tree in Brazil alleviates bruising. It obtains quantities of the leaves (with appropriate consents) and isolates and synthesises the active ingredient which it develops and sells. It patents the active ingredient and its use. Would the disclosure requirement apply?
3. Company A obtains (with appropriate consents) leaves from 100 species of trees in Brazil. It knows nothing about their properties. Using various assay techniques, it discovers that one ingredient of one of the leaves is medically useful. It isolates and synthesises the active ingredient which it develops and sells. It patents the active ingredient and its use. Would the disclosure requirement apply?
4. Under 3, does it make a difference to the applicability of any disclosure obligation if the medical use was known to a community in Brazil but not disclosed to Company A either at the time of collection or before application for the patent?
5. Company A does either 2 or 3 but finds that the ingredient it has isolated and synthesised has unacceptable toxicity. It finds a hitherto unknown analogue of it in the same class of compounds and patents and commercialises that analogue. Would the disclosure requirement apply?
6. Company A does 2, 3 or 5 but does not commercialise the product. On the basis of the patent disclosures of Company A, Company B develops, patents and commercialises a compound in a different class of compounds from those patented by Company A. Is there a need for Company B to disclose the origin of the leaf used by Company A? Does it make a difference if Company A had disclosed its origin?

Scenario 2

One of the thousands of compounds synthesised by Company A as part of its combinatorial chemistry program is Compound X. Its screening processes disclose that this novel compound has a medical use. It patents the compound and its use. However, Company A cannot develop a cost-effective method of producing commercially viable quantities of the compound and does not commercialise it.

Company B is aware of the patent disclosure. It obtains access to a large number of micro-organisms from Brazil and discovers (it is not told) that one of them naturally produces Compound X , but not on a commercially efficient scale or with adequate purity.

Based on this discovery, it analyses a similar micro-organism which is native to Europe and finds that that micro-organism produces Compound X more efficiently than either the micro-organism from Brazil or the synthetic route disclosed in Company A's patent.

Company B genetically modifies the European micro-organism to improve production efficiency still further. It patents the micro-organism and compound X as produced by the micro-organism.

Company C genetically modifies the European micro-organism still further to improve purity of Compound X and obtains relevant patents.

Companies A,B and C cross-licence each other under the patents to enable sale of the commercial products.

Does Company A, B or C have to disclose the Brazilian micro-organism?

Scenario 3

1. Company D is informed that people wash clothes with a plant extract in Chile. It obtains the plant (with appropriate consent) and discovers a new lipase enzyme. It isolates the gene for the enzyme and patents the isolated enzyme, its DNA sequence, its use in laundry detergents and a process for its recombinant production. Would the disclosure requirement apply?
2. Company D is informed that people wash clothes with a plant extract in Chile. It obtains the plant (with appropriate consent) and discovers a new lipase enzyme, isolates its gene, and determines its DNA sequence. The company finds, however, it cannot withstand normal laundry temperatures, and publishes the work. Company E reads the publication and undergoes extensive R&D to mutate the gene to make the gene more heat stable. The new gene shares only 40% sequence identity with the original gene. Company E patents the mutated enzyme, its gene sequence, its use in laundry detergents and a process for its recombinant production. Would the disclosure requirement apply?
3. Under 2, does it make a difference to the applicability of any disclosure obligation if (i) Company D worked with Company E to generate the new enzyme and a joint patent application was filed? (ii) Company E later exclusively licenses Company D to make and sell the enzyme in washing powder? (iii) Company D did not publish, but gave Company E the information under a contractual obligation to pay royalties to Company D should a commercially viable enzyme be marketed.
4. Under 2 or 3, does it make a difference to the applicability of any disclosure obligation if Company D never discloses to Company E the source of the plant, and the plant is also found to be native to the country of Company D and Company E.

Scenario 4

1. Company F is informed that a plant virus is wiping out a cash crop native to Bolivia. The company obtains the plant (with appropriate consent) and discovers a receptor which the virus uses to infect the plant. The DNA sequence of the receptor is found and the receptor is cloned and used to screen compound libraries for chemical antagonists which would prevent viral infection. A patent application is filed on: the new receptor, its gene sequence, methods of finding antagonists, the chemical antagonists themselves, and their use. Would the disclosure requirement apply?

2. Under 1, does it make a difference to the applicability of any disclosure obligation if the receptor was found by the Bolivian Agricultural Department, and its sequence published, and i) Company F was given the vector comprising the gene for the receptor by the Bolivian Agricultural Department and the antagonists were found and patented?, or ii) Company F synthesised the published gene sequence to discover and patent the antagonists?

Scenario 5

Consider all of the above cases and assume that, for whatever reason, relevant patents are held invalid. Producers of generic/unpatented products make large amounts of money selling the products. Are those producers obliged to share the benefits of their sales with the countries which provided the materials?

Scenario 6

In order to make a wheat crop more hardy, plant breeders crossed a conventional wheat variety with a variety obtained from Russia (with appropriate consent). Plant Breeders Rights were obtained (under UPOV) for the new variety. Would the disclosure requirement apply? What if several breeding steps were required to generate the new plant variety, and the Russian variety had been used 20 steps previously to the new variety being generated?

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