TMPDF
TRADE MARKS, PATENTS & DESIGNS FEDERATION

Advancing Industry's View On Intellectual Property Since 1920

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Dear Ron,

Inventions "based on" genetic resources

Mandatory disclosure of source.

TMPDF represents the views of UK industry in matters concerning intellectual property. It has close links with the CBI. Its members include many of the major innovative UK companies, which are represented at meetings of the governing Council and Committees of the Federation by their professional IP managers. Before the Federation takes a position on any issue, official consultation documents and other relevant papers are submitted to the members for debate and dialogue. An appropriate Committee and/or the Council, depending on the issue, then determines the position, taking account of comments.

The published views/opinions/submissions of the Federation are normally approved by consensus. In cases where there is a substantial majority view falling short of consensus, any significant disagreement will be indicated.

We have recently been alerted by UNICE to a Commission "non-paper" on this subject, which was discussed in a Council working group on 9 September. The Commission proposed that the PCT should include a new rule 51ter.1 to make it compulsory under national law to declare the country of origin or specific source of a genetic resource, if the invention is "based on" that resource or its components. A similar declaration relating to traditional knowledge would also be required. Failure to provide the information would result in the refusal of the patent. The provision of partial or erroneous information would be dealt with under national civil or criminal law.

The Commission claimed that this proposal was in line with the views of "a large number of experts", who participated in a meeting last April. We did not participate in that meeting and were not consulted, by either the Commission or UK officials. We now understand, from non-UK sources, that the non-paper was endorsed in general terms by the working group.

Similar proposals may be discussed at the WIPO general assembly at the end of this month, since papers concerning the intergovernmental committee on intellectual property and genetic resources have been distributed.

The Commission appears to consider that it is relatively easy to introduce a major new requirement in national patent laws, unfavourable to applicants, by means of a rule change in PCT that refers to Article 27 PCT. We suggest that the use of the PCT in this way is *ultra vires*. Article 27 governs national requirements concerning the form and content of international applications and permits member states to adopt requirements for such applications **more favourable** from the viewpoint of applicants than those of the PCT. There appears to be no general power by which national laws can be compelled to change adversely to applicants by rule under the

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PCT.

As regards the substance of the Commission proposal, the Federation strongly opposes it. 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 the nature of the invention, into patent law. We call on the UK delegations at forthcoming meetings, whether these are meetings with the Commission, or in WIPO, the WTO or elsewhere, to strenuously resist proposals calling for mandatory disclosure of the source of genetic material in patent applications. The legality or otherwise of the acquisition of genetic material is not a patent matter and should be dealt with outside patent law.

You should be aware that the Federation wrote to IPPD on 26 March 1999 and to your predecessor Alison Brimelow on 14 December 1999 about a similar issue in the context of SPLT discussions. We were not informed about the UK position at that time, but the spokesman for the EU member states spoke against the proposals in WIPO.

Several reasons for resisting genetic source disclosure requirements were set out in the two letters mentioned above and are repeated in the annex to this letter. More detailed reasons are set out in the enclosed paper prepared in response to a recent consultation by the Swedish Board of Trade on the issue of a disclosure requirement relating to genetic materials. Andrew Jenner has already received an earlier draft from David Rosenberg of GSK.

The Federation urges you to ensure that UK delegations emphatically resist these proposals, which will be damaging to UK industry, in whatever fora they may be presented.

Yours sincerely

Sheila Draper

Secretary, for, and on behalf, of TMPDF

Annex

Reasons for resisting mandatory disclosure of genetic source in patent applications.

These reasons are based on those given to the Patent Office in 1999. The arguments apply equally to traditional knowledge.

- The information called for would generally be irrelevant to the sufficiency of the disclosure of the invention.
- The requirement 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.
- Many biotechnological inventions make use of genetic materials that are known and available.
- Genetic material may have been lawfully obtained without the original source being known; for example from a depository, or from raw materials exported in the general course of trade (e.g., timber).
- The geographical origin of a genetic resource may be unknown or anonymous, as when it is taken from a culture created from material from several sources and/or after many reproductions.
- It is not necessarily clear what is meant by the invention being "based on" a genetic resource. Many inventions are based on earlier inventions, though may not depend on the same genetic material.
- A refusal to grant a patent when information about the source 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 a situation opposite to that intended by those seeking to control the dissemination of the genetic material.
- The aim should be to simplify and harmonise formal requirements in patent applications, not to add unreasonable ones with which it may be impossible to comply.

If at some stage it becomes necessary to reach an accommodation, inspiration might be found 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.

TMPDF September 2004

DRAFT Working Document

A Response to the Swedish Board of Trade Questionnaire on "indication of origin of material in patent applications"

a. What are the advantages and disadvantages from your perspective of a requirement to indicate geographical origin?

Opening remarks

In order to assess the advantages and disadvantages of a requirement to indicate geographical origin, each of the following issues must be addressed:

1. what is the objective to be achieved or promoted by the requirement?
2. to what extent does the requirement achieve or promote that objective?
3. to what extent does the requirement have undesirable consequences and do these outweigh the advantages of the requirement?

Issues 2 and 3 can only be addressed by reference to the nature of the requirement (what is required), its precise parameters (i.e. in what circumstances does the requirement arise) and what are the consequences of a failure to comply with the requirement.

Each of these issues will be addressed in this response to the questionnaire.

What is the objective to be achieved or promoted by a disclosure requirement?

The apparent objective of a requirement to indicate the geographical origin of genetic material is to implement obligations of the Convention on Biological Diversity (CBD).

Key provisions of CBD in this regard are (with emphasis added):

1. Article 1 which provides

   "The objectives of this Convention are the conservation of biological diversity, the sustainable use of its components and **the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources** and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

2. Article 15(5) which provides

   "**Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources**, unless otherwise determined by that Party."

3. Article 15(7) which provides

   "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 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**."

In essence, it is argued that a disclosure requirement would assist countries providing access to genetic resources to monitor and keep track of compliance with their national access and benefit sharing rules.

It is important to appreciate that under the Convention's model, private entities, such as companies or universities, are to play a critically important role – namely, collecting the resources, and performing research and development on or with them that might yield commercial or non-commercial "benefits."[1] This significant role cannot be discounted in discussions regarding the "merits" of a possible patent disclosure requirement. Indeed, without the *voluntary* participation of the private sector, particularly industry, the "benefits" envisioned under the Convention's benefit sharing provisions will never materialize. Clearly, then, measures of any form that are designed to promote the objectives of the CBD – including "benefit sharing" – must be evaluated as to whether they will encourage or discourage the private sector to seek access to "genetic resources" and to undertake efforts to develop those resources into "benefits." Measures that discourage use of genetic resources– particularly those that make successful commercialization riskier or more likely to fail – would create serious disadvantages.

Thus, whether a special new patent disclosure requirement would provide advantages or disadvantages must be measured by reference to its relationship to the activities governed by the CBD and, in particular, to its ability to promote the obtaining of prior informed consent and equitable benefit sharing.

The scope of the CBD

Because the objective of any disclosure requirement is to promote the objectives of the CBD, the scope of the CBD must be analyzed.

Important parameters defined by the CBD are as follows:

1. It applies only where there is commercial or other utilisation of "genetic resources" which are defined as "**genetic material** of actual or potential value". "Genetic material" is "any material of plant, animal, microbial or other origin containing functional units of heredity".

2. It applies only to **non-human** genetic resources [2]

3. The genetic resource is collected from the country of origin on or after the date that the Convention entered into force in the country from which the materials are collected (1992 for most countries).[3]

Any proposals to impose a disclosure requirement of broader scope than these parameters must have an objective beyond assisting in the implementation of the CBD. Such objective must be articulated in order to allow an assessment of whether it is legitimate, whether the disclosure requirement would promote achievement of the objective, and what undesirable consequences might flow from it.

To what extent would a disclosure requirement achieve or promote the CBD objectives outlined above?

As noted above, it is suggested that a patent disclosure obligation will facilitate the discovery of unauthorized uses of genetic resources, and will enable countries of origin to monitor and enforce

[1] The concept of commercial benefit is key in this regard as "genetic resources" are defined as "genetic material of actual or potential value" (Article 2 CBD). Under the Convention, benefits can range from early sharing of research results, compensation for access to or based on successful commercial development of an invention derived from use of the resource, or even licensing of intellectual property rights. Under the explicit structure of the CBD, all of these arrangements regarding "benefit sharing" are to be worked out in advance between the involved parties (i.e., before access is granted). Indeed, the mutual agreement requirement found throughout the Convention is designed to reinforce that the process of collecting, evaluating and developing genetic resources is a cooperative effort that can yield mutual advantages to all parties.

[2] The Convention does not apply to human genetic materials. See, CBD Decision II/11, para. 2 and Bonn Guideline 9.

[3] CDB Article 15(3). See also Handbook of the Convention on Biological Diversity, prepared by the CBD Secretariat, 2001, p. 157.

benefit sharing and prior informed consent provisions arising under the CBD[4] . However, this is not an effective or efficient means for achieving this end.

Patent disclosure obligations cannot be expected, except under rarely occurring circumstances, to help countries monitor or enforce obligations arising under the CBD for at least the following reasons:

1. Very few uses of genetic resources will ever result in an "invention" that can be protected by a patent. Typically, many thousands or even hundreds of thousands of samples must be screened to identify potential leads for investigation. Once identified, those leads rarely yield compounds that merit serious investigation, and fewer still yield compounds that possess attributes that could merit the filing of a patent application. As such, very few patent applications are likely to be filed that concern inventions derived from uses of genetic resources governed by the CBD. A patent disclosure requirement will reveal only a small fraction of the possible "uses" of genetic resources that could occur that would be governed by the CBD.

2. By no means all "uses" of a genetic resource are driven by a commercial motivation. Many researchers never intend to use accessed genetic resources to develop commercial products and will not file patent applications. In such situations, uses of genetic resources could occur that would yield "benefits"– including scientific knowledge – that could be theoretically shared with the country of origin. Yet, the uses will not be linked in any way to a patent application. A patent disclosure requirement thus will do nothing to identify such uses or to promote the sharing of benefits in any of these situations.

3. Some uses with a commercial purpose and value will be kept secret and not published in a patent application. A patent disclosure obligation will not assist in achieving CBD objectives in relation to these uses.

4. In the pharmaceutical industry at least, there will be many years between the publication of a patent application and any commercialisation of a product, and very few commercialised products arise from patent applications. It is commercialisation of the product that is likely to give rise to implementation of obligations to share benefits. A disclosure of origin in a patent application is unlikely to be an effective means of monitoring whether or not, several years later, benefits have been derived form the genetic resource. Contractual arrangements entered into as part of the process of obtaining access to the resource concerned are far more likely to be an efficient tool to allow monitoring of generation of benefits than a disclosure requirement.

5. Where a company (as the vast majority do) has obtained the consents to access and use genetic resources required by national law in the country of origin and has entered into arrangements for benefit sharing, the disclosure obligation provides no advantage. Any advantage of a disclosure obligation is likely to arise only on the very few occasions where these requirements are not met. On those occasions, a company which has breached national laws on access and benefit sharing is unlikely to draw attention to the fact by disclosing the origin of the genetic resource in a patent application. Thus, the monitoring function of any disclosure obligation will be ineffective.

[4] Indeed, it appears that a disclosure requirement is intended by many to be a substitute for national laws on access and benefit-sharing national. Although twelve years have elapsed since the entry into force of the CBD, we understand that less than one-third of the Contracting Parties have an access and benefit-sharing regime Yet, many of these Contracting Parties actively urge the adoption of requirements to indicate source. Thus, it would appear that requirements to indicate geographical origin are intended by some to be a substitute for national laws, rather than a tool for achieving CBD objectives. Notably, where countries have not implemented national laws on access and benefit-sharing, a disclosure obligation simply cannot achieve the apparent objective of its advocates. That objective, to enable monitoring and enforcement of national laws on access and benefit-sharing , cannot be achieved where there are no such laws.

6. To the extent that any sanction for failure to disclose will mean a patent is not granted or enforced, it is a particularly inappropriate means of ensuring benefit sharing. Patents give rise to the benefit to be shared and provide the necessary incentive for the very significant investment in progressing the medicines to market. Without an enforceable patent, there will be no benefits to share and the objectives of the CBD will be frustrated.

In view of these factors, we believe a patent disclosure obligation would be a highly inefficient tool for countries to use to assist their efforts in identifying uses of genetic resources or in regulating access to their genetic resources.

The inefficiency of the disclosure obligation as a tool must be viewed in parallel to the scale of the alleged problem which it seeks to address. There is very little use of genetic resources by the pharmaceutical industry which falls within the limits of the CBD outlined above, particularly the restriction to non-human resources obtained from countries of origin after 1992. The scale of the alleged problem has not been identified or substantiated. The "Checklist of Issues" submitted to the TRIPs Council by Brazil and others in March 2004[5] appears to suggest that "bio-piracy is today accepted as a major problem". There is no good evidence that there is a significant practical problem and industry does not believe that there is one. The "problem" is one of political rhetoric. The absence of evidence of a real problem is of significance given the problems associated with a disclosure obligation that we outline below.

In our view, the only effective way to manage access to and use of genetic resources is to create national mechanisms that directly regulate these activities and to use contractual arrangements to determine equitable benefit-sharing . Several countries have established such regimes, and others are presently developing their regimes. We have no reason to doubt the effectiveness of these regimes, which usually require entities to work through designated contact points prior to engaging in bioprospecting activities, and to agree to appropriate contractual terms governing prior informed consent and benefit sharing.

And, as noted above, where countries have not implemented national laws on access and benefit-sharing, a disclosure obligation simply cannot achieve the apparent objective of its advocates. That objective, to enable monitoring and enforcement of national laws on access and benefit-sharing , cannot be achieved where there are no such laws.

As a disclosure requirement of the type that is under discussion will not achieve or promote its stated objectives to any significant degree, it is difficult to identify any advantages of such a requirement.

To what extent does the requirement have undesirable consequences and do these outweigh the advantages of the requirement?

The extent of any undesirable consequences which may arise from a disclosure requirement will depend upon the following factors:

1. the scope of the requirement – exactly what is required and in what circumstances and what cost and effort is required for compliance?

2. the degree of legal certainty as to the boundaries of the requirement – the limits of the requirement must be clear and not susceptible to abuse

3. the nature of any sanctions which result from non-compliance with the requirement

[5] (IP/C/W/420)

Companies and others who invest in research must have certainty as to what is needed to ensure the legal security of that investment. Although there is inherent commercial risk as to whether research will be successful, legal risk that the fruits of investment can, in effect, be removed on grounds of failure to comply with legal requirements of a formal nature must be minimal.

As legal certainly decreases and the consequences of sanctions increase, the likelihood of investment in development of genetic resources will decrease. As investment decreases, not only is the likelihood of innovation diminished, but the objectives of the CBD are frustrated. Without research investment, there will be no commercial rewards which can be shared with countries of origin and no technology to transfer to those countries.

This certainty should, of course, be present in all national laws. It would not be sufficient, for example, for the EU to take the view that so long as its laws display sufficient certainty, it has no responsibility relating to the laws of other countries. Great care is needed to ensure that the outcome of current international discussions leads to legal certainty worldwide.

As we shall now see, there are enormous difficulties in providing legal certainty and the various proposals which have been made to date give no confidence that those problems will be solved to any significant degree[6]. We shall focus on three areas:

1. the nature of the material which would be the subject of the requirement

2. the meaning of "origin" of the material

3. the nexus between the material and the patented invention which gives rise to the requirement

The nature of the material which would be the subject of the requirement – "genetic resource", "biological resource", "biological material" or something else?

It is self-evident that clarity is needed as to the nature of the source material which would be the subject of any requirement.

Article 15(7) of the CBD indicates that access and benefit sharing goals must be met with regard to "genetic resources." The Bonn Guidelines also indicate that the scope of the guidelines is limited to access to and benefits arising from use of "genetic resources." As noted above, the definition of "genetic resources" is "genetic material of actual or potential value"[7] and "genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity."

These terms are distinct from the term "biological resources," which is defined as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity." Thus, the term "genetic resource" is clearly narrower, and encompassed within the broader term, "biological resource."

However, this distinction is not adequately addressed in proposals and legislation relating to a disclosure requirement.

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[6] Note that several proposals encompass within their scope disclosure of the origin of "traditional knowledge" which has some nexus with the ultimate product. We do not discuss this concept in this paper as it is not referred to in the questionnaire. However, there is no doubt whatsoever that all the issues identified in this paper would be magnified significantly if any requirements extended to "traditional knowledge, a term which is used , but not defined, in CBD and which has no commonly agreed meaning.

7 Article 2, CBD.

For example, while the Swiss Proposal [8] distinguishes between "genetic resources" and "biological material," and limits disclosure requirements to "genetic resources," the EU Biotech Directive indicates that patent applications in which inventions are based on "biological material"[9] should disclose the geographical origin of that material.[10] Based on the EU Biotech Directive, Sweden, Norway, and Denmark have introduced mandatory disclosure requirements for use of *biological material*[11]

Draft South African legislation[12] refers to "disclosure of origin of genetic or biological resource or knowledge" and "biological or genetic material". None of these terms is defined.

Unlike the CBD, most of the implemented legislations do not clearly distinguish between human and non-human material. It seems that only the Norwegian legislation makes such express distinction. The terms corresponding to the term "the plant and animal kingdom" which are used in the Swedish and Danish legislations are arguably open to different interpretations. If one relies on the distinction between "genetic resource" and "biological resource" provided in the CBD, it is clear that these disclosure requirements go beyond the scope of the CBD. The inconsistent, even contradictory, use of terms renders it impossible for a patent applicant to know if he has met the requirements in force in any particular country. Are the various legislations meant only to impose the requirements of the CBD, or are they to be interpreted as broader than the CBD? Indeed, is the patent applicant to assume that disclosure is required only when genetic materials are used (consistent with the definitions in the CBD), despite the use of the term "biological material" in many existing laws? Or is "biological material" equivalent to "biological resource," as defined in the CBD? Or is "biological material" a term that is distinct from both "genetic resource" and "biological resource?" And what of the limitation in the CBD to non-human materials?

The patent applicant is left to guess whether the obligation is satisfied in each country that may require such disclosure. As a result, the applicant may face increasing delays, fines, or even loss of the right to patent his invention if he makes an incorrect determination.

The meaning of "origin" of the material

The primary focus of the Bonn Guidelines is on mechanisms to ensure access and benefit sharing, including suggested elements for material transfer agreements between CBD Member States. Only in Article 16(d)(ii) of the Bonn Guidelines is it suggested that parties may implement measures to encourage disclosure of country of origin. However, it is not clear exactly what "country of origin" should mean. According to the CBD, "country of origin of genetic resources" refers to the country that possesses such genetic resources in *in-situ* conditions. Similar use of the term "origin" is found in the Communication from the Commission to the European Parliament and the Council[13], the EU Biotech Directive[14], and the Joint Communication from the African Group to the TRIPS Council.[15] A submission to the TRIPS Council from a number of developing countries uses both terms, thereby suggesting that not only the immediate source of genetic resources, but also the country of origin, must be disclosed.[16]

Attempting to define the obligation, the EC Concept Paper indicates that where the "origin" of genetic resources is unknown, the applicant may disclose the "research centre, gene bank or entity from which they acquired the resource."[17] The reasonable interpretation is that when one is able to trace a

8 PCT/R/WG/4/13 and IP/C/W/423

9 Defined in Art 2 as "any material containing genetic information and capable of reproducing or being reproduced in a biological system"

10 98/44/EC, Rectal 27.

11 See Sweden, Patents Decree Article 5a; Norway, Patent Law Article 8b; Denmark, Patents Decree, Chapter 2, Article 3, Section 4.

12 Government Gazette, Vol 464, No 26017, page 1, 11 February 2004

13 COM(2003) 821 final

14 98/44/EC

15 IP/C/W/404

16 IP/C/W/403, Para. 1(i).

17 Communication by the European Communities and their Member States to the TRIPS Council on the Review of Article 27.3(B) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the CBD and the Protection of

genetic resource to its *in situ* location, that location should be disclosed; however, where that is not possible, the immediate location from which the genetic resource was obtained is sufficient. In contrast, the Swiss Proposal suggests that the term "source" may be interpreted as broadly as is possible.[18] Thus, "source" could include "origin," which suggests it is incumbent upon the patentee to trace a genetic resource used back to its *in situ* location. Alternatively, it could require indicating the "Contracting Party providing genetic resources."[19]

As discussed above, several Nordic countries have recently implemented disclosure requirements. Under Norway's legislation, not only is the applicant required to disclose the member state from which a genetic resource has been received, but also the country in which the genetic resource is found in its natural environment.

The lack of clarity as to how far a patent applicant's obligation extends could become a significant burden. A paper submitted to the TRIPs Council by Switzerland in June 2004[20] notes that "a multitude of entities may be involved in access and benefit sharing" and refers to the statement in the Bonn Guidelines that "due to the diversity of stakeholders and their diverging interests, their appropriate involvement can only be determined on a case by case basis.". So, a determination of "source" could involve significant effort and, even when this effort has been expended, could leave uncertainty as to whether legal requirements have been satisfied and, therefore, whether sanctions should apply.

Many genetic resources useful in the pharmaceutical industry have long since been removed from their natural environment. (Examples include vectors, plasmids, cell lines, and other genetic resources that have been used for decades.) Is a patent applicant required to expend significant resources to identify the country or origin, or is the source from which the genetic resource was immediately received sufficient? How many years should that search extend?

While the CBD makes it clear that it relates only to resources acquired after entry into force of the CBD, the legislation we have seen does not make this clear, nor do most of the various proposals and discussion papers in the WTO or elsewhere seek to clarify this.

While it has often been suggested, and the EU has reiterated,[21] that any requirement for disclosure should not be retroactive, even this requires clarification. For example, a cell line that has been in use for decades should theoretically not fall under the disclosure requirement because that could be viewed as retroactive application of the requirement. However, without certainty on the point, it might be argued that the obligation applies to a scientific investigator obtaining that cell line from a repository for the first time. This creates an uncertainty in the obligation for which current proposals and legislation provide no clarification.

The nexus between the material and the patented invention which gives rise to the requirement

Before framing any obligation, it will be necessary to determine, as a matter of policy, what nexus or connection there needs to be between the patented invention (and its embodiment in a commercialised product) which generates commercial value and the material whose geographical origin must be disclosed. Once that policy determination has been made, a means of defining that nexus must be found which provides adequate certainty and guarantees against abuse for stakeholders who may utilise the materials in question.

These questions can only be adequately addressed by considering real world facts and questions. There is a myriad of ways in which relevant materials might in some way be involved in the development of a product. In this section, and in the Annex to this paper, we identify some of them and some of the types of issue that need to be considered before framing a requirement which would have **practical** effect

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Traditional Knowledge and Folklore, Page 13-14. Hereinafter "EC Concept Paper."
18 PCT/R/WG/4/13, Para. 22.
19 CBD, Article 2.
20 Additional comments by Switzerland on its proposals submitted to WIPO, IP/C/W/423, Annex para 19.
21 See, for example, COM(2003) 821, Page 19.

These issues were not addressed in the CBD. This is not surprising as nowhere does the CBD suggest that its access and benefit-sharing goals would or should be promoted by disclosure requirements in patents; nor are they addressed to any significant extent in the Bonn Guidelines

It appears many policy makers are not sufficiently aware of the practical complexities, subtleties and implications of the issue. We hope that this paper will therefore assist in developing this awareness.

Various proposals have supported disclosure requirements, but they do not adequately define the required nexus. Some propose that the requirement should apply if an invention "uses" the genetic resource or if that genetic resource is "used in the invention".[22] Alternatively, the requirement may apply if the genetic resource "constitutes some input in the inventions claimed,"[23] or is "involved in the claimed invention."[24] The EU Biotech Directive suggests the obligation applies if the invention is "based on" or if it "uses" the genetic resource.[25] Finally, the Swiss Proposal indicates that an invention must be "directly based on" the genetic resource, and further states that this term makes clear that "immediate use" of the genetic resource is required.[26]

The myriad ways in which genetic resources may be used in the development of an invention are likely to make it impossible in large numbers of cases in practice to determine whether a particular disclosure obligation would apply. At one end of the possible uses of genetic resources is the use that the CBD was intended to capture. Such a situation arises specifically when a genetic resource is obtained from a member state, a gene sequence is isolated from that resource, and that gene sequence is the invention that provides value. At the opposite extreme is the situation in which a patent applicant uses purely synthetic mechanisms to develop novel small molecule compounds, but tests the utility of those compounds with long-existing genetic resources, such as cell lines. Under such a scenario, the claimed invention does not encompass a genetic resource. However, due to the lack of clarity in proposed and existing legislations, one could argue that the invention "uses" a genetic resource or even is "directly based" on the genetic resource, merely because the genetic resource was used as a means of showing utility. Thus, any requirement to introduce a disclosure requirement would introduce uncertainty that a patent holder could not resolve at the time of filing a patent application. Only through lengthy and costly judicial proceedings will these ambiguities be clarified.

Even if a disclosure requirement is limited to isolated genetic materials that are the subject of a patent claim, other uncertainties continue to exist. For instance, while an isolated gene sequence that is part of the claimed invention may invoke a disclosure requirement, does this requirement still apply if an applicant makes inventive modifications to the gene sequence? Does the requirement apply if the invention claims multiple mutations, or even a single mutation, that make the invention distinct from the isolated gene sequence? Does the requirement apply if the genetic resource leads to the discovery of naturally occurring splice variants of the gene?

In the Annex to this paper we set out a few further examples of the types of research activity that might easily be undertaken by companies in practice. The purpose of doing so is to enable consideration to be given to whether a disclosure requirement should apply as a matter of policy and how to draft a law with clarity as to when such a requirement should or should not apply.

It seems clear that, unless the requirement is to extend way beyond what can be derived from the CBD, it will not be possible to frame it so as to give adequate legal certainty.

Summary of advantages and disadvantages

22 See, for example, EC Concept Paper, page 13; COM(2003) 821, page 19; Norway Patent Law Article 8(b); Denmark Patents Decree, Chapter 2, Article 3, Section 4; proposed South African legislation
23 Joint Communication from African Group to TRIPS Council, IP/C/W/404, page 3.
24 Id., page 6.
25 98/44/EC, Recital 27.
26 PCT/R/WG/4/13, Para. 24.

Once political rhetoric is set aside and a careful analysis of the alleged advantages of a disclosure requirement is undertaken, it becomes clear that it will result in few, if any, practical advantages. It is equally clear that any such requirement is likely to result in significant disadvantages.

We note that few companies presently conduct research programs based on screening of samples of "genetic resources" collected by bioprospecting (i.e., samples of naturally occurring plants, microorganisms and non-human animals collected by the entity from a country that is asserting sovereignty over its genetic resources). For example, the focus of most pharmaceutically-oriented biotechnology companies is on discovery of the mechanisms of action of various human biological systems, and the design of agents and methods for treating disorders and disease linked to those mechanisms. Those investigations do not start with or depend in any way on use of a collected sample of a "genetic resource." Similarly, research in the agricultural biotechnology sector rarely is focused on collection and evaluation of samples of "genetic resources." Rather, it often is focused on use of sophisticated analytical tools (e.g., computer-based genomic analysis) using information generated by the company or obtained from the public domain. Alternatively, many agriculturally-focused companies use their own private collections of improved plant varieties and breeding lines that existed prior to the CBD, or were derived from those lines.

Some have argued that a properly framed requirement will increase the confidence of those who may engage in collection and development of resources. We believe this is simply factually wrong.

In fact, in our view, any proposal that is likely to satisfy the *demandeurs* in this debate is likely to be so broad and/or unclear as to radically reduce incentives to undertake research and development in this field. Any special disclosure requirements will seriously diminish, and most likely eliminate interest from the private sector in obtaining and developing "genetic resources" It will, therefore, reduce the prospects of successful innovation and sharing of the benefits of that innovation.

b. What are the advantages and disadvantages from your perspective of having some form of sanctions in cases where applicants fail to live up to such a requirement?

Sanctions for any breach of a law should be proportionate to the "wrong" caused by the breach. This can be measured in terms of either the damage done to the wronged party or the benefit which wrongfully accrues to the party in breach.

It is particularly important that sanctions should not be applicable if the scope of the requirements which may give rise to them are not clear. Clarity as to what acts or omissions will or will not give rise to sanctions is vital as a matter of natural justice.

However, to the extent that sanctions are deemed appropriate, they should aim at compensating for the loss actually caused by the wrong, not at punishing or deterring.

c. There are a number of different sanctions being discussed. What are your views with regard to the following types of sanctions?

i. Sanctions outside of patent law – for example in the form of fines or administrative fees,

Provided that these are proportionate to the wrong done, sanctions of this nature would be the least objectionable form. However, in order to ensure a compensatory element, provision should be made to ensure that any fines or fees are paid to the party or parties which would have been entitled to share in the benefits derived from the invention.

ii. Procedural sanctions – for example a patent application would not be handled until sufficient information has been provided (if the information provided turns out to be incorrect this would not, at a later stage, affect the patent as such),

Any sanction that delays grant of a patent or can affect its enforceability will deter research and development. Further, it will prevent benefits accruing to the patent owner

and thus prevent them being shared. In essence, such sanctions frustrate the objectives of the CBD.

iii. A combination of i. and ii. above,

Our comments on (ii) above make it clear that this is option cannot be viewed as appropriate.

iv. A situation where the failure to provide accurate information could affect the validity of a patent if incorrect information was provided with fraudulent intent.

While this approach attempts to clarify that validity of a patent will only be affected in the event of fraud, this option still has the undesirable aspects outlined in respect of (ii) above.

A finding of fraud is a finding that requires determination of the patentee's state of mind. It would involve examination of all those involved in the collection of and development of the material and the preparation and prosecution of the patent application. Such a finding would come only as a result of lengthy and costly judicial proceedings and the outocme of proceedings could vary from country to country.

Experience in the United States with the concepts of inequitable conduct and fraud on the Patent Office shows the vagaries and inherent difficulties of such a sanction.

Thus, even with the apparent limitations of such a sanction, the patent holder faces increased unpredictability and significant costs in defending the patent. As is the case more generally, no advantage would appear to arise from a disclosure requirement backed by such a sanction and a finding that the patent was invalid for fraud would do nothing to benefit the country of origin.

DRAFT - 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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