

Proposals for a Disclosure Requirement in Patent Applications

The Issue

Some members of the international community, including a number of developing countries, have expressed concern that the patent system promotes “biopiracy” (ie. the unauthorized use without compensation of biological resources by third parties) in contravention of the objectives of the Convention on Biological Diversity (CBD). Paragraph 19 of the WTO Doha Declaration of November 2001 therefore directed the TRIPS Council “*to examine the relationship between TRIPS Agreement and the Convention on Biological Diversity, protection of traditional knowledge, and folklore*”.

One of the main demands of those who believe there is a problem is the introduction of a patent-based “solution”, preferably in TRIPs itself, whereby patent applications would have to disclose the following new information: (i) the origin of genetic resources used in the invention; (ii) evidence of prior informed consent from the relevant national authority to access and use genetic resources; and (iii) evidence of fair and equitable sharing of the benefits derived from the genetic resource.

It is argued that such a disclosure requirement within the patent system would promote the CBD objectives (namely, the conservation of biological diversity and the fair and equitable sharing of the benefits from the use of genetic resources) and would help prevent biopiracy. This argument is deeply flawed. In fact, such a requirement, particularly if coupled with a significant sanction for breach (including patent invalidation) would not only fail to support the CBD objectives, it would actively undermine the pharmaceutical industry’s willingness to engage in R&D involving anything that may be regarded as being derived from genetic resources. This scenario would be bad for patients (as fewer new medicines would be forthcoming) and bad for developing countries (as there would be fewer benefits to be shared). This paper expands upon these dangers and proposes an alternative, non-patent based solution for ensuring that the CBD objectives are met.

GSK's Position

- GSK supports the CBD and its implementation in order to (1) ensure authorised access to genetic resources and (2) achieve equitable sharing of the benefits arising from the use of genetic resources.
- There is limited evidence of “biopiracy” or that it is somehow facilitated by the patent system. As such, there is no evidence that it would be reduced by new disclosure obligations in patent applications.
- The patent system was designed to promote innovation and to provide economic development incentives. It was not designed to regulate or enforce rules relating to conduct. It will not promote the CBD’s objectives or assist in monitoring compliance with local laws

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

- The difficulty of defining the precise scope of any disclosure obligation would create huge legal uncertainties for researchers and those who develop commercial products.
- These legal and commercial uncertainties would significantly reduce incentives to develop products which in any way involve “genetic resources”. This would lead to a reduction in innovation (and the societal benefits that arise from it). It would also frustrate the Access and Benefit sharing objectives of the CBD for if there is no research, then there will be no benefits to share.
- The CBD provides a clear mandate for Governments to establish access and benefit sharing provisions in their national laws for users and owners of genetic resources. GSK believes that once countries have adopted such local laws (based – if they choose – on the guidance on Access and Benefit Sharing (ABS) set out in the *Bonn Guidelines*), they will receive the protection and compensation envisaged under the CBD.
- To date, the practical implications of a disclosure requirement have not been fully addressed or appreciated. They are such that further discussion is best suited to the expert arenas of the CBD and WIPO (where these issues are already being discussed by experts) not the WTO.

BACKGROUND

The Convention on Biological Diversity

The Convention on Biological Diversity (CBD) agreed in 1992 sets out commitments for maintaining the world's ecological systems. It establishes three main goals: (1) the conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits from the use of genetic resources. All CBD discussions to date indicate that the Convention does not cover human genetic resources.

The CBD does not suggest or require that countries modify their patent laws in any way; it does not require, or even mention, patent disclosure requirements. The Convention does, however, have a mandate to elaborate and negotiate an international regime on access to genetic resources and benefit sharing (in support of objective 3 of the Convention).

To this end, the *Bonn Guidelines* (<http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp>) on genetic resources were adopted by signatories to the CBD in April 2002. The Guidelines advise governments on how to set fair and practical conditions for users of genetic resources, along with advice on the roles and responsibilities of the various parties. The users are expected to consider benefits such as sharing of profits, payment of royalties, scientific collaboration, or training. The Guidelines are voluntary but a number of countries have used them as guidance on how to implement national laws.

Further discussions relating to a possible international regime on benefit sharing, building on the Bonn Guidelines, were mandated by the CBD Conference of the Parties in Malaysia in February 2004 and are continuing.

The World Intellectual Property Organisation (WIPO) is also involved in considering disclosure obligations. Any discussion of the disclosure issue should occur in this expert forum, not the WTO.

The Alleged Objective of the Proposed Disclosure Requirement

Notwithstanding the agreement reached around the *Bonn Guidelines*, some stakeholders argue that the CBD's objectives would be more effectively promoted by requiring patent applications to disclose the origin of genetic resources used in the invention, evidence of prior informed consent to their use and evidence of fair and equitable sharing of the benefits accruing from the invention. They argue that these requirements – coupled with significant sanctions for non-compliance, including patent invalidation - would assist in monitoring performance of CBD objectives, particularly compliance with local laws implementing those objectives. In other words, these requirements would help prevent “biopiracy” by third parties (including the private sector).

The scale of the alleged “biopiracy” problem has not been identified or substantiated. The “Checklist of Issues” submitted to the TRIPs Council by Brazil and others in March 2004 appears to suggest that bio-piracy is widely accepted as being a major problem. However, there is no good evidence that it is a significant practical problem.

Arguments Against A Disclosure Requirement

1) It would not promote the CBD's objectives

- **It would not support prior informed consent provisions:** If the goal is to ensure authorised access based on prior informed consent, only local laws governing access to genetic resources, preferably coupled to contracts that clearly establish the rights and obligations of the entities involved prior to any access to genetic resources, can ensure this. A disclosure in a patent application would not.
- **It would not promote benefit sharing where no relevant patents exist:** A disclosure requirement would not address problems associated with any access and use of resources under the CBD which do **not** lead to patent applications. 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” that should theoretically be shared with the country of origin. However these uses would not be linked in any way to a patent application. A patent disclosure requirement would therefore do nothing in these cases to promote benefit sharing.

In such cases, benefits would realistically only flow to the relevant communities if a domestic access and benefit-sharing framework is first in place to facilitate a contractual arrangement that would lead to benefit-sharing on mutually agreed terms as is required by the CBD.

- **It is likely to reduce the benefits to be shared where relevant patents do exist:** Patents provide a means of rewarding innovation. Commercially significant sanctions for breach of a disclosure requirement, including invalidation of a patent, would reduce the commercial benefits which may flow from development of the genetic resource and that could otherwise be shared.

2) It would not help to monitor compliance with local laws.

The vast majority of undertakings, commercial or otherwise, take great pains to abide by local laws and perform their contractual undertakings. Providing a clear local legal framework controlling access to genetic resources and ABS agreements will, in the vast majority of cases, be the most effective and self-policing method of ensuring compliance with local laws and fulfillment of CBD objectives.

On the rare occasions where a company has deliberately failed to comply with its obligations relating to access and benefit sharing, it is hardly likely to incriminate itself by drawing attention to this fact by disclosing the use of genetic material in a patent application. The fact that local laws had not been complied with would be undetectable. This is particularly true where, as is usual in cases involving the use of genetic resources, the genetic resource which is used as a starting point for a development project undergoes substantial modification and variation before becoming the final product.

Furthermore, any economic benefits arising from use of the patent system may not occur for many years after access to the resource, assuming any economic return occurs at all. Even if the origin of a genetic material is disclosed in a patent application, it is most unlikely in fact that anyone will monitor the appearance of commercial products which might be associated with that patent application over a period of many years. Monitoring under these circumstances will be conducted under the auspices of the ABS agreement.

In short, disclosure requirements would not allow detection of **failure** to comply with local laws. And, even where local ABS laws do exist, they would not help to monitor compliance with local laws.

3) It would create legal uncertainty

Before committing resources to research, companies ask themselves whether they can clearly identify what their obligations relating to that research and its outcomes are. If the scope of an obligation is unclear in practice and the sanction for breach of the obligation is significant, companies will be reluctant to undertake research. To date, it is clear that many significant questions in relation to disclosure requirements, and the practical implications of the answers to those questions, have not been adequately addressed or understood. For example:

- **To what type of materials would the obligation apply?** It is clear from the Bonn Guidelines that human genetic resources are not covered by the Guidelines. However, only the recent proposal by the European Community and its Member States to WIPO specifies that the disclosure obligation is not to apply to human genetic resources. Further, it is not clear whether materials such as viral strains and bacteria extracted from humans (with which much medical research may be involved) are proposed to be covered by the disclosure requirement.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

- **What connection is needed between the genetic resource and the invention to give rise to the disclosure obligation?** Genetic resources, both human and non-human, are used throughout medical research. For example:
 - There are cases where a genetic resource might be the starting point from which the patented end product is ultimately derived. However, the end product will generally be a synthetic or isolated form of the genetic material or a significant variation or modification of the isolated or synthesised form. The end product disclosed in the patent may bear little relationship to the starting point. Should this be disclosed? How will a failure to disclose this link be unearthed?
 - More often, genetic resources are elements of preclinical research and screening programmes. They are, in effect, tools used in the process which leads to an end product, but are not part of the end product itself. Should the origin of such tools be disclosed?

Proposals to describe the link between the genetic resource and the invention in terms such as “directly based” or “make immediate use of” give insufficient practical guidance, far less an acceptable degree of certainty, to those involved in the innovation process.

- **Is the obligation to apply to all genetic resources, wherever and whenever they were obtained?** For example, is the disclosure obligation intended to apply to a product derived from a herb which is brought by the developer from a retail outlet in Chile? Similarly, is the obligation to apply to a product developed from a plant which was originally indigenous to India which is now freely available in and was obtained by the developer from a botanical garden or even a retail outlet in the EU or US? In these examples, does it make a difference whether the herb or plant used in the development process, or the herb or plant from which that plant or herb in question was descended, was taken from Chile or Peru before or after the CBD came into effect?

It is absolutely vital that all these questions are answered in a way clear enough to enable those engaged in the development of genetic resources to accurately assess, in practice, whether an obligation to disclose the origin of a genetic resource arises. If an international obligation to disclose is not framed with a great deal of practical clarity, it will be implemented and interpreted in national laws in different ways, creating further uncertainties for researchers. It could also lead to abuse of the patent system in an attempt to achieve national objectives which go far beyond any legitimate interpretation of the CBD.

4) It would adversely impact on innovation and thereby on any “benefits” to be shared.

A combination of uncertainty as to the scope of the disclosure obligation and significant commercial consequences of its breach would inevitably and significantly reduce R&D potentially involving “genetic resources”, innovation and the benefits that might accrue for sharing.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

As stated earlier, 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 in any research in the sense that it may not lead to a commercially viable product, legal risk that the fruits of successful investment can, in effect, be removed on grounds of failure to comply with legal requirements should be minimal. As the degree of legal certainty of a disclosure requirement decreases and its potential scope and the consequences of sanctions increase, the likelihood of companies like GSK investing in the development of genetic resources will decrease. As investment decreases, the likelihood of innovation, and of benefits accruing from innovation, is diminished. A disclosure obligation which leads to a reduction in innovation and benefit sharing would be of no benefit to society and would run contrary to the benefit sharing objectives of the CBD.

A Non-Patent Based Solution

The patent system was designed to promote innovation and to provide economic development incentives. It was not designed to regulate or enforce rules relating to conduct and it will not promote CBD objectives or assist in monitoring compliance with local laws.

Meanwhile the CBD itself acknowledges that effective enforcement regimes for access and benefit-sharing should be part of national laws and should be *specifically* designed to facilitate authorised access and benefit-sharing on mutually agreed terms. Such laws can include provisions that allow for the witting or unwitting breach of the agreed terms and that will secure, not undermine, the benefits to the source country. They could be facilitated and reinforced by industry Codes of Conduct.

Proponents of the new disclosure requirements acknowledge that they would not substitute for but would *supplement* and ensure the effective enforcement of national ABS regimes. However, a majority of CBD members have not yet implemented national ABS regimes. Under these circumstances, it is difficult to see how any disclosure requirement can be designed to supplement national legislation that is not in place in the majority of Members.

Establishing and analysing the efficiency of national access and benefit-sharing systems, along the lines suggested in the Bonn Guidelines, is essential *before* engaging in discussion of any supplementary measures that might be needed. This is particularly true given the potential harm to innovation and research that too premature or ill-considered a patent-based solution would represent.

October 2005