GSK Public policy positions

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" (i.e. the unauthorised 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" 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 access & benefit sharing (ABS), 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 lends GSK's support to national laws and the ABS compliance mechanism set out in the Nagoya Protocol of December 2010 as the most effective way of realising the CBD's ABS objectives.

GSK's Position

– GSK supports the CBD objective "to provide fair and 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.

– 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 uncertainties would 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 rise from it. It would also frustrate the ABS objectives of the CBD for if there is less research, there will be fewer benefits to share.

– The CBD provides a clear mandate for Governments to establish ABS 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 ABS guidance set out in the Nagoya Protocol, they will receive the protection and compensation envisaged under the CBD.

– To date, discussions within international institutions (including the WTO and WIPO) around the practical implications of a disclosure requirement have failed to reach any concrete conclusions and consensus - underscoring the complexity involved in introducing a disclosure obligation.

– It would arguably be best to give the Nagoya Protocol ratification and implementation process time to work rather than to rush to amend any international patent treaties on the basis of unproven benefits.

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.

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. It provides a framework - together with the Bonn Guidelines and Nagoya Protocol - which, Governments are encouraged to adopt in support of ABS.

The Bonn Guidelines

Adopted by the CBD in 2002, the Bonn 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.

A disclosure obligation is referenced in the Guidelines as a possible means of supporting compliance with prior informed consent; however, it is one of multiple compliance options tabled for consideration by provider countries. GSK does not believe it will help compliance.

The Nagoya Protocol

Notwithstanding the role of the Bonn Guidelines in supporting Government ABS efforts, further negotiations around the practical implementation of the CBD took place between 2004-2010. In October 2010, agreement was reached around the Nagoya Protocol on *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation.*

The Protocol reaffirms the importance of legal certainty, clarity and transparency in systems regulating access to genetic resources and the fair and equitable sharing of benefits from their use. Importantly, it does not mention a disclosure obligation as a possible compliance mechanism and it affirms the key principle in the CBD that the terms associated with access and benefit sharing should be mutually agreed by the provider and user of the genetic resources.

WIPO and a Disclosure Obligation

Discussions about a disclosure obligation have been ongoing within the expert arena of the World Intellectual Property Organisation (WIPO) since 2000. Numerous reports and technical studies have been prepared by various expert working groups. Few conclusions have yet been reached as negotiators continue to grapple with issues of scope, definition and enforcement. The length and inconclusive nature of these negotiations underscore the sheer complexity of the issues involved. And how the international community should not rush to introduce an obligation, the implications and scope of which are not yet fully understood or appreciated.

The Alleged Objective of the Proposed Disclosure Requirement

Despite the agreement reached around the *Bonn Guidelines* and *Nagoya Protocol,* some stakeholders continue to argue that the CBD's objectives would be more effectively promoted via the introduction of a disclosure obligation in TRIPs. They argue that a formal obligation – coupled with significant sanctions for non-compliance, including patent invalidation - would assist in ensuring and monitoring performance of CBD objectives, particularly compliance with local laws. In other words, these requirements would help prevent "biopiracy" by third parties (including the private sector).

The scale of the alleged "biopiracy" problem however has not been identified or substantiated.

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.

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.

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. This is likely to make effective third-party monitoring of the appearance of commercial products which might be associated with a particular patent application over a period of many years extremely challenging. Monitoring under these circumstances will most appropriately and feasibly be conducted under the auspices of an ABS Agreement.

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, as demonstrated by the ongoing discussions within WIPO, 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:

– 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 bought 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 India 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 therefore 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.

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 ABS should be part of national laws and should be *specifically* designed to facilitate authorised ABS 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.

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, many CBD members have not yet implemented national ABS regimes. Under these circumstances, it is difficult to see how any disclosure requirements can be designed to supplement national legislation that is not in place in the majority of Members.

Proponents of a disclosure obligation also argue that a disclosure obligation would address the lack of a formal mechanism to ensure *cross-border* compliance with national ABS laws. Article 15 of the *Nagoya Protocol* however proposes a mechanism of mutual recognition of domestic legislation as a means of addressing this issue. Specifically, Parties to the Protocol are required to take *"appropriate, effective and proportionate"* measures to ensure that any genetic resources used in their jurisdiction have been accessed elsewhere in accordance with Prior Informed Consent (PIC) and that ABS has been on mutually agreed terms.

Key to the success of this provision will be its interpretation and implementation. Mutual recognition by one Party of another Party's unreasonable ABS legislation (including penalties) will undermine the spirit and intention of Article 15. However, if the Parties to the Protocol succeed in adopting a measured approach to this provision, it could prove to be a viable, non-patent-based solution to the cross-border compliance issue.

February 2014