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Topic Brief 8

Genetic resources and traditional knowledge - the key IP issues

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Brief 8

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Background

Intellectual property law is largely a creature of the industrial West. Patents and trade secrets can protect new inventions; trade marks protect the reputations of traders and their goods; copyright protects the creative output of authors, artists and musicians (and their publishers). But not all valuable intellectual creations can be protected. One class of creation, which is (in general) not capable of such protection is the indigenous knowledge of traditional societies, frequently referred to as "traditional knowledge" ("TK").

Western science tends to be disdainful of such knowledge: as at best unsystematic and unproven, at worst mere superstition ("old wives' tales"). Nevertheless such knowledge has formed the basis of numerous advances that have been of value to the world as a whole. Many drugs are based on TK – starting with aspirin (originally a derivative of the willow tree): and more recently the new antimalarial, artemisinin, is based on a chemical derived from a traditional Chinese medicinal herb.

There is no general system for recognising the contribution of TK to modern developments, or rewarding the communities who have preserved and handed on such the knowledge on which they are based. Similarly, artistic works based on traditional folk-tunes, or stories, or traditional styles of ornamentation, are exploited without reward or even reference to the originating communities: and sometimes in ways which scandalise them (for example, misuse for commercial purposes of sacred emblems of Australian aborigines). This is seen as unjust, particularly where those communities are poor, and those who exploit the developments make substantial profits from them. The exploiters, however, see the knowledge they have used as part of "the public domain" (like a large proportion of published Western science and technology). For them, public knowledge that has not been specifically protected is (and should remain) free for all to use.

A special grievance for indigenous peoples is the patenting of indigenous knowledge. This is termed "bio-piracy", and a number of examples are notorious: patents which feature neem[74], turmeric[75], and Basmati rice[76]. The practice of patenting genes found in indigenous and other natural resources is also widespread. Indigenous people say that these patents are an unconscionable attempt to monopolise knowledge freely provided by them. The patents enrich the patentees at the expense of the indigenous people: who are at the same time deprived of the right to continue age-old practices.

74 e.g., European Patent no 405701
75 US Patent no 5,401,504
76 US Patent no 5,663,484

In reply, patentees defend the principles of patenting, even if the practice is sometimes deficient. The patents on neem and turmeric were both revoked after being challenged by the Indian government (after much time and expense). Neither patent claimed the indigenous material as such: rather, in both cases particular formulations or uses were claimed as new. These were eventually shown not to be new, and hence unpatentable. Similarly, the Basmati rice patent, upon challenge, was reduced to claiming three specific new varieties of rice of the Basmati type: but it never claimed traditional Basmati rice as such, only an allegedly new form of it. Patentees say that in principle public traditional knowledge is not patentable, because no patent can legally take out of the public domain what is already known. Whatever has been done traditionally cannot be impeded by a subsequent patent. Patents such as those cited arise only because searches carried out by Patent Offices are inherently fallible. They say, however, that inventive improvements to traditional knowledge are and must remain patentable, to encourage further development for the benefit of all (e.g. artemisinin could be crucially important in combating malaria, especially in poor countries).

How are these concerns being tackled?

Three international organisations are involved:

- The World Trade Organisation (WTO).
- The World Intellectual Property Organisation (WIPO).
- The Convention on Biological Diversity (CBD).

Each organisation has different priorities, emphases and approaches - the WTO deals with world trade, WIPO with intellectual property, and the CBD with genetic resources and the environment – but two lines are being followed in each organisation:

[A] general scheme for IP-like protection of genetic resources (GR) and indigenous or traditional knowledge (TK); and

[B] specific ‘disclosure of origin’ proposal to require patent applicants to disclose the origin of biological resources used in their inventions.

[A] general scheme

At WIPO, developing countries seek an international treaty to control access to and use of genetic resources and traditional knowledge. Their objectives are: to eliminate bio-piracy; to control use of GR and TK; and to obtain a fair return for its use. Developed countries see little need for a treaty, and are concerned about extending exclusive rights to cover subject-matter which (particularly in the case of TK) is very difficult to define, and may mean paying royalties on, or ceasing to use, materials and methods which are well-known (in the ‘public domain’).

Matters are complicated by the presence at the negotiations of numerous observer representatives of indigenous peoples, who also seek control over their TK, but not necessarily in order to recover royalties from its use: some reject the idea of an IP right on TK at large, as being inconsistent with their world-view. Also they have many disagreements with their own governments over ownership of their TK, human rights, access to tribal lands, etc.

[B] specific 'disclosure of origin' proposal

This is put forward for two reasons: to inhibit bio-piracy and to promote observance of the CBD. This international treaty (with over 190 country members, but so far excluding USA) has three objectives: to conserve biodiversity; to promote its sustainable use; and to share equitably the benefits of such use. Access to genetic resources is promoted, but to balance this, Benefits from such access are to be Shared (hence the acronym 'ABS').

To promote these objectives, Article 15 provides that each party will allow the others access to genetic resources, but only on Mutually Agreed Terms (MAT) with the Prior Informed Consent (PIC) of the party providing the resources. To support Article 15, it is proposed that any mention of genetic (or perhaps biological) resources in patent applications should require disclosure of the origin of the resource, and (in some versions) to provide evidence of PIC or MAT, or both. Similar requirements are suggested for TK (which is mentioned in Article 8j of the CBD). **THE BIODIVERSITY CONVENTION (CBD)**

It is here that most progress has been made to date. The Nagoya Protocol to the CBD was negotiated in Japan in October 2010: it came into force on 12 October 2014. It has so far (February 2016) been ratified by 71 parties. The European Union has passed a Regulation to implement it (see below).

The Nagoya Protocol develops and formalises ABS requirements. The objective is the 'fair and equitable sharing of the benefits arising from the utilization of genetic resources' (Article 1). 'Utilization' is however defined very specifically (Article 2) as "to conduct r**esearch and development** on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology" (emphasis added). Article 5 provides that "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources". However, this applies only where the provider country is "the country of origin of such resources" or "acquired the genetic resources in accordance with the [CBD]". The terms for the sharing are to be mutually agreed (MAT).

Access to GR is subject to PIC of the providing country (Article 6) "unless otherwise determined by that Party". Enforcement of the Protocol is provided for in Article 15 (by "appropriate, effective and proportionate legislative, administrative or policy measures" and Article 17 requires countries to provide 'checkpoints' with the power to

check that ‘utilizers’ of GR conform to the Protocol. These ‘checkpoints’ might be, for example, national authorities, who fund research or authorise marketing of products; academic journals; or intellectual property offices.

It is still not clear how well these provisions will work in practice. They are designed for what is seen as the typical case – ‘bio-prospecting’. In ‘bio-prospecting’ a researcher travels to a country where novel GR abounds, collects samples and takes them home for research. In such cases, it is reasonable, proper and straightforward for the researcher to respect the laws of the country he visits. If these require MAT and PIC, he must negotiate with the country’s authorities before taking any samples, and meet fully the requirements of local law. However, ‘bio-prospecting’ is the exception rather than the rule. Most ‘utilization’ of (i.e., research on) genetic resources is done on materials that are readily available in the researcher’s home country, and (typically) not clearly associated with any specific source country. In such cases, typically, fulfilling the requirements of the Nagoya Protocol is neither reasonable nor straightforward. Nevertheless, in every case the researcher is effectively required to prove (or at least give evidence of) a negative: that the material was not accessed in breach of the rights of a ‘provider country’. The ‘country of origin’ of a genetic resource is defined in the CBD (Art. 2) as the country in which the GR is growing in in situ conditions. Alternatively, for domesticated varieties, it is the surroundings where it developed its distinctive properties. This raises both theoretical and practical difficulties. How do you find out where a GR is growing in in situ conditions? Nagoya requires permission from – and ‘sharing of benefits’ with – the ‘country providing resources’ (unless it waives its right to control such access, as several developed countries – Including UK – have done). However, this only applies where the ‘country providing resources’ is:

a member of Nagoya and either

is a ‘country of origin’ of the resources or

has ‘acquired the genetic resources in accordance with the Convention’ (Nagoya Art. 5.1).Suppose you access the material in a Nagoya member, which is clearly not (according to the CBD definition) a ‘country of origin’? How do you tell if that member obtained the material ‘in accordance with the CBD’? Indeed, as a question of law, what counts as ‘access in accordance with the CBD’? Does it require that the person from whom you receive the material has to demonstrate PIC and MAT? Suppose he has acquired it from a country (such as the UK) that does not require PIC and MAT, as visualised in Nagoya Art. 6 – or is not a member of Nagoya at all? Until clear answers are available to these questions (and others) the effect of Nagoya must be to discourage the ‘utilization’ of GR rather than promote it.

EU regulation

The Nagoya Protocol came into force in October 2014. Currently (February 2016) it has 71 members. The EU has ratified it, and all its member states have also ratified or intend to do so. An EU Regulation giving effect to the Protocol has been passed. This requires researchers on genetic resources to demonstrate 'due diligence' in seeking any necessary access permissions from the 'provider country' of the resources they investigate, and that they have undertaken to share benefits appropriately with that country. A preferred way of doing this is by a certificate from the 'provider country' (if available). What will constitute 'due diligence' remains to be prescribed in detail[77] – it will probably differ according to circumstances (e.g. for academic or industrial research, and between various fields of study). Researchers are obliged to keep the details of their access available for 20 years after their research ceases. Declarations of 'due diligence', with details of any necessary permissions, must be made by researchers at two stages – when research grants are received, and when the results of the research are embodied in new products. Certain breaches of the Regulation become criminal offences.

The Regulation came into force at the same time as Nagoya in October 2014. It is not retrospective: research on GR acquired before October 2014 is not controlled. It will make future EU research on a wide range of genetic resources considerably more complicated, which will discourage such work. Whether there will be compensating effects in ensuring returns to 'countries of origin', leading to more effort to conserve genetic resources in those countries, remains to be seen. In late 2015 the EU Commission issued a consultation on draft 'guidance' on compliance with the Regulation. In February 2016 the consultation was still continuing.

An objective of the EU Regulation is to enforce the access laws of 'countries of origin'. However, EU law is not necessarily consistent with other access laws. The EU thinks of 'access' in terms of possession – physical access. Several 'countries of origin' think 'access' means the legal right to do research – and they say that mere possession of GR (whether before or after Nagoya came into force) does not give this right. This divergence of views increases the risks of doing research of this kind. It is also notable that the Regulation defines 'access' as 'acquisition of genetic resources … in a party to the Nagoya protocol' (Art.3.3). So (apparently) potentially onerous obligations imposed by the Regulation may be avoided by accessing genetic resources in non-parties to Nagoya (such as, for example, the USA).

WTO

Here the emphasis has been on the 'specific proposal' for disclosure of origin in patent specifications. As part of the Doha Round, Brazil and other biodiversity-rich countries have pressed this proposal. It has been resisted by several developed countries. The Doha Round is currently moribund, and so progress in this forum is stalled.

77 The Commission's draft advice says that if "a user takes reasonable measures in the seeking, keeping, transferring and analysing of information [relevant to source and origin, presumably] the user will be compliant with the EU ABS Regulation"

WIPO

Discussions on the protection of 'Genetic Resources, Traditional Knowledge and Folklore' ('GRTKF') have been taking place in Geneva (in an Intergovernmental Committee) since 2000. Progress has been limited and slow. The mandate of the Committee is to produce an international instrument that will 'effectively protect' GRTKF. But consensus between developed and developing countries is lacking. Developing countries want a binding agreement: developed countries think this is too difficult. Other major disagreements concern: term of protection (fixed or continuing indefinitely?); powers of right-owners (to forbid use? only to charge royalties? only to require attribution of authorship?) Another difficult topic is 'public domain'. Will right-owners have the power to control TK and GR already published, perhaps already in use? There are also conflicts between representatives of indigenous peoples and their national governments, which do not make discussions easier.

One particular source of friction is the 'specific proposal' for disclosure of origin of GR and TK in patent specifications. This was discussed in Nagoya, but not agreed there, on the basis that IP matters were better dealt with in WIPO. Here the views of participants split on slightly different lines. Developing countries generally support such disclosure; but not all developed countries are against it in any form. While USA, Japan and South Korea (for example) remain strongly against the idea, the EU could accept a modified version (provided sanctions did not include revocation of the patent). Some European countries (e.g., Norway and Switzerland) have already amended their laws to introduce disclosure requirements.

Proponents say that such disclosure requirements would discourage illegal access to genetic resources, and inhibit the grant of patents improperly claiming TK already known. Patent applicants say that genetic resources are widely distributed, and in large part legally accessible without formality. Only for 'bio-prospecting' ventures do the requirements make any sense. In other situations they are neither appropriate nor effective nor proportionate (thus clashing specifically with the requirements of Nagoya Art. 15). They would discourage use of genetic resources, and do little to promote sharing of benefits from such use. It does not appear that the revised laws of Switzerland and Norway have helped developing countries to any appreciable extent. To be effective, 'disclosure requirements' would require amendment of the Patent Cooperation Treaty. In Autumn 2014 WIPO was unable to agree a programme for these topics, so discussions were stalled here too. However, in Autumn 2015, a further two-year programme was agreed – though the first meeting in February 2016 on GRs made little progress.

Suggested further reading:

- General background to TRIPs and the CBD – World Trade Organisation (WTO)[78]
- TRIPs and the Biodiversity Convention – International Chamber of Commerce (ICC) paper[79]
- IP and genetic resources, traditional knowledge and folklore – WIPO resources[80]
- WTO discussion papers from the different parties to the controversy[81]
- Objections to 'disclosure of origin' in patents specifications – ICC Paper[82]
- Access and benefit sharing – EU Regulation 511/14 to implement Nagoya Protocol – May 2014[83*]

78 http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm
79 http://www.iccwbo.org/Advocacy-Codes-and-Rules/Document-centre/1999/TRIPS-and-the-Biodiversity-Convention--what-conflict-/
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