The Nagoya Protocol – what you should know

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In the chemical industries, a large number of our research materials are derived directly or indirectly from natural products or genetic resources. If you use either, you should know about the Nagoya Protocol. The Protocol is an extension agreement to the Convention on Biological Diversity (CBD) and its main aims are to facilitate access to genetic resources from each sovereign state, and to ensure the fair sharing of benefits arising from the research, development and commercialisation of those resources. The Protocol was initially adopted on 29 October 2010 in Nagoya, Japan and aims to provide a legal framework to regulate and legitimise the use of genetic resources and traditional knowledge,[1] particularly by third party countries or corporations. On 14 July 2014 Uruguay became the 50th state to ratify the Nagoya Protocol thus triggering the coming into force of the treaty itself some 90 days later. At present neither New Zealand nor Australia have ratified the Protocol.

Bioprospecting

The term bioprospecting is defined by the CBD Secretariat as "the exploration of biodiversity for commercially valuable genetic and biochemical resources".[2] Such resources are generally accepted to include chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature.

Bioprospecting (sometimes referred to as biodiscovery or biopiracy depending on your stance) is an age-old activity used to obtain new and improved products in industries including medicine, agriculture, cosmetics and materials science. It has the potential to increase economic prosperity and can encourage the conservation of habitats and biodiversity. Bioprospecting has led to many important medical innovations and the future use of genetic resources has potential to bring previously unknown or undeveloped medical treatments to the global population. One recent success story is the discovery of a new antibiotic – anthracimycin – said to be effective against anthrax and MRSA.[3] The compound is isolated from a marine actinomycete from the Pacific Ocean seabed off the coast of California.

The problem

When carried out in an unregulated fashion, bioprospecting can cause social resentment, especially where a community or country feels there has been an affront to their culture, rights or dignity. This often occurs where the bioprospector has not gained prior consent to access the resource from relevant stakeholders such as land-owners and indigenous/local communities. Environmental problems such as destruction of habitats and overexploitation of the genetic resource can also occur if bioprospecting is mismanaged or not effectively regulated.

The solution?

The Nagoya Protocol aims to establish accepted practices around bioprospecting and therefore reduce its negative consequences, especially by dominant states or corporations. To do this, states that have signed up to the Protocol will enact a set of legal principles that govern:

a) access to genetic resources;
b) sharing of benefits from the use of those resources; and
c) compliance with the principles agreed under the Protocol.

In practical terms, this means that if a researcher or collector wishes to remove genetic resources from the country of origin, or to make use of traditional knowledge they must (if the country requires) agree on the terms of access and how any benefits arising from the development of the resource are shared.

Access to genetic resources

A key tenet to the access principle is that the *user* of the genetic resource must obtain *prior informed consent* (PIC)[4] to access the resource from the *provider*. Informed consent means the *provider* is aware of who is accessing the resource, their general purpose, and the expected use of the resource. PIC may be granted via the state itself or, if the resource originates from an indigenous/local community, the *provider* state must first agree with the *provider* community terms under which access can be granted to *users*.

Benefit sharing

The second strand of the Nagoya Protocol is the establishment of measures to allow a share of the benefits arising from the *use* of genetic resources to be shared with the *provider*(s) of the genetic resources. Benefits may be monetary or non-monetary[5] and could include up-front payments, royalties or capacity building (e.g. innovation capacity, institutional development, education and training).

Compliance

Provider countries that have signed up to the Protocol will be expected to ensure that the genetic resources from within their jurisdiction have been accessed in accordance with prior informed consent and under mutually agreed terms. They should also have mechanisms to deal with disputes over access or ownership of the genetic resources and provide access to justice for relevant parties.

A bureaucratic burden?

The three principles of the Nagoya Protocol - access, benefit sharing and compliance - will be addressed in each signatory country by new or amended legislation, and/

or the formation of state administrative bodies. In some states, there is concern that the enactment of the Nagoya Protocol will lead to an excessive bureaucratic burden and restrict potential users of the genetic resources, possibly ultimately inhibiting rather than encouraging natural products research. A particular point of contention is that the definition of *use* of genetic resources includes not only research and development on the genetic or biochemical composition of genetic resources, but also their *subsequent applications and commercialisation*.

So what does this mean in practice? Well, the European Union (EU) has drafted legislation that requires any downstream users of a genetic resource to exercise *due diligence* to ascertain that genetic resources and associated traditional knowledge were accessed in accordance with legal requirements around access and benefit sharing from the provider state. This means that users would need to keep (for 20 years after their work has ended), and transfer to subsequent users, all information concerning when, where and how a resource was obtained, and details of the benefit sharing arrangements. It is likely that other states will follow the EU's general lead on this.

However, some researchers may view this as a serious bureaucratic burden that will be difficult to monitor. In addition, there is the issue of when such *due diligence* obligations are exhausted. As a case in point, Squibb's development of the drug captopril in the 1970s to treat hypertension and congestive heart failure ultimately resulted from research on snake venom isolated from the Brazilian arrowhead viper (*Bothrops jararaca*). However, the discovery process required many steps over a number of years. In summary, it involved fractionation and screening of the venom, identification of an angiotensin-converting enzyme (ACE) inhibitor candidate peptide, synthesis and trials to find an orally active analogue, compound efficacy optimisation by a number of chemical modifications, then animal and clinical trials.[6] There was no payment of royalties to the Brazilians who believed they were due.[7] Such a process is not unusual and begs the question of when a benefit sharing obligation should be present and when it is exhausted (especially if the provider knew nothing of the beneficial effect).

The lack of a signature on the dotted line from the USA will no doubt be a source of consternation for researchers from states bound by the Protocol as the strict obligations around access and benefit sharing will simply not apply to US-based institutions or corporates.

How do intellectual property (IP) and patents come into this?

There is a widely held misconception that patents can grant a monopoly covering genetic resources as they are found in nature (e.g. patenting genes in the human body, patenting native plants). This is incorrect; patent laws throughout the world exclude from patentability products as found in nature. Although there are some minor differences between countries exactly where the line is drawn, the general rule is that to constitute an invention, the resource must have been modified *by the hand of man*.

Despite this, there are some examples of patents inadvertently being granted covering products which already existed. For example in 1997 the United States Patent and Trademark Office (USPTO) granted a patent covering certain basmati rice lines and grains to a US company called RiceTec. The Indian government claimed that the patent covered existing lines of basmati that had been grown in India for centuries. They were outraged that a US corporation could engage in biopiracy and attempt to monopolise an age-old genetic resource. A USPTO review of the decision to grant led to RiceTec losing most of the coverage of the patent and restricted their monopoly to three rice strains developed by the company. In this case, it was initially difficult for the USPTO examiner to reject the application because prior knowledge regarding other types of rice that could have led to a finding of lack of novelty was not available in usual publications or was not published at all. Another issue was that at the time, the USPTO assessed novelty of inventions under the *relative novelty* threshold. This means that *prior use* is only regarded as novelty-destroying if that use occurred in the USA; use in India didn't compromise novelty. Such allegations of biopiracy have fuelled the fire against corporations and bioprospectors irrespective of whether they obtain prior informed consent and engage in access and benefit sharing partnerships or not.

Clearly the way to address concerns is to establish consistent and transparent guidelines and practices and that is exactly what Nagoya aims to do. However, it remains to be seen whether parties to the Protocol will meet their obligations under Nagoya.

Matauranga Māori (Māori Knowledge)

In New Zealand, the status of rights to genetic resources and traditional knowledge was the subject of a major Treaty of Waitangi claim – the Wai 262 *flora, fauna and cultural intellectual property* claim. The Ministry of Foreign Affairs and Trade (MFAT) has stated that New Zealand should not become Party to the Nagoya Protocol until domestic policy issues relating to the Wai 262 claim, and ambiguity regarding the application of the Protocol to certain sectors (e.g. agriculture), are resolved or clarified.[8]

The Wai 262 report by the Waitangi Tribunal was released in July 2011 and it recommended reforms to laws and policies affecting Māori genetic resources and traditional knowledge. In that report it was established that the Treaty of Waitangi allows the Crown to put in place laws and policies relating to research into and commercialisation of the genetic and biological resources in New Zealand. This includes IP laws, and laws controlling aspects of the research process such as bioprospecting and genetic modification. However, in return the Crown must protect the authority of the Māori people in relation to their taonga (treasure) species. The Tribunal also recommended that decisions about bioprospecting in areas under NZ Department of Conservation control be made jointly by the department and the affected communities.

Although the official government response to the Wai 262 claim has not yet been forthcoming, the new Patents Act 2013 does make some attempt to address Māori concerns

regarding patents. These concerns are centred on the prospect that patents are granted for inventions that rely on Māori traditional knowledge or involve indigenous flora/fauna. The 2013 Act requires that a Māori Advisory Committee is established to advise the Commissioner on whether a claimed invention is derived from Māori traditional knowledge or from indigenous plants or animals; and if so, whether the commercial exploitation of that invention is likely to be contrary to Māori values. The new Act does not go so far as to provide the Committee with the right to make a determinative decision on patentability, and the Committee is only involved if invited to be so by the Commissioner.

The recognition of Māori interests in the legislative process for patents is an important one. Although the Committee will not have any say on whether an invention is novel, inventive or patentable in other respects, it will certainly provide a means for Māori concerns to be addressed. For example if it is contended that a component of a Māori traditional medicine is the subject of a patent application, the Committee will be able to raise such concerns. This could lead to the examiner making investigations to determine whether the invention is novel over the use of the traditional medicine or not.

The proposals of Wai 262 appear to fit well with the principles set out in the Nagoya Protocol and if the government is to adopt more of the proposals, the legal framework and principles regarding engagement with indigenous/local communities set out in the Nagoya Protocol would make a good starting point.

To date there appears to have been few policy developments around biodiscovery/bioprospecting activities in New Zealand and there is no comprehensive policy framework. Despite this, there is no indication that New Zealand has an acute biopiracy problem that needs addressing. As with many political hot-potatoes, perhaps impetus for change will only come if a high profile bioprospecting matter goes before the court of public opinion.

Some tips for compliance with the Nagoya Protocol

Despite the lack of a domestic framework for access and benefit sharing, general property law and environmental legislation (Wildlife Act, Fisheries Act, Conservation Act, Resource Management Act etc.) must still be respected when considering access to resource sites and use of material from those sites. If a researcher intends to access genetic resources, to reduce the risk of a claim under such laws, we recommend obtaining written prior informed consent from the land owner and any other party who may have a claim such as local iwi or conservation authorities. In addition, if the resource is likely to be shared with overseas partners, it would be prudent to put systems in place to ensure your collection complies with Nagoya Protocol requirements.

Neither New Zealand nor Australia has ratified the Nagoya Protocol and therefore the governments have no obligation to put its principles into effect. In turn, New Zealand-based researchers collecting or using genetic resources or traditional knowledge have no obligation to determine, document or declare where they originate. However, the legal framework currently being built in Europe and other countries may affect New Zealand researchers if they receive or transfer material overseas, or develop products from genetic resources for overseas markets. In such cases, they may be required to provide assurances to other countries as to the source of any material, irrespective of whether New Zealand signs up to the Protocol.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact: tim.stirrup@baldwins.com or katherine.hebditch@baldwins.com, Patent Proze, Baldwins Intellectual Property, PO Box 5999, Wellesley Street, Auckland

References and notes

1. See *http://www.wipo.int/tk/en/tk/* accessed 30 September 2014
2. Bioprospecting is defined by the Convention on Biological Diversity (CBD) Secretariat (UNEP/CBD/COP/5/INF/7) as "the exploration of biodiversity for commercially valuable genetic and biochemical resources". Such resources are generally accepted to include chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature.
3. Jang, K. H. *et al.*, *Angew. Chem. Int. Ed.*, **2013**, *52*: 7822–7824
4. See Article 6 of the Protocol (http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf). Accessed 30 September 2014
5. See Annex of the Protocol (http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf) for more details. Accessed 30 September 2014.
6. Sneader W., *Drug Discovery. A History.* John Wiley & Sons Ltd. 2005 p280
7. See http://www.nytimes.com/2007/08/28/science/28biophtml?pagewanted=print&_r=0 Accessed 30 September 2014.
8. See http://www.mfat.govt.nz/Foreign-Relations/1-Global-Issues/Environment/7-Species-Conservation/geneticres.php Accessed 30 September 2014.

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