



Traditional knowledge: free to use or
deserving of protection?

14 November 2017

Linklaters



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7 December 2017

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Lykiardopoulos QC**

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Traditional knowledge: free to use or deserving of protection?

Trevor Cook (Wilmer Hale)

Chair

Professor Graham Dutfield

Professor of International Governance
School of Law, University of Leeds

Darren Smyth (EIP)

Partner, Patent and Design Attorney

Tim Roberts (Brookes IP)

Consultant

With thanks to **Linklaters** for hosting us.



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Professor Graham Dutfield

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Nagoya Protocol and Declarations of Origin

Prepared for
AIPPI

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Background - I

- 1992 - Convention on Biological Diversity signed at the Rio Earth Summit
- Only non-Parties of CBD are Andorra, Holy See, South Sudan ... and ... United States of America
- Article 1 – “The objectives of this Convention ... are ... the fair and equitable sharing of the benefits arising out of the utilization of genetic resources”
- Article 15 – “Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.”

Background - II

- 2010 - The Nagoya Protocol on “Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization” is signed
- Entered into force on 12 October 2014
- No provisions for Traditional Knowledge unless associated with genetic resources
- EU Regulation 511/2014 of 16 April 2014 sets out the rules on compliance for EU countries
- SI 2015 No 821 (The Nagoya Protocol (Compliance) Regulations 2015) sets out sanctions in UK

Nagoya Provisions

- Nagoya Protocol itself found on principles of:
 - Prior informed consent of Party (=country) before access to genetic resource is permitted (Article 6)
 - Fair and equitable sharing with Party of benefits arising from utilisation of genetic resources on mutually agreed terms (Article 5; examples of benefits in Annex)
 - Applies also to associated traditional knowledge (Article 7)
- These are not further elaborated in the Regulation; instead a “due diligence” obligation is created

Due diligence – Regulation Article 4

Users (=researchers) required to exercise “due diligence” to ascertain that genetic resources have been accessed in accordance with ABS/regulatory requirements; and keep for 20 years after end of utilisation “Internationally recognised certificate of compliance” [cf Protocol Art 6(3)(e)] or information/documents concerning:

- Date and place of access
- Description of genetic resource utilised
- Direct source of genetic resource and subsequent users
- Access and Benefit Sharing (ABS) agreements, access permits, mutually agreed terms including benefit-sharing, and any rights or obligations related to ABS

Declaration – Regulation Article 7

- Users (=researchers) required to declare “due diligence” exercised on receipt of research funding
- At final stage of development of product, compliance must also be declared AND the corresponding documents submitted to competent authority
- Proposal by Parliament to require similar declaration in patent applications was removed at Trilogue

Due diligence – Penalties

- Rules on penalties left to Member States of EU
- Penalties are required (Article 11) in relation to compliance with Articles 4 to 7 of Regulation and required to be “effective, proportionate and dissuasive”
- In UK sanctions for non-compliance with the due diligence obligations are mainly civil sanctions in Part 3 of the SI
- Part 6 sets out criminal sanctions - for failure to comply with a compliance notice or a stop notice or
- For failure to comply with Article 4(6) of the EU Regulation (obligation to keep information for 20 years after utilisation) – sanction is criminal but maximum penalty is £5000 fine

Declarations of Origin

- EU Parliament tried to introduce requirement for declaration of compliance into patent applications
- There is a patchwork of national laws relating to disclosure in patent applications, with very different requirements and sanctions

Europe

- Directive 98/44/EC – “Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”
- But some countries have gone further than this
- France requires mandatory disclosure to INPI, with criminal sanctions of fines and imprisonment

Switzerland

- The patent application must contain information on the source:
 - a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource;
 - b. of traditional knowledge of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this resource.
- Patent application shall be rejected if non-compliant

India

- Patent application must disclose the source and geographical origin of the biological material in the specification, when used in an invention.
- Patent may be opposed or revoked for non-compliance

Other countries

- WIPO lists requirements for:
- Andean Community, Belgium, Brazil, Burundi, China, Costa Rica, Cuba, Denmark, Djibouti, Ecuador, Egypt, Ethiopia, EU, France, Germany, India, Indonesia, Italy, Kyrgyzstan, Namibia, Norway, Panama, Peru, Philippines, Romania, Samoa, South Africa, Spain, Sweden, Switzerland, Uganda, Vanuatu, Vietnam
- http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf

TRADITIONAL KNOWLEDGE

THE RAZOR

“Entia non sunt multiplicanda praeter necessitatem”

(William of Occam, 1287-1347)



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innovation
since 1852

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DOES THAT APPLY TO NEW IP RIGHTS?

- Yes!
- “IP rights, once created, have proved almost impossible to abolish. In a period of rapid technological and industrial change, the standards of evidence required must be particularly high. A fundamental point relates to the **onus of proof**. Any new intellectual property right is likely to bring **costs**. Someone needs to pay.
- **It is therefore up to the proponents of new rights to show what these costs are, who will carry them, and that the costs are necessary and proportionate; and to provide verifiable evidence.”**

(EIPR, 2016, 38(10), 591-595)

Assuming the evidence is compelling..

- What might work?
- Something **not too ambitious**: e.g.:
 - **Limited** – in scope; term; protection?
 - **Notice** to third parties of what is protected
 - Exception for '**public domain**'
- **Independent adjudication** of infringement
- Any practicable right must **avoid clash** with developed world IP systems
 - Because unless there's **wide take-up**, there's no point
 - See ICC paper (tabled at GRTKF, IC31. September 2016)
<https://iccwbo.org/publication/icc-paper-on-protecting-traditional-knowledge/>



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THANK YOU!