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COMMENT



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The Nagoya Protocol was adopted on 29 October 2010 at the tenth meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD). 193 countries agreed on the Protocol after six years of challenging negotiations. These 'years of intense, complex and fractious talks ... frequently pitted developed countries against developing countries, and providers of genetic resources against users of those resources'.¹

The Protocol will enter into force 90 days after the 50th party has ratified the instrument. More than three years after its adoption, only 26 countries have done so. To date, just one high-income Northern country has acceded, namely Norway, the usual beacon of just policy making.

Nagoya's sister protocol, the Cartagena Protocol on Biosafety, did much better. It was adopted on 29 January 2000 and less than 2.5 years later had achieved 50 ratifications, so that it could enter into force on 11 September 2003. Obviously, there was a greater hurry to limit any danger from the movement of living modified organisms (LMOs) than there is to achieve benefit sharing for the providers of genetic resources.

In those countries' defence who have not yet acceded, the Protocol does include at least four highly ambitious sub-projects, which require due consideration prior to implementation.

First, the Global Multilateral Benefit-Sharing Mechanism (Art 10) and the encouragement of Transboundary Co-operation (Art 11) allow a range of ground-breaking ideas for access and benefit sharing to be voiced. In this special issue, both de Jonge and Kamau & Winter present such ideas. Kamau & Winter (p. 106) want to enable common pools of genetic resources with benefit sharing linked directly to the *use* of genetic resources. This approach would avoid the high transaction costs and

bureaucratic hurdles of bilateral agreements. In a similar move, de Jonge (p. 241) wants to shift the main burden of responsibility for benefit sharing to the user countries; partly for reasons of fairness (he refers to Henry Shue who argues that those who have the most resources should contribute the most to any common endeavours) and partly for reasons of feasibility. How, he rightly asks, can the countries of origin control the international movement of non-rival and non-excludable resources? Both suggestions might also resolve long-standing disagreements over resources available in Northern user country collections.

Second, the Nagoya Protocol links benefit sharing discussions of *all* genetic resources by referring to human genetic resources, namely human pathogens, in the introduction.

Mindful of the International Health Regulations (2005) of the World Health Organization (WHO) and the importance of ensuring access to human pathogens for public health preparedness and response purposes.

When the Convention on Biological Diversity was first adopted in 1992, it was meant to cover genetic resources of human *and* non-human origin. Only in 1995 were human genetic resources excluded from its remit. This is proving increasingly complex, as the Indonesian government's refusal to provide human pathogens (avian flu samples) to the World Health Organization in 2007 showed. In refusing to share samples, Indonesia argued as follows:

Disease affected countries, which are usually developing countries, provide information and share biological specimens/virus with the WHO system; then pharmaceutical industries of developed countries obtain free access to this information and specimens, produce and patent the products (diagnostics, vaccines, therapeutics or other technologies), and sell them back to the developing countries at unaffordable prices. Although it is general knowledge that this practice has been going on for a long time for other major communicable diseases – not just for avian

1 Pamela Andanda et al., 'Legal Frameworks for Benefit Sharing: From Biodiversity to Human Genomics', in Doris Schroeder and Julie Cook Lucas eds, *Benefit Sharing – From Biodiversity to Human Genetics* 33, 42 (Berlin: Springer, 2013).

influenza – the fear of potential pandemic influenza has magnified this gap.²

This stance is reminiscent of pre-CBD debates about the exploitation of developing countries. Meanwhile, in 2011, the World Health Assembly adopted the 'Pandemic Influenza Preparedness Framework for the Sharing of Influenza Virus and Access to Vaccines and Other Benefits', which confirms national sovereignty over biological resources, human *and* non-human. As such, the Nagoya Protocol has taken a cautious step towards a more holistic approach to governing access to and use of genetic resources by making reference to human pathogens. At the same time, this more holistic approach favoured by many³ would open doors to more commercially minded accessing of human DNA and pathogens. Such access was previously firmly hidden behind the veil of altruistic donation, the dominant sharing mechanism in human medical research.

Third, and going into a similar direction, the Protocol has strengthened global justice concerns in Art 8. Not only does the article want 'to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries', as one would expect from a CBD-related Protocol. In addition, the article makes reference to emergency situations and 'access to affordable treatments by those in need, especially in developing countries', as well as food security. One could almost venture that these provisions import a Rawlsian Difference Principle into the Protocol, a demand argued for by Kleba in this special issue of LEAD Journal (p. 221).

Fourth, Art 12 requires that Parties 'shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional

knowledge associated with genetic resources'. As Vermeylen (p. 185) and Tobin (p. 142) show in two separate articles in this special issue, customary law and formal law are not easily wedded, despite the Protocol's forward looking insistence on recognising customary law. An example given by Vermeylen is the rich oral traditions of customary law, where formal law might talk of hearsay and customary law of valid testimonies.

Whilst the ratification of the Nagoya Protocol is proceeding slowly, it is encouraging to read in Chennells' paper in this special issue of LEAD Journal (p. 163) that the San community in Southern Africa are continuing to be at the forefront of concrete, viable benefit sharing agreements.⁴ One could venture that the Sceletium benefit sharing agreement might tick all the boxes for a good practice agreement: early acknowledgement of the traditional knowledge holders by the researchers, close collaboration between researchers and traditional knowledge holders in the development of a product, prior informed consent, generous negotiations between different knowledge holders (San and Nama), and finally a marketed product with international buyers leading to regular royalty payments into a trust fund. Bilateral agreements can work, as this example shows, but I agree with de Jonge and Kamau & Winter that justice for the providers of genetic resources, including related traditional knowledge, might be easier to achieve in multilateral agreements based on resource *use*.

2 E.R. Sedyaningsih et al., 'Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia' 37/6 *Annals of the Academy of Medicine* 482, 486 (2008).

3 Sachin Chaturvedi et al., 'Harmonizing Policy on Human Genetic Resources and Benefit Sharing' 30 *Nature Biotechnology* 1169 (2012).

4 Rachel Wynberg, Doris Schroeder and Roger Chennells eds, *Indigenous Peoples, Consent and Benefit Sharing – Learning Lessons from the San-Hoodia Case* (Berlin: Springer, 2009).

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