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TRANSBOUNDARY RESOURCES, CONSENT AND CUSTOMARY LAW

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This Special Issue comprises an outstanding and comprehensive collection of articles concerning the Nagoya Protocol. Without exception they are highly insightful contributions to the debate on the meaning of the Protocol and its implementation. All I can add are a few brief reflections.

In many ways Nagoya represents a considerable advance. The references to prior informed consent, customary laws and community protocols and procedures are undeniably encouraging. Of course, the feel-good language is qualified by the usual strategic vagueness, frustrating those of us seeking unequivocal, firm and legally binding obligations on states and businesses. But this is as good as it was ever likely to get. It does not help to be overly cynical or pessimistic.

There are two major lacunae which the Protocol does at least acknowledge even if it offers no solution for the time being. I would like to take most of the space permitted for my contribution to discuss these at some length. Article 10 ('Global multilateral benefit-sharing mechanism') requires parties to:

> consider the need for and modalities of a global multilateral benefit sharing mechanism to address the fair and equitable sharing of benefits derived from the utilisation of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.

Two questions arise. First, how much of the existing stock of genetic resources and traditional knowledge associated with them *does* occur in transboundary situations? Second, under what circumstances might their use occur without the grant or acquisition of prior informed consent being possible?

Whilst it is difficult to say what proportion of genetic resources and traditional knowledge (TK) is cross-boundary, the overall extent of transboundaryness is likely to be very high. Political boundaries are artificial and many ethnic groups' territories straddle borders. The chances are that this situation is frequently going to complicate negotiations between users and providers and thereby increase transaction costs to a potentially prohibitive scale. Another potential negative outcome is that the existence of other countries with overlapping resources and knowledge endowments will undermine providers' bargaining power. Article 10 acknowledges that the Protocol cannot yet resolve this, at least until a *workable* multilateral mechanism is in place to deal with this specific issue *assuming that such a mechanism is politically or practically attainable* (emphasis added).

Consider the example of Hoodia described in Chennells' article. It is not clear or certain, at least to me, that Hoodia is known about or used by all San communities in the six countries they inhabit. Furthermore, evidence suggests that other non-San peoples have also used Hoodia. Despite Hoodia's highly scattered distribution, and without helpful legislation in any of these countries, and with the above uncertainties, workable benefit sharing schemes *were* put into place involving various state and non-state organisations including pharmaceutical businesses.[1]

In the late 1990s, patents were filed in numerous countries on the active compounds of Hoodia and several were subsequently granted. Several firms became involved in efforts to develop Hoodia-based pharmaceuticals, natural health products, and food supplements. Despite this, and after many years of scientific investigation and deal-making, Hoodia still has *no proven pharmaceutical value.* Some clinical studies were encouraging,[2] whereas one produced rather disappointing results on both efficacy and safety grounds.[3] So there is both commercial potential and risk. Unfortunately, Phytopharm, Pfizer and Unilever for a number of different reasons

1 For definitive literature presenting and analysing the San-hoodia agreements including by those involved in negotiating them, *see* Rachel Wynberg, Doris Schroeder and Roger Chennells eds, *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case* (Dordrecht: Springer, 2009).

2 V.J. Maharaj, 'Summary Reports for Key Hoodia Clinical Studies' (Council for Scientific and Industrial Research, 2011), available at http://researchspace.csir.co.za/dspace/handle/10204/5375.

3 Wendy A.M. Blom et.al., 'Effects of 15-d Repeated Consumption of *Hoodia gordonii* Purified Extract on Safety, ad Libitum Energy Intake, and Body Weight in Healthy, Overweight Women: A Randomized Controlled Trial' 94/5 *American Journal of Clinical Nutrition* 1171 (2011).

withdrew from the Hoodia scene. It is now highly unlikely that Hoodia will be the long hoped-for first African blockbuster drug. There may be sufficient benefits to help improve the lives of some San people, and this can only be seen as a good thing; but one must doubt that they will ever be substantial.

Hoodia provides a few lessons, both positive and negative. On the one hand, it shows that implementing formal benefit sharing arrangements concerning transboundary resources and knowledge can be done with neither the multilateral mechanism envisaged in Article 10 of the Nagoya Protocol, nor even a national TK protection law. The fact that the people, knowledge and resources were in more than one country certainly added complications including additional transaction costs. But the concern about bargaining power mentioned above seems irrelevant here. In this case, Hoodia was known about and patented before commercial partners were sought and the benefit sharing negotiations were initiated. The patents were all held by one entity, the South African government's Council for Scientific and Industrial Research (CSIR). Those seeking to use the active ingredients of the plant for commercial ends had little choice but to approach CSIR first.

This does not make the diminished bargaining position issue irrelevant though. What about the situation where a foreign company wishes to visit a country with access and benefit sharing regulations in place in order to search for genetic resources and TK with limited published information in patent documents or scientific publications to go on? If the country's neighbours are similarly biologically and culturally diverse but have no access and benefit sharing regulations or ones that are less strict, the likelihood arises that driving a hard bargain will encourage the company to try those other nations.

In Article 11, the Nagoya Protocol itself urges cooperation rather than competition where the same genetic resources and TK straddle national boundaries. Where blocs of neighbouring countries adopt common access and benefit sharing regulations, as does the Andean Community,[4] this appears to be a workable approach. However, in most cases individual countries will have their own rules. Accordingly, opportunities to cooperate meaningfully are in most cases rather limited. For countries that welcome users on the basis of mutually agreed terms of access and benefit sharing, competitiveness is bound to creep in. Like the rest of us, companies respond to carrots as well as sticks. In the market economy, frequently, multiple suppliers exist for identical but similar goods yet some are better at attracting customers than others despite starting off with similar endowments. Companies do not want to waste time and money rummaging around blindly. They want direction. If there are lots of capable and easily contactable people and institutions in one country, such as taxonomists and other plant scientists, knowledgeable indigenous peoples and good universities, who can direct them to what might be valuable, but fewer of them in another, that might influence their choice where to go even if such useful partners insist that rigorous access and benefit sharing rules be properly observed. In such situations, companies prefer legal and regulatory certainty. Scientific capacity building is key here. This is so whether we are talking of university-trained scientists or indigenous people with sophisticated knowledge about local resources and ecosystems. South African scientists had the expertise, equipment and financial resources to identify the active Hoodia compounds and file patent applications.

There is another rather vital lesson from the Hoodia case study: being able to turn something promising enough to attract serious business interest into a successful commercial product of the kind that can generate substantial benefits is probably a very rare feat indeed. Most benefits will be modest and the more ways the share has to be divided among knowledge holders and resource owners, the less that any interested party will end up getting.

Turning to the second question, that of what circumstances would make granting or obtaining prior informed consent impossible, one influential legal guide to the Protocol has this to say:

> ... it would not be possible to obtain PIC for the utilisation of genetic resources obtained from a country that has decided not to

4 This is by virtue of Andean Community Decision 391: Common system on access to genetic resources.

> establish access requirements. Another possible instance would be in cases in which there is utilisation of genetic resources from *ex-situ* collections with no information on country or countries of origin. Although *ex-situ* collections, such as gene banks and other repositories of biological or genetic material, increasingly maintain information about where and when a sample was collected, such information does not always allow identification of the country of origin of the genetic material utilised or the pertinent PIC to be obtained. In these circumstances, a global multilateral benefit-sharing mechanism would nevertheless allow discharge of benefit-sharing requirements.[5]

The authors also observe that:

> An international instrument does not apply retroactively – that is, it cannot be binding to acts that took place before or situations that ceased to exist prior to its entry into force. Nevertheless, new benefits arising from prior or ongoing uses could be considered as new situations for benefit-sharing requirements – though access requirements would not apply retroactively. A global multilateral benefit-sharing mechanism could potentially cover these cases.[6]

What are we to make of this? First, genetic resources and TK that are in general circulation may no longer have traceable origins or else have known origins that may go back a long time, possibly centuries. The sources of the genetic resources and the knowledge may be completely different. A good example is the rosy periwinkle (*Catharanthus roseus*), the source of the valuable anti-cancer vinca alkaloids, Vincristine and Vinblastine, which entered the market in the 1960s and have generated very large revenues for Eli Lilly over the decades. The plant originally comes from Madagascar but now grows throughout the tropics and has grown in the Caribbean long enough to be considered as a native plant there. It is many years since the company relied on Madagascar for supplies of the plant, and most now come from plantations in Texas. The Eli Lilly researchers who discovered and patented[7] Vincristine and its anti-cancer properties decided to study the plant when a literature search uncovered its use by rural populations in the Philippines. Those at the University of Western Ontario who discovered and patented[8] Vinblastine received plant samples from Jamaica that were considered worth testing, again, because people used the plant for therapeutic purposes there. In both countries the plant was used by rural communities not to treat cancer but diabetes.[9] Neither of the research teams made any secret in their publications of the fact that they were inspired by TK. On the other hand, only the University of Western Ontario team was relying upon both overseas sources of plant material and unpublished ethnobotanical information when it began research on the periwinkle.

The rosy periwinkle case exemplifies the fact that portraying pharmaceutical development as a linear process taking place over a relatively short period is grossly inaccurate with many if not most drugs.[10] It also suggests that in many cases a prior informed consent requirement is not practicable or applicable. Madagascar has no compelling legal (or moral) claims to a share of the billions of dollars generated since these drugs came onto the market half a century ago and at no point did a bioprospecting trip to that country ever need to be undertaken. The

5 T. Greiber et.al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit* 129 (Gland: IUCN, 2012)

6 Ibid.

7 *See* US Patent No. 3,205,220 (issued September 7, 1965) ('Leursidine and Leurocristine and their production').

8 *See* US Patent No. 3,097,137 (issued July 9, 1963) ('Vincaleukoblastine'). The patent was assigned by the inventors, Beer, Cutts and Noble, to Canadian Patents and Development Ltd., who made a deal with Eli Lilly allowing the latter company to commercially exploit the invention.

9 As expressed by three medical researchers at the University of Western Ontario, 'the disease of cancer was certainly far from our thoughts when we learned of a tea made from the leaves of a West Indian shrub that was supposedly useful in the control of diabetes mellitus'. *See* R.L. Noble, C.T. Beer and J.H. Cutts, 'Role of Chance Observation in Chemotherapy: Vinca Rosea' 76 *Annals of the New York Academy of Sciences* 882 (1958).

10 Graham Dutfield, 'Why Traditional Knowledge is Important in Drug Discovery' 2/9 *Future Medicinal Chemistry* 1405 (2010).

information on use of the rosy periwinkle was already in the public domain, and while this should not in itself make benefit sharing inapplicable, it would require a very strict legal regime of broad geographical scope for prior informed consent to be mandatory in such circumstances. There was no necessity at any point for the scientists to have visited the Philippines once the proverbial cat was out of the bag and the plant grew in various other countries anyway. It was only with Vinblastine that ethnobiological information and plant samples were directly acquired from local people. But this was more than 50 years ago.

I would like to close with a point about customary law. In my view we have been far too reductionist, which is to say that we have focused on a part when we should have been looking at the whole. What use is ecological knowledge without land rights? How can traditional medicinal knowledge stay in use if the lands where the plants grew have been ploughed over? Why do decisions affecting the indigenous peoples continue to be made by urban educated elites, well-meaning as they so often are? We need to provide, actually to cede, political space to allow the indigenous peoples themselves to establish the rules of engagement. The 2007 United Nations Declaration on the Rights of Indigenous Peoples affirms territorial rights and self-determination and these need to be essential aspects of strategies, activities, laws and regulations. As Darrell Posey used to say: 'rights first, access later'.[11] He did not mean rights in TK per se, but the full range of rights – what he called 'Traditional Resource Rights' covering every issue affecting their daily lives and long term futures for which quite separate legal norms may already be available.[12]

Legally and conceptually speaking, there needs to be a shift from imposing *our* legal 'solutions' to accepting *theirs:* their own customary practices, norms and laws. Upon reading Vermeylen's and Tobin's articles, it is impossible to conclude otherwise. It is now time to turn this conceptual reorientation into practical and effective responses to the manifold threats to the indigenous people's own intensely knowledge- and genetic resource-based economies.

11 Various pers. comms, 1993-1996.

12 D.A. Posey et.al., *Traditional Resource Rights: International Instruments for Protection and Compensation for Indigenous Peoples and Local Communities* (Gland: IUCN, 1996).

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