RECIEL 12 (3) 2003. ISSN 0962 8797

WSSD and an International Regime on Access and Benefit Sharing: Is a Protocol the Appropriate Legal Instrument?

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On 19 April 2002, at the Sixth Session of the Conference of the Parties to the Convention on Biological Diversity (COP-6), parties adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.[1] Less than a year later in September 2002, a newly formed coalition of 15 of the most biologically diverse countries in the world tabled a successful proposal at the World Summit on Sustainable Development (WSSD), which called for a process towards an international regime on access and benefit sharing (ABS).[2] The coalition was formed, in part, out of frustration over the Convention on Biological Diversity's (CBD)[3] languorous speed on issues they believed were important to those nations' development, and, in part, out of the need to protect and be rightly compensated for use of their natural genetic resources. The coalition argued that a legally binding international regime should, in fact, depart where the Bonn Guidelines left off and work towards a full protocol to the CBD.[4]

In many ways, the proposal for a protocol on ABS is surprising so soon after the conclusion of 2 years of direct negotiations on the Bonn Guidelines. The possibility of a protocol was considered at CBD COP-4, where it was decided to set up an expert group on ABS and discuss 'all the options' for access and benefit-sharing arrangements.[5] It was then further discussed at two meetings of the CBD's Panel of Experts on ABS, the CBD's Scientific Body on Technology and Technological Advice (SBTTA), and in the final deliberations at COP-6 where the Bonn Guidelines were formally adopted.[6] In these discussions, most countries agreed that ABS is an issue more contingent on national regulation than on international regulation. Thus, where an internationally harmonized regime could not accommodate the diversity of national approaches, countries agreed that a set of guidelines, which set forth broad principles, was the preferred choice of legal instrument.

These events raise many questions. Are the like-minded, mega-diverse countries pushing an unwanted agenda on the international community?[7] Or, was the idea of a potential protocol avoided during the Bonn Guidelines negotiations to avoid unnecessary controversy and protracted negotiations? Is the international community now ready to reopen the discussions? If so, is the most appropriate legal instrument a binding protocol?[8]

[1] The Bonn Guidelines (hereinafter Bonn Guidelines or Guidelines) to the Convention on Biological Diversity (CBD), Conference of the Parties (COP), Decision VI/24 (2002), Annex.

[2] World Summit on Sustainable Development, Plan of Implementation states that parties should 'Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources'. See Johannesburg Plan of Implementation (hereinafter JPOI), *Report of the World Summit on Sustainable Development* (A/CONF.199/20, 4 September 2002), Resolution 2, Annex, para. 44(o).

[3] Convention on Biological Diversity (Rio de Janeiro, 5 June 1992).

[4] Presentation by the Secretariat of the Group of Like-Minded Mega-Diverse Countries at the *Critical Role of Biodiversity & Ecosystem Services in Achieving the UN Millennium Development Goals* (London, 2–4 March 2003), available at <http://www.undp.org/equatorinitiative/secondary/biodiversity_agenda.htm>. Also, for more information on the like-minded mega-diverse countries, see the Cancun Declaration of Like-Minded Megadiverse Countries (Cancun, 18 February 2002), available at <http://www.megadiverse.org/armado_ingles/PDF/three/three1.pdf>.

[5] See CBD Decision IV/8 (1998).

[6] The Expert Panel on ABS (hereinafter the expert panel) met in San Jose Costa Rica (4–8 October 1999). It was then decided at COP-5 under CBD Decision V/267A (2000) to reconvene the expert panel with additional government nominees and a more focused mandate. The panel then met again in Montreal, 19–22 March 2001. The report from the expert meetings was forwarded to SBSTTA, which met in Bonn and agreed on draft guidelines to be put forward to COP-6 in The Hague in 2002.

[7] The like-minded mega-diverse countries are 15 of the most biologically endowed and diverse developing countries of the world that formed a coalition by signing the Cancun Declaration on 18 February 2002 'as a mechanism for consultation and cooperation to promote [the group's] interests and priorities related to the preservation and sustainable use of biological diversity'. The signatory countries are Bolivia, Brazil, China, Costa Rica, Colombia, Ecuador, India, Indonesia, Kenya, Mexico, Malaysia, Peru, Philippines, South Africa and Venezuela. See Cancun Declaration, n. 4 above.

[8] At the Open-Ended Intersessional Meeting on the Multi-Year Programme of the Work of the Conference of the Parties (MYPOW) up to 2010, the parties to the CBD 'recommend[ed] that the Ad

This article examines the implications of these controversial questions by looking at the main provisions that are most likely to be dealt with under a potential international regime. To address these questions, the article will first introduce the Bonn Guidelines that the Johannesburg Plan of Implementation (JPOI) requests should be taken into consideration when negotiating an international regime on ABS.[9] Then, it will turn to the Bonn Guidelines' substantive provisions on benefit sharing, intellectual property, prior informed consent and material transfer agreements, the potential impact of a protocol on these issues, and, conversely, how these issues may affect the choice of legal instrument. The article analyses the advice given to the SBTTA by the expert panels on its justifications for a guideline, and considers the role of soft law and whether the necessary environment exists for a harder legal approach to ABS.

OVERVIEW OF THE BONN GUIDELINES

The Bonn Guidelines are a non-binding framework that was not intended to replace national legislation, but to enhance it, or provide guidance for its development. The Guidelines are a voluntary agreement that has been put in place to facilitate the access to genetic resources and to ensure that the benefits of any commercialization, or research and development derived from those resources are rightfully shared with their owners. It is based on a bilateral approach. In other words, it proposes a system between the parties that will use the genetic resources and those that will provide them. The Guidelines stipulate, however, that the use of the genetic resources by any third parties must be based on a new application with the provider.[10]

Although the Bonn Guidelines are intended to be simple in their structure (as stated in paragraph 7(b)) they are, in fact, quite elaborate. There are two main reasons for the level of detail. First, because the Guidelines are not binding, governments were more inclined to accept detailed elaborations. In a legally binding setting, governments would normally try to avoid this as it often leaves open the chance for loopholes and wider interpretations. During the negotiations of the Guidelines, however, governments were more accommodating to a wider spectrum of views. In essence, since the agreement was only meant as a guide, there was less incentive to refine the document. In some ways the Bonn Guidelines resemble a wish list for every country's interests, so it is unsurprising that the parties agreed upon its provisions relatively quickly.[11]

The Bonn Guidelines are meant to be evolutionary and not the final word on their respective goals.[12] One might look upon the Bonn Guidelines as similar to the 1983 International Undertaking that was recently negotiated into the International Treaty on Plant and Genetic Resources for Agriculture adopted in 2001.[13] Like the Undertaking, the Guidelines could represent the beginning of a process, which perhaps may, eventually, grow into a fully fledged treaty. The Guidelines do not state this intent expressly, although the option was considered and pushed by countries, including the Philippines and Ethiopia, at COP-6.[14]

As evidence of its evolutionary nature, the Bonn Guidelines have their fair share of areas that are still not agreed upon. The use of terms, the substantive issues surrounding derivatives from genetic resources, and measures for realizing compliance with the Bonn Guidelines' prior informed consent provisions were sources of disagreement at COP-6. They will have to await consensus in the coming years. To negotiate the outstanding issues, the CBD created an ad hoc open-ended working group that will work to make recommendations on these areas to COP-7 in 2004.

Perhaps one of the most practical steps the Bonn Guidelines provide is a framework for creating focal points and competent authorities. ABS focal points are to be established, and will be responsible for providing information on procedures for gaining prior informed consent and mutually agreed terms, and identification of the relevant stakeholders and competent national authorities through the CBD clearing-house mechanism.[15] National authorities will also advise on the negotiating process, requirements for prior informed consent, national ABS arrangements and mechanisms for effective participation of stakeholders in the ABS process.

Hoc Open-Ended Working Group on Access and Benefit-Sharing should, in its consideration of other approaches, in accordance with its mandate as specified in decision VI/24 A, consider the process, nature, scope, elements and modalities of an international regime and provide advice to the Conference of the Parties at its seventh meeting on how it may wish to address this issue'. See *Report of Open-Ended Intersessional Meeting on the Multi-Year Programme of the Work of the Conference of the Parties up to 2010* (UNEP/CBD/COP/7/5, 25 March 2003), Annex 5 (International Regime on ABS), para. 4.

[9] See JPOI, at para. 44(o).

[10] Bonn Guidelines, paras 34 and 16(b)(viii).

[11] W.B. Chambers, 'Emerging International Rules on Commercialization of Genetic Resources: The FAO International Plant Genetic Treaty and the CBD Bonn Guidelines', 6:2 *The Journal of World Intellectual Property* (2003), 311, at 314–315.

[12] See CBD Decision VI/24 (2002), Part A, para. 6.

[13] See Resolution 8/83, Twenty-Second Session of the Food and Agriculture Organization (FAO) Conference (Rome, 23 November 1983) and International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, 3 November 2001).

[14] See 'CBD COP 6 Highlights', 9:231 *Earth Negotiations Bulletin* (9 April 2002), at 2.

[15] Bonn Guidelines, para. 13.

Biotechnology companies and intermediaries have long complained of the bureaucratic red tape and lack of organization at the national level for granting access to genetic materials. They claim that this has been a major barrier for foreign investment in genetic resources and has increased the likelihood of biopiracy (the unauthorized commercialization of genetic resources and associated traditional knowledge).[16] Now under the Bonn Guidelines, competent national authorities will have the power to grant access to users themselves, or may choose to delegate authority to grant access to other entities as appropriate. The new system, if properly implemented, should address many of the biotechnology industry's concerns.

Another component of the Bonn Guidelines' practical approach is the creation of an overall strategy for access and benefit sharing. The strategy envisioned by the Guidelines proposes three basic components: (1) identify all the steps that a user must follow to gain access and make this process transparent; (2) set up a system for obtaining prior informed consent of the owners of the genetic resource; (3) create a set of mutually agreed terms that are legally clear, that minimize costs and that ensure that the interests of the providers are met, including the types of equitable benefit-sharing arrangements the country foresees.[17]

MAJOR ELEMENTS OF THE BONN GUIDELINES AND IMPLICATIONS OF A PROTOCOL

BENEFIT-SHARING ARRANGEMENTS

The Bonn Guidelines have a comprehensive section on benefit sharing. It is inclusive of benefits derived from 'all genetic resources and associated traditional knowledge, innovations and practices covered by the CBD'.[18] The scope of the Guidelines is therefore very broad, particularly when considering that the CBD covers all biodiversity both *in situ* and *ex situ*. The Bonn Guidelines also distinguish between monetary and non-monetary benefits as set out in its appendix.[19] The scope of benefits covers a variety of different types, ranging from licensing fees and joint ventures, to capacity building and simple recognition.[20]

The Bonn Guidelines provide a flexible approach whereby the partners agree on arrangements suited to their particular circumstances. These arrangements would then be legally recognized in material transfer agreements or some form of contractual arrangements that set out 'mutually agreed terms'.[21] The Guidelines have also attempted to address the issue of derivatives (products that are adapted or modified from an original genetic resource and contain essential elements of the parent substance), but decisions about this issue did not make much progress.[22] The problem lies in how to agree on a definition of derivatives that would allow for a practical application. The CBD's first expert panel, for example, concluded that it would be counterproductive to request prior informed consent 'because of the impracticability of the implementation of such measures in view of the infinite range of derivatives that exist or may be produced, and their distribution'.[23] They also suggested that there was need for further work on an official definition, and that a team of scientists and lawyers could be created to comment on the implications of a definition.[24] At COP-6, the parties referred the issue back to the ad hoc open-ended working group to address and make recommendations to COP-7 in February 2004. The negotiators of the potential international regime, however, could profit from these deliberations and perhaps make some progress in creating a system for defining and managing derivatives.

The first expert panel was very careful to map out the different types of benefits that were possible and provided, in many ways, an exhaustive list.[25] The predominant thinking in the panel, which continued through the Bonn Guidelines' negotiations, was that benefit-sharing arrangements would not be conducive to a strict international protocol, due to their diverse nature. Many experts and the parties themselves believed that the benefit-sharing arrangements should be some type of 'consistent national system'. Such an approach is used in Australia, where the system is agreed upon through negotiations involving both the

[16] See, for example, A.C. Revkin, 'Biologist Sought a Treaty; Now They Fault It', *New York Times* (7 May 2002).
[17] Bonn Guidelines, para. 45.
[18] Ibid., para. 9.
[19] Ibid., Appendix II.
[20] Ibid. See the section on monetary and non-monetary benefits in the Bonn Guidelines, Appendix II.
[21] Ibid., paras 41 and 42(g).
[22] For a more exact definition of derivatives see CBD Information Paper, *Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines to Assist with their Implementation and Explanatory Text* (UNEP/CBD/WG-ABS/1/INF/1, 12 September 2001): 'Derivatives include, but are not limited to any progeny, extracts and compounds obtained from genetic resources and analogues of those compounds'. Derivatives have also been considered as synthetic materials that have copied the genetic make-up of the natural genetic resource. See ibid.
[23] *Report of Experts on Benefit-Sharing Arrangements* (UNEP/CBD/COP/5/8, 2 November 1999), para. 98.
[24] Ibid., para. 100.
[25] Ibid., paras 74–90.

users and genetic resources' owners.[26] Such variance would therefore be difficult to capture in a binding legal instrument.

Implications of a Protocol for Benefit-Sharing Agreements Flexibility and a legally binding regime need not be mutually exclusive. A legally binding protocol could, in fact, build in flexibility and allow for different national approaches. In fact, many modern treaties recognize that allowing a country to choose its own course of implementation could be more effective and create greater ownership towards meeting the goals of the treaty. For example, the Kyoto Protocol negotiators were very much concerned about the varied economic implications of a standard approach for reducing greenhouse gas emissions on individual countries. Many countries argued that it was better simply to state the targets and allow each country to implement its own policies and measures to meet them.[27] Article 2 of the Kyoto Protocol therefore states that each party should 'implement and/or further elaborate policies and measures in accordance with its national circumstances' and then catalogues an indicative list of various measures.[28] A similar approach that provides flexibility could be adopted in a possible protocol on benefit sharing.

One of the recommendations from the second expert panel was that benefits should be fairly and equitably shared at the national level and in ways that promote conservation and sustainable use of biodiversity.[29] A legally binding regime could require that certain principles that promote biodiversity be instilled into national legislation. This potential for an ABS protocol to protect biodiversity as a secondary result of the regime would certainly be a reason to favour a legally binding instrument.

However, building such conditionality into an ABS protocol would present some jurisdictional problems – both in terms of the CBD and among sovereign nations. Genetic resources are recognized under Article 3 of the CBD as the sovereign assets of each country and States are to 'exploit their own resources pursuant to their own environmental policies'.[30] Therefore, to what extent should a binding international regime intrude into another State's affairs concerning the use of benefits? As long as the use of benefits does not harm other countries in accordance with international law, then the degree to which benefits are shared will depend largely on how much sovereignty States agree to cede to any international regime. Historically, countries have been very reluctant to allow treaties to determine how they use their natural resources.[31]

In summary, a closer analysis of the advice put forward by the expert panel shows that their concerns over benefit sharing in a legally binding protocol might not be as serious as one might think at the outset. A protocol, like many modern treaties, is still able to allow flexibility for countries to choose their own menu for implementation, based on their own needs and experiences. On the other side of the coin, the advice the panel gave supporting the need for a legally binding regime, as a means for ensuring that the benefits derived from a country's genetic resources are put back into biodiversity, may in fact be politically too strong an infringement over a country's sovereign right to use its natural resources in the ways it deems fit.

PRIOR INFORMED CONSENT AND INTELLECTUAL PROPERTY RIGHTS

Under the Bonn Guidelines, provisions on the right to know, or prior informed consent, request that users and intermediaries who acquire genetic resources obtain consent from the original owners.[32] One of the most difficult issues is identifying the true owner of the genetic resource. The Guidelines recognize the sovereign rights of States over natural resources; however, access must be granted by prior informed consent from the contracting party providing that resource, which may not be the State.[33] The Bonn Guidelines acknowledge the difficulties associated with obtaining access because of the 'diversity of stakeholders and their diverging interests'.[34] They also note the difficulties in determining 'their appropriate involvement' and stress that a set system cannot work for all cases.[35] Nevertheless, the Guidelines see an overall strategy, with prior informed consent as a primary component, as the best approach.

The prior informed consent component of the Bonn Guidelines' ABS strategy extends responsibilities to both the users and the providers of genetic resources. At the national level, providers are to ensure that

[26] See *Report of Second Expert Panel on Access and Benefit Sharing* (UNEP/CBD/WG-ABS/1/2, 9 April 2001), para. 17 (presentation by Australia).
[27] For example, the USA strongly resisted the European Union's attempt to implement harmonized policy and measures. See S. Oberthur and H.E. Ott, *The Kyoto Protocol: International Climate Policy for the 21st Century* (Springer, 1999), at 105.
[28] Kyoto Protocol to the United Nations Framework Convention on Climate Change (Kyoto, 11 December 1997), Article 2.
[29] See *Report of Second Expert Panel*, n. 26 above, at para. 110.
[30] CBD, Article 3.
[31] See Stockholm Declaration on the Human Environment (UN Doc. A/CONF.48/14, Stockholm, 1972), Principle 21.
[32] Bonn Guidelines, Section C.
[33] CBD, Article 15.
[34] Bonn Guidelines, para. 17.
[35] Ibid.

stakeholders, from the community to the government level, are informed, and that legal rights associated with genetic resources are respected when dealing with indigenous and local communities. In the same way, when traditional knowledge has been used, it should be obtained with proper approval and in accordance with traditional practices and domestic laws and policies.[36] National responsibilities also include the need to make available a written and transparent document of whether prior informed consent is granted or denied. Such a document could be in the form of an application, permit system or 'appropriate procedures'.[37] In the event that prior informed consent is required from a different level of government, the provider must duly specify this requirement to the user.

The responsibilities on the part of users primarily revolve around the imperative of obtaining prior informed consent. The Bonn Guidelines stipulate that if the genetic resources are used for a different purpose than otherwise indicated, then new prior informed consent must be obtained.[38] Similarly, if the resources are provided to a third party, a new prior informed consent must also be obtained. A noteworthy provision in the Guidelines is that for genetic resources held *ex situ*, in botanical gardens, gene banks and the like, consent to use these resources or pass them to third parties is also required from the competent authority and/or the governing body that owns or administers those resources.[39]

Overall, the prior informed consent procedure contained in the Guidelines should ensure legal clarity, cost-effectiveness, transparency, timeliness and informed consent to all relevant stakeholders.[40] The Guidelines provide some standard elements that could be included in a typical prior informed consent application procedure: the description of the user (e.g. institutions); the geographical scope of bioprospecting; and the treatment of confidential information.[41]

The Bonn Guidelines do not set any specific restrictions on intellectual property rights (IPR) for genetic resources. Provisions on IPR are set out in Section C, in the same Decision VI/24 as the Guidelines, and call for a closer examination of the role of IPR in genetic resources, their access and scientific research.[42] The decision also has the potential for IPR procedures to promote the patentee's compliance with prior informed consent and benefit sharing.[43] The decision invites parties to encourage the disclosure of country of origin and of the use of any indigenous knowledge in patent applications for the development of genetic resources.[44]

Implications of a Protocol for Prior Informed Consent and IPR One of the more persuasive arguments for a binding protocol on ABS concerns the issue of biopiracy. The main concern of biopiracy is how to ensure that the rightful owners of genetic resources give consent prior to their commercialization. If parties to a protocol were encouraged to ensure that patentees show that they received prior informed consent from the genetic resource or traditional knowledge holder when registering their patents, then this would be an effective tool for eliminating biopiracy. Further deterrence could be achieved if the patent were actually conditional upon such a disclosure of origin.

As with the benefit-sharing agreement, such a provision in a legally binding protocol raises the question of what is the appropriate multilateral process for this issue. With provisions requiring a patentee to disclose prior informed consent, perhaps the CBD would not be the best legal instrument to host such a protocol. Would not an institution that is already specialized in intellectual property and has created the legal regimes for international patent protection, such as the World Intellectual Property Organization (WIPO), be a much more effective institution? WIPO's Patent Cooperation Treaty[45] is the international standard for patentees to take out intellectual property protection in more than one country and could be modified to require prior informed consent as a prerequisite for securing an international patent.[46] The World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPs) is also an important legal

[36] Ibid., para. 3(1).
[37] Ibid., paras 38 and 39.
[38] Bonn Guidelines, paras 34 and 16(b)(viii).
[39] Ibid., para. 32.
[40] Ibid., para. 26.
[41] Ibid., para. 27.
[42] See CBD Decision VI/24 (2002), Section C.
[43] Ibid., para. 1.
[44] Ibid., para. 2.
[45] Patent Cooperation Treaty (PCT) (Washington, 19 June 1970), amended on 2 October 1979 and modified on 3 February 1984, and Regulations under the PCT (as in force on 1 January 1985), modified 3 October 2001 (amendments in force 1 April 2002).
[46] In October 2000, the WIPO established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) to examine and discuss the connections between intellectual property (IP) and traditional knowledge, genetic resources and traditional cultural expressions. See WIPO, *Matters Concerning Intellectual Property and Genetic Resource, Traditional Knowledge and Folklore* (WIPO Document WO/GA/26/6, 25 August 2000). A technical study on the consistency with obligations in treaties administered by WIPO for 'requiring the disclosure within patent applications on genetic resources used in the development of the claimed inventions, the country of origin of genetic resources used in the claimed inventions, associated traditional knowledge, innovations and practices used in the development of the claimed inventions, the source of associated traditional knowledge, innovations and practices' is being prepared by WIPO for the CBD COP-7. See WIPO, *Certain Decisions of the Sixth Conference of the Parties to the Convention on Biological Diversity* (WIPO/GRTKF/IC/3/12, 24 May 2002).

instrument where prior informed consent could be more effectively facilitated as it creates harmonized standards for WTO members (140 countries) and stipulates conditions on trade-related aspects of intellectual property rights, such as parallel imports.[47] TRIPs is currently under review at the WTO and some countries have already raised the issue of tying TRIPs with a prerequisite of disclosure of origin.[48] Positions, however, are spilt between those countries that see scope for TRIPs creating a requirement for prior informed consent, and those that view access and benefit sharing and enforcing prior informed consent as outside of the TRIPs' objectives and legal mandate.[49]

MATERIAL TRANSFER AGREEMENTS AND MUTUALLY AGREED TERMS

Material transfer agreements (MTAs) are the engine of the Bonn Guidelines; it is through these arrangements that the terms between users and providers will be legally determined. These agreements will govern the transfer of intangible material between parties. They will set up terms on the use of the materials, and the rights of users and providers. MTAs will also often cover the use and commercialization of derivatives, as discussed above.[50] There has been a sizeable portion of work done by the international legal community on MTAs and this has made its way into the Guidelines.[51]

The parties were able to agree in the Bonn Guidelines on the basic elements that should be included in a standard MTA, and these are set out in Appendix I to the Guidelines. One distinction that should be made is the difference between MTA and MAT (mutually agreed terms). The CBD uses the terminology for access to be granted 'on mutually agreed terms'.[52] This means that users and providers of genetic resources must agree on certain terms (e.g. confidentiality, recognition of sovereign rights of country of origin)[53] for sharing the utilization and commercial use of genetic resources. As mentioned above, the Guidelines make several basic insights of what these terms should entail, but, in the end, it will be the MTAs that execute and embody such terms.

Implications for a Protocol: MATs and MTAs At first glance, it would be easy to assume that a legally binding protocol would have no particular advantage in conveying MATs or in setting the contents of a MTA. MTAs imply that both parties agree upon the terms for a transfer of genetic resources, that these arrangements are ad hoc, and that they are the outcomes of bilateral negotiations between the parties. Thus, an MTA is contingent upon many changing variables. However, there could be certain advantages to standardizing terms within a protocol, particularly for users that require stability and assurances for their investments.

Users of genetic resources have long complained of difficulties, such as the lack of expertise on the part of the provider, time required for responses from providers and sometimes of the unrealistic expectations that providers may have for the users. A protocol that stipulates the basic perimeters of MTAs could address many of these concerns and provide more legal certainty to the parties in the case of disputes. For providers who may not have access to adequate representation or expertise for negotiating MTAs, a basic standardized system could ensure that a certain level of protection from exploitation was guaranteed.

A model of how such a system could actually work, and the advantages it could offer, is the United Nations Convention on the International Sale of Goods (CISG).[54] While the CISG might seem an unlikely comparison to a potential protocol concerning the benefit sharing of genetic resources, the general concerns that have been raised about the standardization of MTAs are similar to those that were raised in the development of CISG. CISG grew out of the basic need to harmonize international trade rules, to ensure a 'basis of equality and mutual benefit', and to level the playing field in terms of bargaining power for developing countries.[55] CISG was adopted taking 'into account the different social, economic and legal systems [that] would contribute to the removal of legal

[47] For potential interlinkages between CBD and TRIPs, see CBD, *The CBD and Trade Related Intellectual Property Agreement: Relationships and Synergies* (UNEP/CBD/COP/3/23, 5 October 1996).
[48] TRIPs Council, Communication from India (IP/C/W/195, 12 July 2000), para. 16.
[49] TRIPs Council, Communication from the United States (IP/C/W/257, 13 June 2001). For a summary of country positions, see TRIPs Council, *The Relationship between the TRIPs Agreement and the Convention on Biological Diversity: TRIPs Summary of Issues Raised and Points Made* (WTO Doc IP/C/W/368, 8 August 2002).
[50] See U.C. Berkeley, *A Quick Guide to Material Transfer Agreements at University of California, Berkeley* (U.C. Berkeley, 2003), available at <http://www.spo.berkeley.edu/guide/mtaquick.html>.
[51] See, for example, L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources* (World Conservation Union, June 1998); F. Latorre Garcia *et al*., *Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines to Assist with their Implementations and Text* (Kew Gardens, March 2001).
[52] CBD, Article 15(4) and 15(7).
[53] For an indicative list of MATs, see Bonn Guidelines, para. 44.
[54] United Nations Convention on the International Sale of Goods (Vienna, 11 April 1980) (hereinafter CISG).
[55] See, generally, H. Gabriel, *Practitioner's Guide to the Convention on Contracts for the International Sale of Goods (CISG) and the Uniform Commercial Code* (Oceana, 1994); and J.O. Honnold, *Uniform Law for International Sales under the 1980 United Nations Convention* (Kluwer, 1991).

barriers in international trade and promote the development of international trade'.[56] It puts in place rules on dispute-settlement procedures, obligations of the buyer, seller and third parties, and breaches of such arrangements. One advantage of CISG is its flexibility, in that parties can opt out of the convention, or any part of it, if they prefer to use their own arrangements. This opt-out provision was created for companies that had operations in CISG Contracting States, but who may not wish to be bound by its rules. Accordingly, the extent to which a contractee wishes to be bound by CISG is entirely voluntary and is decided during the negotiation of terms.[57]

There are certain similarities between the international sales of goods and the accessing of genetic resources. Ultimately, both are examples of basic buyer and seller arrangements that take place across domestic jurisdictions. With access issues, many genetic resources are in developing countries, where, like CISG, there is concern for mutual terms that are equitable and fair. Initiatives for accessing genetic resources are normally commercially motivated, requiring certainty for the investment and the minimization of costs. A protocol on ABS that stipulates the nature and core elements of MTA and fleshes out the details of the basic arrangements, while remaining flexible enough to allow for providers, users and even intermediaries mutually to opt out and agree on their own system, if need be, would be advantageous for those reasons.[58]

An additional benefit of a protocol with standardized criteria for MTAs would be to provide the parties with more clarity in the event of a dispute. A protocol could harmonize terms and definitions, describe the type of breaches, and legally stipulate the relationship with third parties who have accessed the resource *vis-à-vis* users. The first report of the panel stressed that Bonn Guidelines are preferable, as they would compliment existing legislation; however, many of the transactions between users and providers are generally of an international character, and may occur outside the jurisdiction of national authorities. Given this fact, and that the relationships with third parties could take place in a multitude of countries, it is important to have strong international standards that are in legally clear and enforceable language.

Another important consideration that was overlooked by the panel was that many developing countries still do not have access legislation.[59] In this context, it is in fact very difficult for guidelines to compliment domestic legislation where in many developing countries such legislation is non-existent.[60] However, by internationalizing the standards for MTAs through a legally binding protocol, it could guarantee a certain level of protection for developing countries in the event that the resources are accessed and there is no access legislation in place.

Assuming there are then certain advantages to standardizing legally MTAs, the question then becomes whether this is a feasible approach. From analysis of the advice of the expert panel on MTAs, there was overwhelming concern for the 'enormous difference in the circumstances of particular cases of access and benefit-sharing, as well as the evolving nature of the legal regimes to implement the Convention'.[61] Experts believed that although there 'were a number of aspects of contractual arrangements and mutually agreed terms for a common understanding to emerge', guidelines were preferable over a protocol given the diversity of experiences on MTAs.[62]

The advice of the panel again raises doubts if the conclusions reflect the facts. Although MTAs do vary, they can be standardized into the language of a potential protocol. In fact, most MTAs follow very basic patterns and, therefore, 'they are applicable to diverse collaborations'.[63] It is true that standard provisions for an MTA could not include the diversity of benefit arrangements,[64] but otherwise most parts are fairly common. These provisions may include those relating to the following: defining differences between tangible property, intellectual property and, often, references to traditional knowledge; the identification of contracting parties, users and providers and their obligation *vis-à-vis* third parties; identification of the source country and the location of the genetic resource within that country (state, province, etc.); description and ownership of potential inventions; confidentiality; duration; grounds for termination and or nullification; prior informed consent; and the applicable law of the contract.

[56] CISG, Preamble.
[57] A.S. Winer, 'The CISG Convention and Thomas Franck's Theory of Legitimacy', 19:1 *Northwestern Journal of International Law & Business* (1998), 15.
[58] CISG, Article 6 states that 'The parties may exclude the application of this Convention or derogate from or vary the effect of any of its provisions'.
[59] It is estimated that about 50 countries 'either adopted or are in the process of adopting measures to exercise and secure their sovereign rights over genetic resources'. See UNU/IAS, *User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit Sharing of the Convention of Biological Diversity* (UNU/IAS, March 2003), at 14.
[60] The guidelines could of course form a basis for the development of national access legislation.
[61] See *Report of Experts on Benefit-Sharing Arrangements*, n. 23 above.
[62] Ibid.
[63] D.M. Putterman, 'Model Material Transfer Agreements for Equitable Biodiversity Prospecting', 7:1 *Colorado Journal International Environmental Law and Policy* (1996), at 149.
[64] Benefit sharing could therefore be varied according to the circumstances, but the important element of a protocol would be to make a benefit-sharing requirement obligatory on mutually agreed terms.

To summarize, the possibility of standardizing MTAs to the degree that they achieve greater legal clarity for use of terms, definitions and dispute settlement, and to ensure a basic level of protection for countries without national legislation is a positive approach. Since a protocol could be a means to oblige parties legally to follow basic MTA models, the standardization approach may be considered a strong argument for a legally binding protocol.

SOFT LAW OR HARD LAW?

An important question as to whether a set of guidelines or a protocol would be most appropriate for ABS concerns the role of soft law versus hard law. Traditionally, soft-law approaches were viewed as starting points for consensus-building processes between countries. When countries could not foresee agreeing on a binding international agreement, but still wanted to demonstrate cooperation on an emerging problem, soft law became a plausible option. As the commitment to a problem grew, soft law, such as a code, a declaration or guideline, was often negotiated into an agreement, treaty or convention. There have been several successful examples of this over the last 30 years. The principle of prior informed consent, for example, developed over 15 years into a binding principle for the use of pesticides and hazardous chemicals. In 1985, the Food and Agricultural Organization's (FAO) Code of Conduct on the Distribution and Use of Pesticides was created;[65] 4 years later the United Nations Environment Programme's (UNEP) London Guidelines for the Exchange of Information on Chemicals in International Trade came into being.[66] The pesticide and chemical industry, seeing the writing on the wall, increasingly became more cooperative with governments and voluntarily complied with an even stronger measure in the 1994 Code of Ethics on International Trade in Chemicals.[67] All of this finally led to a hardening of the law and the promulgation of a Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade in 1998.[68] Similar developments occurred in the case of the 1959 Antarctic Treaty, which developed into a system of treaty-based international rules and soft law, or what Chris Joyner called quasi-legislative[69] norms, and in the case of the United Nations General Assembly's moratorium on large-scale pelagic drift net fishing in 1991.[70]

Thus, soft law plays an important role in the development and strengthening of international law. When international consensus for a harder agreement does not exist, soft law can also be an important marker to remind parties of their previous progress as negotiations move ahead over time. But how much time is needed before a hardening of the law occurs? Past experience shows that this is dependent on two variables: the first is the level of implementation achieved by the existing agreement; and the second is the level of consensus achieved to support a move to a stronger legal commitment.

Concerning the first factor, it has only been a relatively short period since April 2002 when the Bonn Guidelines were adopted. Most countries have not yet started to work on implementation. The CBD has yet even to initiate programmes to assist developing countries on the Guidelines. On the second factor, the lack of support for a binding protocol during the WSSD negotiations would seem to indicate that there still remains significant disagreement and that it has not yet been enough time for new progress on a harder legal agreement. This may indicate that, although a negotiation on an international regime is expected to get underway, progress may be very slow.

For instance, the negotiations of paragraph 44(o) of the JPOI, the paragraph calling for an international process towards an international regime on access and benefit sharing, clearly shows distinct differences among countries. The original paragraph first appeared in the chairman's paper from the second session of the WSSD preparatory process (Prepcom II). It was suggested as an input from the Latin America and Caribbean regional preparatory session and supported by Mexico.[71] It called for the promotion of 'an effective, transparent and predictable framework for access to genetic resources and equitable sharing of benefits from their use'.[72]

[65] FAO, *Code of Conduct on the Distribution and Use of Pesticides* (FAO/CONF/RES 10/85, 28 November 1985).
[66] UNEP, *London Guidelines for the Exchange of Information on Chemicals in International Trade* (UN Doc. UNEP/GC/DEC 15/30, 25 May 1989).
[67] UNEP, *Code of Ethics on International Trade in Chemicals* (UNEP, 1994), available at <http://irptc.unep.ch/ethics/default.html>.
[68] Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam, 11 September 1998).
[69] C. Joyner, 'The Legal Status and Effect of Antarctic Recommended Measures Treaty System', in D. Shelton (ed.), *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal* (Oxford University Press, 2000), at 182.
[70] D. Rothwell, 'The General Assembly Ban on Driftnet Fishing', in ibid., at 145.
[71] The UN Economic and Social Council states: 'To ensure equitable access to the benefits afforded by the use of genetic resources through the implementation of national and international regulatory schemes for this purpose, taking into account all rights pertaining to these resources and technologies, and through appropriate financing and the transfer of relevant technologies'. See UN Economic and Social Council, *Rio de Janeiro Platform for Action on the Road to Johannesburg 2002* (E/CN.17/2002/PC.2/5/Add.2, 24 October 2001), para. 51.
[72] See Chairman's Paper (A/CONF.199/PC/L.1, 12 February 2002).

At the third session of the WSSD preparatory process (Prepcom III) many developed countries appeared to be in disagreement over the paragraph. The USA repeatedly introduced language on the paragraph that called for actions on ABS to be taken at the national level, and rephrasing the term 'framework' into weaker language such as 'arrangement'.[73] Japan was also clearly in favour of voluntary commitments and proposed inserting 'on a voluntary basis' before the words 'benefit-sharing equitably with indigenous and local communities'.[74] Its concerns were mainly over increasing the regulatory burdens on its large biotechnology and pharmaceutical sectors. Other countries, such as Canada, New Zealand and South Korea, promoted consistency with the ongoing forums at WIPO and the WTO. The EU at this time was already expecting the imminent endorsement of the Bonn Guidelines at COP-6 and introduced language that supported its full implementation.[75] Norway and Switzerland introduced what they saw as a compromise by introducing the idea of an 'international regime' for access to genetic resources and equitable sharing of benefits.[76] Other countries were reluctant to make any final conclusion on the paragraph.

One reason for this was that during the period between Prepcom III in March/April 2002 and Prepcom IV in May/June 2002, COP-6 was to take place and decide on the fate of the Bonn Guidelines. By Prepcom IV, COP-6 had adopted the Guidelines and, thus, this was behind the negotiators, and, as a result, negotiations on the ABS paragraph were intensified. Another factor that increased tension regarding the paragraph was that by Prepcom IV the coalition of like-minded mega-diverse countries had officially been formed and had sent a letter to the UN Secretary General introducing itself as a coalition to Prepcom IV, asking him to circulate the group's Cancun Declaration, which called for a binding regime on ABS.[77] The group's collaboration now also became a strong factor in supporting the paragraph, as it was the Latin American members of this group that had first introduced the necessity of a binding international instrument on ABS, and the group as a whole had formed to create a unified political front to push for greater protection of its genetic resources.

At Prepcom IV, a fresh chairman's paper introduced a completely new iteration of the ABS paragraph. It stated that the parties should '[p]romote an effective and transparent framework for access to the results and benefits arising from biotechnologies based upon genetic resources, in accordance with article 19 of the CBD'.[78] However, the new language was unacceptable to most countries, as it was too vague for those countries that wanted a binding regime and too strong for those that did not, and by the conclusion of Prepcom IV a similar paragraph to what had been the basis of the negotiations before had worked itself back into the draft text. But the paragraph now introduced the words 'international regime', which was language that Norway and Switzerland had suggested as an alternative at Prepcom III.[79] The paragraph called for the negotiation and 'the creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components'.[80] The USA, however, made it clear that it interpreted the word 'regime' only as voluntary, while the like-minded mega-diverse countries, under the leadership of Mexico, continued to view the idea of the 'international regime' as binding.

This set the stage for the WSSD in Johannesburg. At the WSSD, the like-minded mega-diverse countries linked the negotiation of the ABS paragraph with another outstanding issue on an actual time-bound target concerning the reduction of biodiversity loss. This was a strategic move by the like-minded mega-diverse countries to tie the two controversial issues and force an outcome. These countries knew that many northern developed countries, particularly European countries, were determined to set a target for biodiversity loss. But other developing countries would not commit to a target without financing, as they argued that poorer countries were more dependent on biodiversity for their livelihoods. By linking the two issues together there would be greater flexibility for trade-offs. The tactic paid off and eventually a compromise by Canada allowed for a deal to be struck. The deal set the time-bound target for 2010, but it recognized that 'a significant reduction in the current loss of biodiversity by 2010 would require new and additional financial and technical resources to developing countries'.[81] For this commitment, the like-minded mega-diverse countries and the rest of the G77/China agreed to delete 'legally binding', and

[73] On 4 April 2002, during plenary, the USA also clearly stated that it would not support an international regime or framework on ABS. See 'Summary of PrepCom III', 22:29 *Earth Negotiations Bulletin* (8 April 2002).
[74] Working Group One, Compilation Text, Prepcom III (31 March 2002), chapters I, II, III and IV, para. 15(c), alt. 2.
[75] Ibid., para. 15(d), alt. 2.
[76] Ibid., para. 15, alt. 3.
[77] Letter dated 5 April 2002 from the Permanent Representative of Mexico addressed to the Secretary General (A/CONF.199/PC/17, 15 April 2002).
[78] UN Economic and Social Council, Note by Secretariat Transmitting Chairman's Revised Paper (A/CONF.199/PC/L.1/Rev.1, May 2002), para. 39(j).
[79] Commission on Sustainable Development, Draft Plan of Implementation for the World Summit on Sustainable Development, advanced unedited text (12 June 2002), para. 42(o).
[80] Ibid.
[81] JPOI, para. 44(o).

stressed retaining reference to 'regime', which they interpreted as being of a binding nature.[82] In the final plenary speeches at the WSSD, the USA reiterated its position that an 'international regime' meant a 'voluntary regime'.

In the end, the JPOI did not create clear-cut consensus on an international regime and leaves open the scope of its negotiation. Paragraph 44(o) distinguishes the 'international regime' from the Bonn Guidelines as it requests the parties to promote its implementation in paragraph 44(n).[83] The JPOI also shows that the parties wished to see a successful conclusion to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore and WTO processes, which indicates that they saw scope for an international regime outside of this process.[84] But if the international regime is non-binding, and there already exists the Guidelines, which is a voluntary agreement and comprehensively covers ABS issues, how would a new voluntary international regime be distinct from what already exists? Would not another voluntary agreement be redundant? Or should the paragraph be interpreted according to the like-minded megadiverse countries and G77/China as calling for a binding regime based on the Bonn Guidelines, but distinct from the other regimes underway at WIPO?[85] Only time will tell how paragraph 44(o) will be interpreted; however, the disagreement in the WSSD negotiations will not be resolved easily. At the first intergovernmental meeting on ABS following the WSSD,[86] there was still strong disagreement over the negotiation of a harder international law on ABS.

IS SOFT LAW AN EFFECTIVE APPROACH?

The lack of consensus over an international regime suggests that perhaps the Bonn Guidelines are not such a weak outcome in terms of legal effectiveness. Whereas soft law was previously regarded as a weaker version of its harder counterpart, Dinah Shelton has argued that, to a large degree, parties often comply with soft-law measures.[87] Shelton stresses that compliance is more a question of process and commitment than of obligation and coercion. The process approach and understanding to international law is by no means new,[88] but the realization of the apparent effectiveness of soft law shows that the choice of legal instrument is not always the only determinant of whether the instrument will be followed or not.

This is certainly the case in more recent international instruments, where the divisions between soft law and hard law become increasingly blurred. Many modern international treaties are a mix of soft law and hard provisions. In fact, the technique of using framework conventions such as the United Nations Framework Convention on Climate Change[89] and United Nations Convention to Combat Desertification[90] can be seen as part of a progression from softer to harder law, as protocols (e.g. Kyoto Protocol) or amendments are made to softer framework conventions.[91] The technique reflects the profound changes that international law making has undergone in the last 30 years. New international law-making techniques, using market mechanisms, management systems and partnerships, have melted away what are considered the barriers between international law, governance and policy making. Soft law is only one of a battery of these techniques that can be used to accomplish the goals that are called for by international agenda setters.

By examining these legal techniques, it becomes apparent that effectiveness corresponds, not so much to the choice of the legal instrument, but rather to the degree to which the process behind the instrument can create an international norm to which governments and non-State actors will adhere. Thus, the choice of legal instrument is not always the governing factor in adherence. Rather, the process preceding implementation of the instrument and, correspondingly, as Shelton points out, the degree of commitment by countries are also significant factors in compliance with international instruments – both binding and non-binding.

[82] See 'Summary WSSD', 22:51 *Earth Negotiations Bulletin* (6 September 2002).
[83] JPOI, para. 44(n).
[84] The JPOI only refers to the successful conclusion of the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore; see JPOI, para. 44(p).
[85] There is also the possibility that JPOI provisions related to ABS refer to an 'international regime' as focusing specifically on the international aspects of ABS, such as closure of origin, transport and certification. These areas are sometimes referred to as so-called 'user measures'. A recent report by the UN University Institute of Advanced Studies elaborates and analyses some of these options. See UNU/IAS, n. 59 above.
[86] See *Report of the Open-Ended Intersessional Meeting on the Multiple Year Plan of Work – CBD* (UNEP/CBD/COP/7/5, 18 March 2003).
[87] See D. Shelton, *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System* (Oxford University Press, 2000).
[88] See R. Higgins, *Problems and Process: International Law and How it is Used* (Clarendon Press, 1994).
[89] United Nations Framework Convention on Climate Change (New York, 9 May 1992).
[90] United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (Paris, 17 June 1994).
[91] See A. Kiss, 'The Environment and Natural Resources', in D. Shelton, n. 69 above, 230.

CONCLUSION: TOWARD AN INTERNATIONAL REGIME FOR ABS?

As the ABS regime and many other biodiversity-related instruments continue to develop, scientific and technological advances have left many questions unanswered. Before the international community goes too far down the path of developing an expensive international regime, a needs-assessment analysis is urgently needed. Perhaps protection of genetic resources in the context of an international regime is not something that every country requires; maybe only a handful of countries, such as the main users and providers, require it. Or maybe countries can develop additional components of the regime or join on an as-needed basis. Or indeed do the costs and risks warrant the need for an international regime?[92]

This article has suggested that a certain degree of scope for a protocol does exist and that the concerns expressed by the expert panel may be overstated in that the diversity and variation of national experience on ABS would not lend itself well to a protocol. With the exception of benefit-sharing arrangements, which may vary according to the value of the genetic resource, potential inventions, scientific and educative purposes, or the preferences of the genetic resources holders, there is ample basis for a protocol in setting criteria for access, prior informed consent and material transfer agreements. A compliance system and a legally binding obligation to ensure that benefits are shared could provide a safety net for possible exploitation. If prior informed consent is to be linked more closely to the disclosure of origin, there is yet another argument for a legally binding approach, although a protocol under the CBD may not be as an effective approach compared to one under legal instruments that are specialized on patents, such as the WIPO's Patent Cooperation Treaty or the WTO's TRIPs.

In the end, the need for a protocol has less to do with the choice of legal instrument and its corresponding level of effectiveness, and more to do with the political reasons and the process of implementation behind the legal instrument. If the political consensus is not ripe for a stronger hard-law protocol, and countries prefer more flexibility to choose their own course for addressing ABS issues, then a well-financed Bonn Guidelines with a strong capacity-development component is by far the preferred choice.

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[92] There is still not accepted scientific consensus on the value of biodiversity or the level of exploitation in terms of biopiracy. Accepted scientific evidence demonstrating the need for international treaties is considered the first step in regime formation. Scientific assessment plays a key role in narrowing the focus of the issue: determining risk and uncertainty and creating a consensual body of knowledge for the negotiations to begin. See H. Breitmeier, 'International Organizations and the Creation of Environmental Regimes', in O. Young (ed.), *Global Governance: Drawing Insights from the Environmental Experience* (MIT Press, 1997). Also, see generally on the role of science and epistemic communities, P.M. Haas, 'Introduction: Epistemic Communities and International Policy Coordination', 46:1 *International Organization* (1992), 1–36. Also see R.E. Benedick, *Ozone Diplomacy: New Directions in Safeguarding the Planet* (Harvard University Press, 1998).