SOUTH CENTRE

POLICY BRIEF 4

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The Nagoya ABS Protocol and Pathogens

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I. Introduction

The Convention on Biological Diversity (CBD) provides for Parties to regulate access to genetic resources (GR) in their jurisdiction. Article 15 states that access is subject to the prior informed consent (PIC) of the Party. The consent is subject to the sharing of benefits that must be fair and equitable. These benefits must be mutually agreed. This envisages a negotiated contractual agreement. In 2002 the World Summit on Sustainable Development noted that the benefit sharing provisions of the CBD were not being honoured. It called on Parties to establish rules to ensure that benefits flowed from the grant of access. This clarion call was taken up by the CBD at the 7th Meeting of the Conference of Parties in 2004. The meeting mandated Parties to establish international rules for an International Regime on access and benefit sharing of genetic resources and provided the terms of reference. The negotiations were conducted through a variety of meeting modes: working group, Friends of the CoChairs, and such like. After 6 years of arduous negotiations the Nagoya Protocol on Access and Benefit Sharing of Genetic Resources (NP) was adopted in the early hours of October 30, 2010. It will come into effect upon 50 Parties to the CBD ratifying the Protocol.

The Protocol confirms the need for PIC for the grant of access to genetic resources. Genetic resources are given an expansive interpretation. Thus derivatives - which include biochemical components of biological and genetic resources - are included within the scope of the Protocol. Provider countries can require benefit sharing through mutually agreed terms. These benefits must be fair and equitable. Finally, countries with users in their jurisdiction are required to provide effective measures to address cases where resources have not been accessed in accordance with the law of the provider country.

One particular subset of genetic resources has been singled out in the Protocol for special treatment. This relates to viruses, in particular pathogens. At the time the Protocol was being negotiated, the World Health Organisation (WHO) was in the throes of an active debate triggered by the demand by some developing countries that there should be benefit sharing in respect of the influenza virus that they had provided to the collection centres of the WHO under the existing arrangements. These collection centres located in developed countries supplied the virus to, among others, the pharmaceutical industry, which patents the virus, its components or the vaccines made out of the use of the virus - as a prelude to commercialization. Developing countries raised the concern that no benefits accrued to them: they were neither given the vaccines on a preferential basis or on concessional terms; nor indeed given access to the technology for making the vaccines in the fu-

Contents

ture. Developing countries are now pressing for a standard agreement in the WHO forum that would ensure that fair and equitable benefits flow to the country providing the virus on the basis of their sovereign right over the genetic resource.

II. The Proposals by Developed Countries in the Negotiations of the NP

In the negotiations in March 2010, a proposal was put forward to exclude human pathogens from the scope of the Protocol (see UNEP/CBD/WG-ABS/9/ING/1). This was resisted by developing countries who argued that there was no basis to exclude any genetic resource from the Protocol when it was clearly within the scope of the CBD. Then the EU proposed a clause on "special consideration relevant to emergency situation". The proposal required countries to provide immediate access to pathogens which also fall under the scope of relevant international organizations such as the WHO; these pathogens were those of particular public concern for the health of humans, animals, or plants; in ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens; and related benefits established under these international organizations and conventions. In sum, the proposal was to exclude pathogens from the access and benefit sharing requirements of the Protocol altogether and to forever place them under the jurisdiction of other international organizations and subject them to the rules and practices of these organizations - in particular the WHO.

III. The Provisions in the NP

The provisions that were finally agreed upon are set out in Articles 8 (headed as "Special Considerations") and Article 4 paragraphs 3 and 4 (headed as "Relationship with International Agreements and Instruments").

These read as follows:

Article 8

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.

Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially developing countries.

Article 4.3

This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

Article 4.4

This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

IV. Interpretations

Various interpretations have emerged that suggest either that the NP does not cover pathogens, or that there is an obligation by countries when enacting their domestic law to pay regard to the WHO decisions establishing different levels of pandemic threats and the national and international responses. And further that benefit sharing provisions for pathogens are to be those as established by the decisions of the WHO.

The first interpretation - advanced by the US in a "USA Non-Paper" implies that none of the provisions on ABS would apply to pathogens. The second interpretation - advanced by the Council of the European Union in a Commission Report (DS 1803/10, 12 Nov 2010) -implies that the WHO's work and decisions (including present and future work and decisions) could supplant the NP as

regards ABS.

IV.1 A Consideration of the US Interpretation

A. Does the scope of the Nagoya Protocol cover pathogens?

The US argues as follows:
US Argument 1:
The influenza viruses with pandemic potential are not covered by the CBD. The CBD covers ABS of genetic resources; and there must be a direct link to the overall objective of conservation and sustainable use of biodiversity. This objective does not apply in the context of pandemic flu as access is sought to develop a vaccine to eradicate the virus itself.

Response:
A straight reading of the CBD suggests that the US interpretation is unacceptable.

a. The scope of the NP states that the Protocol shall apply to genetic resources within the scope of Article 15 of the CBD (Article 3). The definition in the CBD of the term "genetic resource" applies to the NP. Genetic resources are defined as genetic material. And genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity (Article 2, CBD). There is no doubt that viruses contain functional units of heredity and are replicable

b. The objective of the NP is stated as the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access ...,thereby contributing to the conservation of biological diversity and the sustainable use of its components. This predicates the conservation and sustainable use elements to the benefits that accrue for the utilization of GR. This fits the general scheme of the CBD itself that places benefit sharing as an important element in achieving conservation and sustainable use. Importantly, there is nothing in the CBD or the NP that excludes Parties from applying the ABS requirements unless there is first established a direct link to the overall objective of conservation and sustainable use.

c. Further, if there is any doubt whether the article applies to pathogens, the history of the negotiations may be referred to. The negotiating history shows that, first there was a proposal to exclude pathogens from the scope. It was expressed as follows:
"This Protocol does not apply to: human pathogens".

Another proposal was also made as an alternative to this. It read as follows:
"This Protocol does not apply to: A genetic resource when it constitutes a serious and direct danger to the health of humans as described in the International Health Regulations, and it is covered by and for the purpose of specialized instrument as described in paragraph (b) of Article 6."

The proposal made for Article 6(b) was as follows:
"In the development and implementation of its access and benefit sharing legislation or regulatory requirements, each Party shall:

(b) Provide immediate access to pathogens falling also under the scope of relevant international organizations and conventions such as the World Health Organisation and which are of particular public concern for the health of humans, animals or plants In ways and for uses provided for in existing and future rules, procedures or practices on the sharing of pathogens and related benefits established under those international organizations and conventions."

It was these provisions that later metamorphosed into the present article. This makes it clear that pathogens were and are contemplated by these provisions and that the present Article 8 is about ABS in relation to pathogens.

It is instructive that the EU which introduced this Article and its preceding variations, states in its Commission Report unequivocally that the NP "applies to genetic resources with pathogenic properties".

d. To sum up, all GR are covered by the NP unless expressly excluded. Pathogens are GR. Hence they are within the scope of the NP. Benefits that arise from the access to, and utilization of, pathogens contributes to the conservation and sustainable use of biodiversity. This satisfies the objectives of the CBD and the NP. Finally the proponent of this clause - the EU - has made it clear post-Nagoya that this clause covers pathogens.

US Argument 2:
Preambular paragraph 16 of the NP further supports its view that pathogens are not covered by

the NP.

Preamble 16 reads as follows:

"Mindful of the International Health Regulations (2005) of the World Health Organisation and the importance of ensuring access to human pathogens for public health preparedness and response purposes,"

The US argument proceeds thus. This preamble recognizes the WHO as a separate forum; it concerns only access and not benefit sharing; it deals with "ensuring access" which "seems different from the CBD's establishment of prior informed consent regime for other genetic resources'"

Response:

a. A protocol, treaty or agreement is often divided into 2 parts: the preamble and the articles. The preamble provides the context; while the articles set out the obligations. The articles are the operative part of a protocol. Where the articles are clear, there cannot be recourse to the preamble. Only where the article is unclear or ambiguous, can there be such recourse to interpret the particular article.

b. In the present case, the preamble itself makes an explicit reference to "pathogens". This makes clear that the Protocol includes such genetic resources within its scope, otherwise there would be no need to refer to such a genetic resource.

c. Article 8(b)of the NP that deals with pathogens states that Parties in the development and implementation of their national access AND benefit sharing regulatory laws or requirements, may take into consideration the need for expeditious access to the genetic resources AND expeditious fair and equitable sharing of benefits arising out of their utilization. The Article is clear and unambiguous. The US submission ignores this clear reference to both elements in this operative article. As stated earlier the interpretation of the US limiting the effect of this clear provision by reference to a preamble not only violates the role of a preamble but more importantly flies in the face of the express provisions of the article.

d. The term "ensuring access" in the preamble is not different from the establishment of prior informed consent (PIC) for other genetic resources. To reiterate, Article 8(b) requires Parties in developing and implementing their ABS laws to consider the need for expediting access. The decision may be not to give expedited access; or to do so. In the latter situation, access procedures may be fast tracked or simplified. In either case, Parties are making a decision for access based on their sovereign right over the resource. Any such decision on access is of the same order or genus as any other decision relating to access for other genetic resources. It is not different from the CBD's establishment of prior informed consent regime for other genetic resources, as contended by the US. In any event, to repeat, the preamble cannot be used to limit the clear provision of the operative article.

e. The provisions in Article 8(b) relating to expedited access and benefit sharing are to be read in the context of Article 15 of the CBD which states explicitly that "access to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources, unless determined by that Party" (Article 15.3). It further obliges Parties to take measures for the sharing of benefits arising from the commercial and other utilisation of genetic resources with the provider country, upon mutually agreed terms.

f. The NP confirms these provisions in its Article 5 - on benefit sharing; and Article 6 - on access.

g. The US also argues that human genetic resources are excluded from the framework of the CBD vide its Decision II/11 as also confirmed by the decision adopting the NP. The response is that pathogens, including human pathogens, are genetic materials that are replicable. These materials occur and may replicate within a host such as humans, animals or plants. They are not part of the genome of these hosts.

US argument 3

Even if the CBD and the NP were interpreted to cover pathogens, the NP expressly contemplates that its provisions may not apply where there is a specialized instrument. The World Health Assembly (WHA) resolutions concerning the Pandemic Influenza Preparedness (PIP) Framework constitute such a specialized instrument under 3 bis (now Article 4.4) of the NP. These also fulfil the further requirement in the Article of "being consistent with and not run counter to the objectives of the CBD and the NP".

Response

a. Article 4.4 refers to a specialized international ABS instrument that will then apply in place of the NP. First, the international instrument should be of the same status as the NP -namely, a treaty. It must be binding. [That is why the need for mutual supportiveness in the implementation of the Protocol in Article 4.3 is with other international instruments.]

Secondly it must be a dedicated ABS instrument. The only such instrument is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). It is a binding international treaty. And it covers the field of ABS with regard to plant genetic resources under the multilateral system established with regard to Annex 1 crops and for the purpose of it specifies (hence the reference to "the specific genetic resources covered by and for the purpose of the specialized instrument"). The WHA resolutions and the PIP Framework certainly do not qualify as such a specialized instrument. As Article 4.4 makes explicit the NP is the instrument for the implementation of the ABS provisions of the CBD. These provisions cover all genetic resources, without exception. The WHO resolutions and Framework cannot thus oust the NP.

b. Further the WHO regime regulating ABS for influenza viruses, if and when established, must be consistent with and not run counter to the objectives of the Protocol. In particular, the regime must provide for the fair and equitable sharing of the benefits arising from the utilisation of the pathogens. "Utilisation" is defined in the NP to mean the research and development of the genetic resource and derivatives. Article 8(b) makes explicit that such benefits must include transfer of technology and giving access to affordable treatments by those in need especially developing countries. Thus the vaccines that are made from the viruses must be provided to developing countries at affordable prices.

c. Additionally, the fact that Article 8(b) concerns only the development and implementation of national ABS law and not an international instrument, does not take pathogens outside the scope of the NP, as argued by the US. International treaties may, and routinely do, require national implementation obligations or considerations. This reinforces the applicability of the treaty to the subject matter that is referred to. The CBD is a classic example of this approach.

d. Finally, the fact that the provision in the NP covers resources (pathogens or viruses) beyond influenza viruses does not remove them from the scope of the Article, as suggested by the US. The greater encompasses the lesser.

e. Nor does the fact that the shared substance itself threatens health determine its exclusion from the scope, as the US contends. The essential question is whether pathogens or viruses are genetic resources within the meaning of the NP. If they are then the benefit sharing provision of Article 5 applies and the benefits arising from the utilization of the resource as well as subsequent applications and commercialization must be shared in a fair and equitable way with the Party providing the virus, upon mutually agreed terms.

IV.2 A Consideration of the European Union (EU) Interpretation

On Article 4.3

The EU states in its Commission Report that it holds a strong position that the NP should not interfere with the current or future practices for the sharing of pathogens under the WHO, the IPPC or the World Organisation for Animal Health. The response is that this really depends upon what the NP says about the status of these practices.

The EU acknowledges that the NP applies to genetic resources with pathogenic properties. Hence the provisions of the NP must necessarily govern the regulation of these resources. Article 4.3 states that "due regard should be paid" to ongoing work or practices under relevant international organisations. The WHO is one such organisation. This is not a mandatory requirement. It is an exhortatory expression. The provision requires no more than that Parties consider such work or practices. The EU acknowledges as much when it declares that "these are not obligatory on the Parties". However, the EU Report goes on to state that these should be respected by the Parties. Again, this is not an obligatory requirement. More importantly, this non-obligatory "respect" is qualified. Article 4.3 states that these work or practices must be supportive of and not run counter to the objectives of the CBD and the Protocol. The objective of the NP is the fair and equitable sharing of benefits arising from the utilization of the pathogens, including by appropriate

access and transfer of technologies. Any practice that does not provide for such benefit sharing will run foul of the NP.

On Article 8(b)

The EU states that when developing and implementing national ABS legislation the first sentence of Article 8(b) requiring that due regard be paid to cases of present or imminent emergencies that threaten or damage human, animal or plant health as determined nationally or internationally - gives explicit support to WHO decisions establishing different levels of pandemic threats and related national and international responses.

Secondly, the enabling clause in the second sentence of the Article indicates that the benefit sharing for pathogens is to be approached differently from the general principle of benefit sharing established in Article 5.1.

Response

First, the first sentence of Article 8(b) says no more than that due regard must be paid to cases of present or imminent emergencies as determined nationally or internationally. The determination is, as is almost always the case, within the province of national governments. Further, Article 4.3 clarifies, due regard -and no more -should (and not must) be paid to useful and ongoing relevant work or practices going on under relevant international organizations. However this is provided that the work is supportive of and does not run counter to the objectives of the CBD and the NP.

Secondly, the second sentence of the Article does not establish an approach to benefit sharing for pathogens that is different to that established for other genetic resources. The Article states that Parties may, when developing and implementing their national ABS law, take into consideration the need for expeditious access and expeditious fair and equitable sharing of benefits arising from the use of such resources. This allows Parties to consider whether or not to establish different procedures for access.

This of course allows Parties to the NP to arrive at solutions within the WHO on issues relating to ABS for pathogens. However, as this brief shows, these must be consistent with and not run counter to the objectives of the NP, in particular those relating to the fair and equitable sharing of benefits, including by appropriate access and by appropriate transfer of relevant technologies and affordable access to the vaccines.

V. Summary and Conclusion

Pathogens are clearly within the scope of the NP. Preamble 16 of the NP makes clear that pathogens are within the scope of the NP. Further the preamble does not exclude the application of the benefit sharing provisions of the NP. Indeed it cannot do so in the face of the express objective of the NP for the sharing of benefits. Also there is nothing in paragraphs 3 and 4 of Article 4 that makes the NP inapplicable to pathogens. Article 8(b) also does not establish a special benefit sharing regime for pathogens. The upshot is that :

1. A Party to the Protocol can develop a national law that deals with pathogens as a genetic resource and subject it to the ABS requirements.

2. A Party to the Protocol may also collectively enter into any obligation - including a material transfer agreement in international fora such as the WHO - that reflects the ABS objective of the Protocol. The Agreement must therefore include fair and equitable sharing of benefits arising from the utilisation of the viruses (which should be expeditious if access to the viruses is expeditious), access and transfer of relevant technologies in relation to developing vaccines for pathogens. The vaccines must be made available to developing countries at affordable prices.

3. A Party to the Protocol in developing its national law or administrative or policy measures is not bound to take into account any ongoing work or practice in the WHO relating to pathogens. It needs only to consider taking into account any such work or practice.

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