"Pathogenic" organisms: in or out of the International Regime?

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Biologists and ecologists know how crucial microorganisms are for biodiversity and ecosystem balance. Some CBD Parties are beginning to realise how important microoganisms are for regulating access and ensuring benefit sharing.

Meanwhile, some research institutions and industry have been collecting microorganisms from all over the world and conserving microbial collections. Increasingly they are also locking up more and more of these resources through patents and exploiting them commercially. Think of vaccines and diagnostic kits – these can end up costly for even the middle income and certainly unaffordable for the poor.

So it is not surprising that practically every industry submission to the ABS Working Group on the scope of the International Regime urges for the exclusion of "human, plant and animal pathogens". This included the Access and Benefit Sharing Alliance (ABSA), Biotechnology Industry Association (BIO), Intellectual Property Owners Association (IPO) and the International Chamber of Commerce (ICC).

Yesterday at the plenary session on scope, the European Union for the first time raised the possibility of excluding "particular pathogens" but there is no consensus yet to do so among the Member States.

Japan said that some "specific consideration" should be given to genetic resources under discussion in the WHO for public health.

In sharp contrast, the Group of Like Minded Megadiverse Countries announced that it will be providing a declaration on the ongoing negotiations at the WHO on the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. According to Brazil, the Group's Chair, "We believe this is an issue directly related to issues being discussed here (at the Working Group on ABS)".

Interestingly, when Parties sent in proposals for operative text over the last few months, all of them have been clear that microorganisms, some of them pathogenic to other species (including humans), will not be excluded from the Regime.

The focus on pathogenic microorganisms is triggered by the ongoing ABS negotiations concerning influenza viruses and vaccines derived from those viruses, at the World Health Organisation.

This was sparked by Indonesia's realisation in 2006 that its unconditional contribution of avian influenza viruses to the WHO network of laboratories (almost all in developed countries such as the US, UK and Japan) for public health purposes was being abused. There was shock that some of the laboratories were patenting gene sequences from viruses originating in Indonesia and other countries (such as China, Malaysia, Thailand, Vietnam and Panama), while the vaccine companies that accessed the virus strains were also sometimes patenting genetic material and definitely patenting the diagnostic kits and vaccines developed from the

viruses. There was also a considerable loss of confidence in the WHO as a "trustee" of the virus specimens and the interests of virus providing countries.

The issue of access and benefit sharing was thus pushed to the forefront at the WHO. Indonesia and some other developing countries asserted their sovereign rights over biological resources including microorganisms and invoked the CBD's third objective on fair and equitable benefit sharing.

At the World Health Assembly of May 2007, WHO Member States in Resolution 60.28 recognized the sovereign rights of Member states and stressed the importance for effective and transparent international mechanisms aimed at ensuring fair and equitable sharing of benefits. The Resolution also mandated the formulation of standard terms and conditions for virus sharing. The Intergovernmental Meeting (IGM) process was set up to reform the Global Influenza Surveillance Network that deals with the sharing of seasonal viruses and viruses with pandemic potential.

Its mandate: to ensure that the system is transparent and that the recipients of the viruses and specimens *("Pandemic Influenza Preparedness biological materials" or "PIP biological materials"*) provide fair and equitable benefits (e.g. vaccines, technology) to member states, in particular to developing countries, that tend to suffer a higher disease burden and need assistance to build research and technological capacity.

The IGM has met twice in November 2007 and in December 2008. At the December meeting, delegates considered the Chair's text by Jane Halton of Australia as the basis for negotiation. The outcome document of the December meeting (EB 124/4 Add.1 http://www.who.int/gb/pip/e/E_pip3.html) contains elements for a framework for virus sharing and benefit sharing. It also contains a Standard Material Transfer Agreement (SMTA) intended for use when flu viruses are being transferred to the recipients. The outcome document contains text on which there is consensus and text that is still in brackets and this is expected to be resolved at the ongoing informal consultations on 30 March to 4 April in Montreaux, Switzerland as well as the formal IGM in May in Geneva.

The outcome document currently has strong language on sharing of viruses but rather weak language on benefit sharing. Key benefit sharing proposals continue to remain in brackets. The principle of "fair and equitable" in benefit sharing is not consistently included in the operational part of the outcome document. There is already consensus that "member states have a commitment to share on an **equal footing**" flu viruses of human pandemic potential and the benefits (emphasis added). Analysis is needed on what this means for the CBD International Regime negotiations.

There has also been an attempt by most developed countries to ensure that the SMTA is incomplete and contains as many loopholes as possible to enable flu viruses to be shared with little or no restrictions. These countries have objected vehemently to any recognition of sovereign rights as well as insisted that the country providing biological materials have no ownership over those materials once the materials have been given to laboratories in the WHO network. *In fact these developed countries insisted in the December 2008 IGM meeting that intellectual property rights should be allowed to be claimed, over the biological materials and parts thereof as well as products developed from the use of the biological materials.*

We understand that right now in Montreaux some of the topics being discussed in the informal consultation include the role of industry; scope of the framework including the definition of “biological material”; intellectual property rights; relationship between intellectual property rights and the SMTA; and the role of the CBD.

Why are industry’s arguments unacceptable? First, the same microorganisms under different environmental circumstances or through evolutionary processes can be pathogenic, occasionally pathogenic or not pathogenic. Classification of “human, plant and animal pathogens” would thus be an elusive exercise.

We find the ABSA submission misleading in describing that “human, plant and animal pathogens” are “currently the subject of unrelated benefit sharing negotiations” in the WHO. The WHO negotiations are not as broad as claimed by ABSA, and it is a purely subjective stance to say the negotiations are “unrelated”.

BIO argues that “human, plant and animal pathogens, including viruses” are not within the scope of the CBD – on the contrary the definition of “biological resources” is clearly inclusive of all organisms, including pathogenic ones.

BIO, IPO and ICC all argue that inclusion of these organisms would contradict the CBD’s conservation objective. As we stated above, pathogenic organisms are an inherent part of biodiversity and are essential for the balance in ecosystems. There is no biodiversity without pathogenic organisms. What is central is the USE of an organism that triggers benefit sharing. Selected flu viruses, from which vaccines are derived, are a clear example.

Oddly enough the ones who do conserve pathogens (perhaps more then anyone else) is the pharmaceutical and biotechnology industry itself.

We cannot help but conclude that the only reason to exclude pathogenic organisms is an unwillingness to share benefits, the third CBD objective.

We therefore strongly call on Parties at this session in Paris to do the right thing and NOT exclude organisms, including pathogenic ones, from the scope of the International Regime.