

“Pathogenic” organisms: in or out of the International Regime?

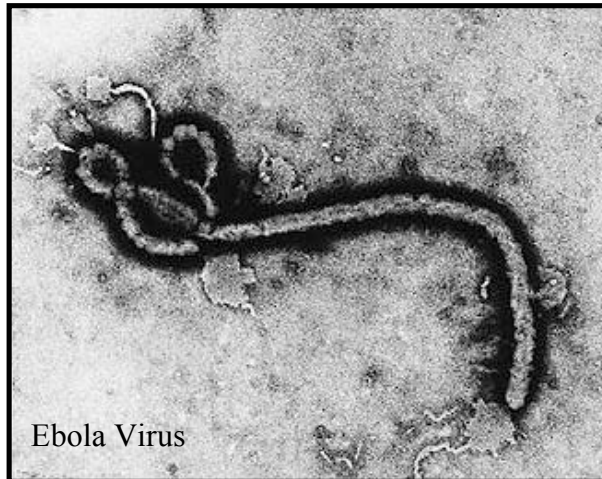
Chee Yoke Ling, François Meienberg and Christine von Weizsäcker

Biologists and ecologists know how crucial microorganisms are for biodiversity and ecosystem balance. Some CBD Parties are beginning to realise how important microorganisms 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 uses of pathogens” but there is no consensus



Ebola Virus

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.

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 make 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

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.

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Pathogenic organisms, continued from Page 1,

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 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 than 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.



Dr. N.D. Bracket and the Wailers

An Anthem for ABS (to the tune of No Woman No Cry)

Thank-you M[esse]r[s] Chairpersons,

Recalling [Bonn][Montreal][Kuala Lumpur][Bangkok][Granada][Curitiba][Montreal][Geneva][Bonn][Paris]... ohhh...[merciful god] let us count the [brackets][ways forward][meetings][airmiles][mojitos] M[iste]r[s]. Chairpersons.... in a moment of [absinthe induced] delirium it occurred to Dr. Bracket that after all of these years we are gravely in need of an Access and Benefit-Sharing Anthem. Yes, Mr. Chairpersons, a glorious soaring tribute to ABS in at least five movements that is easy to hum and dance [sway][jiggle][meander][stagger] along to.

We therefore invite delegations to join in a [competition] [set up][fix][conspiracy] to pen the most appropriate anthem for our deliberations. There will, of course, be a prize for the winning delegation, to be determined, under the [ancient] [unwritten] rules of procedure, by a wholly independent [biddable][persuadable][bribeable][babbling][objectionable] observer [Dr. N.D. Bracket]. Regional contributions are vital and we look forward to facilitated [You Tube] access to the All Star EU Member States Choir [come on EU... what is eternal EU coordination for... if not a giant sing along?]. Other regional contributions will also be welcome [the smart money is on Africa !] but watch out for the reconvened GRULAC Salsa contact group].

So, Mr Chairpersons, we offer the following to assist delegations with getting started [bets/bribes/inducements will be accepted by the suspicious character at the back of the room]. Please assume a Jamaican accent Mr. Chairpersons [ya man, dem brackets gonna go, sing, sing]*:

“No, [brackets], no cry; No, no [brackets], no cry; No, [brackets], no cry; No, [brackets], no cry.

Said - said - said: I remember when we used to sit; In the government yard in [UNESCO] [trenchtown] ; Oba - observing the hypocrites [yes, Brazil, everyone knows what you are up to]; As they would mingle with the good people we meet.; Good friends we have, oh, good friends we've lost; Along the way.

In this great future [please make it stop Mr. Chairpersons], you can't forget your past [Bonn][the Hague][Montreal][Kuala Lumpur][Bangkok][Granada][Curitiba][Geneva][Paris][er... where are we again?]; So dry your tears [Mr. Chairpersons], I seh. [All together now]. No, [brackets], no cry; No, no [brackets], no cry; ere, little darlin'[s][Mr. gorgeous Chairpersons], don't shed no tears: No, [brackets], no cry.

Said - said - said: I remember when-a we used to sit; In the government yard in [UNESCO]; [trenchtown] And then Prof. I.M. Awesome would set the [CBD handbook][Granada Annex] alight, As it was logwood burnin' through the night. Then we would drink [tequilas slammers] [caipirinhas] [gin fizz] [gallons of beer][particularly fine Chianti] [anything we could lay our hands on]; Of which I'll share with you; My feet is my [unstable] [only] carriage, So I've got to [stagger] [push] on through.

But while I'm [asleep] [comatose] [gone], I mean:

Everything's gonna be all right! [products and derivatives, just say yes]; Everything's gonna be all right! [indigenous peoples rights will be recognised, come on Australia...better late than never!]; Everything's gonna be all right! [EU will win regulated facilitated access]; Everything's gonna be all right! [patent disclosure requirements will be tied to incentives]; I said, everything's gonna be all right-a! [think open source and 21st Century rent based economic solutions]; Everything's gonna be all right! [a certain industry delegate may lose her funding/retire]; Everything's gonna be all right, now! [Parties will agree on binding and non-binding components]; Everything's gonna be all right! [Dulce et decorum est, pro ABS mori; preferably at the age of 102 on a nice beach in the Caribbean Mr. Chairpersons!].

So [one more time with feeling!], no [brackets], no cry; No - no, [brackets], no cry; [Distinguished delegados] [gorgeous women and sister[s] of ABS], don't shed no tears; No, [brackets], no cry; No, [brackets], no cry; No, [brackets], no cry; Hey, little darlin'[s][Mr. Chairpersons], say don't shed no tears; No, [brackets], no cry.”

Dr. N.D. Bracket [Ph.D. by photosynthesis][With thanks to Bob Marley] [Oppressed][Submissive][Underling][Chief] [Executive] [Secretary] [Typist] Not Always Entirely Like-Minded Mega Mega Diverse [group/agglomeration/abomination] NAELMMMD Secretariat [~~The Broom Cupboard~~] UNESCO, Paris

* Those not familiar with the tune should consult the following <http://www.youtube.com/watch?v=hg2n039txnk>

Call by Civil Society Organizations - 7th Meeting of the Working Group on Access and Benefit-Sharing

Half a generation of postponing the implementation of one of the three objectives of the CBD has served the spread of organized biopiracy. There is no excuse for further delays. The negotiations now are neither about gap analysis, nor about studies, but about political will and countries' positions.

Civil society will witness the negotiations and name and - if necessary - shame governments who continue to obstruct the negotiations and violate their responsibilities under the CBD.

Our main concerns on some of the key aspects which will be negotiated at this meeting are the following:

On Scope and Definitions

The definition of "use of genetic resources" has to guarantee that all benefits derived out of genetic resources are covered by the International Regime. Substantive benefits, especially for the pharmaceutical and cosmetic industries, are derived from metabolites. In addition, screening is much cheaper and faster, if based on genetic resources with traditional knowledge on their biological activity. Therefore the following uses have to be included into the definitions, thus affecting the scope of the Regime:

- Screening that makes use of genetic resources and traditional knowledge
- Extraction of metabolites
- Chemical synthesis of metabolites
- Synthetic analogue chemicals inspired by naturally occurring metabolites

On Access

We want to point out problematic clauses in the access standards proposed by the European Community. For instance: Respect for customary law and community decision-making processes is crucial. A short time frame and any strong financial restriction for obtaining PIC in the EU proposals run counter to adequate and credible process for reaching Free

Prior Informed Consent by indigenous peoples and local communities.

On Compliance

The growing link between public and commercial research, the shortening of the time-span between basic research and application, and the increasing number of patents filed by public research institutions make it obvious that the research sector cannot be naively exempt from full ABS obligations.

In order to ensure compliance, strong legal measures in user countries are essential. Check points have to be established, such as research funding and publications for non-commercial research and, amongst others, disclosure of compliance in Intellectual Property Rights Applications and applications for market approval.

In this regard we congratulate India for elaborating strong operative text on Intellectual Property Rights and Disclosure.

Affordable access to justice for all has to be guaranteed by a mechanism inside the regime.

We support many of the creative proposals for operative text brought forward by the African group regarding for instance:

- promoting and securing the rights of indigenous peoples and local communities, especially by community protocols
- linking access to sustainable use, also in the context of patents

Civil Society Organizations look forward to all opportunities to discuss these and other topics with delegates over the coming days.

Please note: this statement does not represent the views of all civil society, it emerged out of discussions between some NGO actors present at the 7th meeting on ABS, and was developed for the opening statement for NGOs present at the meeting.

