INB related interactive dialogues
Topic 1. Article 12 (Pathogen Access and Benefit-Sharing System)

Discussion questions proposed by the Bureau for resource persons

28 August 2024

About the Author

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At Covington, Bart Van Vooren has built a unique legal practice focusing on Access and Benefit-Sharing ("ABS"). Since 2013, I have advised on a whole range of ABS legal issues including, *e.g.* ABS permit filings in 'provider' countries; 'user' country compliance checks (*e.g.* EU, UK, Switzerland); due diligence programs; M&A transactions; supply, licensing and R&D agreements; and patent filings and disclosures. By my last count there are more than 100+ ABS regulations globally.

This submission provides my personal views based on my experience as an attorney. The submission is made in my personal capacity and not on behalf of any client.

1. **PABS and Nagoya Protocol related matters**
   If Member States reach consensus on the PABS instrument during the negotiation, including that its design is consistent with, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, and the INB decides that PABS can be recognized as a specialized international access and benefit-sharing instrument (SII):

   1.1. Can PABS, as SII, be universally applied to all Parties to the Pandemic Agreement, i.e. both Parties and non-Parties to the Nagoya Protocol?

PABS v Nagoya: Article 4(4) NP states that where an a specialized ABS instrument is consistent with the objectives of the CBD and Nagoya Protocol, "*this protocol does not apply for the Parties to the SII*" to those resources and for the purpose of the SII. This language is straightforward, binding, and effective for all 141 Nagoya Protocol Parties. All Nagoya Protocol Parties that will ratify or accede to the Pandemic Agreement ("PA") are fully sovereign. In my view, there is no need for a "recognition" of SII status by an international body like a COP. On the basis of a country's sovereignty, in my view, all that is needed under public international law is a statement in the preamble of the PA that, insofar PA Parties are also Parties to the Nagoya Protocol, that these countries "*recognize and confirm that the PABS is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol.*" That statement will have legal effect for the countries that become parties to both PA/PABS and NP. For countries that are not parties to the NP, the issue of Nagoya is simply not relevant. Hence, PABS can be universally applied.

PABS v CBD: The issue for CBD vs PABS is slightly more complicated. In order to pre-empt friction between PA/PABS and the ongoing negotiations for a multilateral mechanism ("MLM") on Digital Sequence Information ("DSI") under the CBD, the PA should also expressly confirm that the PABS is a specialized instrument to the CBD. While there is no express provision on SII in the CBD, that agreement dates from 1992 when the human genome was not even sequenced. Hence, *anno* 2024, it is

appropriate to apply an "evolutive" interpretation to CBD, and to include such a recognition in the PA and PABS. The latest draft COP16 decision from WGDSI in Montreal in August 2024 (available here), though bracketed, recognizes at paragraph 25 that there should be mutual supportiveness with other ABS instruments. Hence, such an evolutive interpretation and approach to avoid fragmentation of international law is permissible and in line with the countries' expressed wishes.

1.2. What criteria and/or mechanism(s) are to be used for the recognition of PABS as a SII?
- For Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- For non-Parties to CBD and the Nagoya Protocol who are Parties to the Pandemic Agreement?
- What domestic legal arrangements are needed, such as amendment of national ABS laws, to recognize PABS and ensure that PABS materials are not subject to additional or different PIC and MAT ?

The mechanism: The sole "mechanism" required for the recognition of PABS as an SII is the exercise of sovereignty by the Parties to PA/PABS that are also Party to CBD and the Nagoya Protocol. By the act of ratifying the PA, any country that is party to both PA/PABS and CBD/Nagoya will have legally confirmed that the PABS is an SII. Since such ratification is binding under international law, they will then have the legal obligation to amend any relevant national (ABS) legislation as is necessary and appropriate in their own legal systems.

The criteria: The sole substantive criterion for recognition as an SII should be whether "benefits are fairly and equitably shared." This is the essence of what is being negotiated in the PABS. Once political consensus has been achieved within INB, in the exercise of their sovereignty, the countries will express their legal agreement through the act of ratifying the PA that PABS will ensure equitable benefit-sharing in global public health.

Domestic legal arrangements: As a lawyer with 10+ years of experience in ABS, I have observed that there are currently more than 100 ABS laws (!) in the 192 Parties to the CBD. Many, though not all, of these ABS laws will need to be amended following adoption of PA/PABS.

The ABS law of France is a good example of how PABS can be implemented into national law. Article L412-5 of the French environmental code contains the general ABS regime: registration for non-commercial use, authorization for commercial use. Section III of that Article confirms in 5° that the general ABS regime does not apply to "*genetic resources collected by laboratories with the goal of prevention and management of significant risks to public health*" and that instead these are "*covered by Article L1413-8 of the public health code.*" In France, getting an ABS registration for non-commercial use can already take more than 6 months. Very wisely, Article L1413-8 of the Public Health code does **not** impose prior informed consent on access to pathogens. Access is not restricted, and the only obligation it imposes is that "*any private or public laboratory must send samples of infectious agents or biological material to a national reference centre.*" By decree, France can adopt additional measures to implement this article of the Public Health Code. Hence, should PABS adopt a system where access is unrestricted, but additional obligations as to benefit-sharing should be implemented, the French law provides an appropriate legal basis. Conversely, should PA/PABS impose prior informed consent on access to pathogens, France's ABS law would arguably not allow it, and it would require amendment.

1.3. During the INB negotiations, what are the considerations that should guide the INB so as to maintain coherence between the future PABS and the Nagoya Protocol?

For the reader's background, I am a partner with the law firm Covington & Burling LLP, where I lead a the global practice on ABS. While I am answering this survey in my personal capacity, for more than a decade I have advised many of the world's leading innovative pharmaceutical companies on ABS. Through this work, I have knowledge of many demonstrated instances of ABS laws resulting in delays or refusals to access samples or data on pathogens for R&D by public and private entities: Seasonal Influenza, Pandemic Influenza, Zika, SARS-CoV-2, African Swine Fever, Foot and Mouth Disease, Dengue, Chikungunya, Japanese Encephalitis, and Ebola.

From a user perspective, a major challenge is lack of transparency, predictability and certainty on the applicable ABS obligations. One issue that I have seen often with pathogens is the question "where they are *from*" and what ABS law applies. Therefore I am very concerned that PABS and Nagoya will create co-existing legal obligations that will create friction. During SARS-CoV-2, this attorney dealt with real life questions about physical samples having been extracted from a severely ill COVID patient in an EU Member State, who had recently returned from Brazil. Under Brazil's ABS law, the sample extracted in Europe is considered its "genetic heritage" and benefit-sharing would be required. Under the EU country's national legislation, ABS did not apply (see, for instance, the example of France in question 1.3 above). The user therefore had to take a decision as to which ABS regime applied? The authorities in both countries had contradicting views as to the issue of "extraterritorial reach" of ABS laws and the basic principle of sovereignty under international law…! Thus, I predict there will be situations where a sample could either fall under PABS or Nagoya ABS laws depending on e.g. the country where the material was isolated. This is guaranteed to cause delays.

To give another example, I had one assignment where a single product that combined physical materials and DSI triggered no less than 50 different ABS laws. That is what modern R&D looks like: there is no simple 1-to-1 relationship between product and genetic resource/sequence. How is a user reasonably supposed to comply with 50 ABS laws? How is one supposed to resolve conflicting claims between them? How does one reconcile the potential stacking of 50 benefit-sharing obligations with commercial viability? The unfortunate solution, in that case, was to eliminate all materials that could trigger ABS laws, and only use the "ABS unburdened" materials. That is a decision not made out of "unwillingness to share benefits" by the nefarious private sector; but the straightforward result of being presented with an unworkable spaghetti bowl of ABS laws.

Therefore, the PABS must rectify the deep flaws of the CBD and the Nagoya Protocol. The PABS should not reproduce the "bilateral" model of PIC and MAT under the Nagoya Protocol, and the INB should agree an innovative approach of open sample and data-sharing, while still legally triggering equitable benefit-sharing by countries and public/private research entities. In my view, the French law provides a real-world example of how it is legally possible to ensure unobstructed pathogen-sharing while imposing binding requirements when doing so (see question 1.2). In question 2.3 below I provide further suggestions based on the Swiss ABS law.

1.4. Are there any specific issues in the PABS under ongoing INB negotiations that may prejudge the ongoing discussions on the handling of DSI within the CBD and the Nagoya Protocol?

No. In Montreal in August 2024, the Parties to CBD were clearly converging on an understanding that the COP16 Decision operationalizing the multilateral mechanism for DSI will be "non-binding" and only "soft law". Therefore, the legally binding PABS will not impact the CBD DSI process.

1.5. In principle a non-Party to PABS who is a Party to the Nagoya Protocol could view that PABS is not 'consistent with and not run counter to the objectives of the CBD and the NP'. In this case, is the non-Party to PABS that is affected by the conclusion of a SII entitled to dispute settlement under Article 27 of the CBD?

Yes. The non-Party to PABS could consider the question of compatibility between PABS and CBD "a dispute between Contracting Parties concerning the interpretation and application of this Convention" under Article 27.1 CBD.

1.6. What are elements or designs of PABS that would be inconsistent with and run counter to the objectives of the CBD and the Nagoya Protocol?

2. Issues related to access to PABS materials and sequence information

2.1. What are the current most up-to-date progresses in CBD on definition and scope of digital sequence data (DSI)? Will the current negotiated text using "sequence information" contradict/hamper the ongoing negotiation of the CBD?

The CBD and the PABS both lack a definition of DSI. This is a major problem for users, as this definition is essential to understand the scope of application either ABS regime.

I propose that the PABS uses the definition from the PIP Framework under point 4.2 which reads: "*Genetic sequences means the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus.*"

2.2. What are the effective technical or operational measures to ensure all users (primary users and secondary users shared by primary users) of materials and sequence information account to benefit sharing arise from the use of them?

Please see my proposal in question 2.3 below.

2.3. What are the effective "traceability" measures which ensure users of materials and sequence information account to benefit sharing obligations?

Traceability at the level of each individual sample or each individual sequence, purely for the sake of enforcement of benefit-sharing, imposes a major human and financial resource cost on both the (WHO) administrators of the PABS, as well as the users of the PABS. It would require a system such as the Influenza Virus Traceability Mechanism (IVTM) that also supports the PIP Framework. Expanding such a system to cover many more pathogens would be extraordinarily costly. If it would support global surveillance, the investment of human and financial resources would be justified. Purely for the purpose of enforcing benefit-sharing, it would not.

As a possible compromise landing zone, and purely in my personal capacity, I invite the INB to explore modeling the PABS on the ABS laws of France (see question 1.3) **and Switzerland:**

I quote key provisions from Switzerland's ABS legislation:

- Article 8 (3) of the Swiss Nagoya Ordinance requires that "[t]*he user must notify the* [Swiss authority] *of the information* [on the user and the resource accessed] *before market approval or, if such approval is not required, before the commercialization of products developed on the basis of utilised genetic resources.*"
- Under Article 8 (5) of the Nagoya Ordinance, "[t]*he user receives a register number as evidence of the notification and, on request, an attestation to the effect that the Swiss provisions on access and sharing of benefits have been complied with.*"
- Under Article 3 (4) of the Nagoya Ordinance, it states that "[i]*n an internationally or nationally recognized emergency that threatens the health of humans, animals or plants or the environment, it suffices if the due diligence requirement for the utilization of genetic resources that are pathogenic or harmful organisms is fully met at the time of the commercialization of products developed on the basis of the utilized genetic resources.*"
- Finally, under Article 4(5), "[a]*s part of the market authorisation procedure, the user must specify to the competent authority … whether the product to be commercialised has been developed on the basis of utilised genetic resources subject to due diligence and notification requirements, and where applicable, the register number.*"

The Swiss (and French, see above) approach to ABS is recommended because it does not impose an administrative obstacle on the access to the sample or data; while still imposing obligations at a later time. A user is free to physically acquire, or download, the material; and can start the R&D, as long as before commercialization the Swiss authority is notified. This is in contrast to many other ABS laws of the world. In many ABS laws (I prefer not to name them), R&D on the pathogen sample or data could not start unless a permit is first obtained. Since ABS administrative procedures can take months and longer, this causes delays or shifts the focus of R&D. In global public health, even a single day lost in admin costs lives.

The Swiss approach has been shown to work in practice. For seasonal influenza, the WHO makes a recommendation on vaccine composition every six months. In case a Swiss sample has been shared through GISRS, the Swiss National Influenza Centre will have notified it to the Swiss authority. The register number will "accompany" that sample, so that subsequent users – e.g. the reference labs and vaccine manufacturers, can use that registration number to demonstrate compliance with the Swiss ABS law.

In short, the PABS should be modeled on open sharing (like in France), or at most a simple notification (like in Switzerland) by the public or private user, to a single central authority. This notification can occur at any moment, so long it is prior to commercialization. Subsequently, the legally binding benefit-sharing obligation can be laid down in the national ABS law implementing PABS, and would be triggered in case there is commercialization. This would give the authority and the relevant public or private user to flesh out the details of benefit-sharing without obstructing life-saving R&D.

3. Issues related to benefit sharing

3.1. What are the positive or negative consequences to manufacturers should a PABS system be established in which there are a legally binding benefit sharing requirements to allocate certain percentage of vaccines, therapeutics and diagnostics (VTD) on a free-of-charge basis and at not-for-profit prices, as well as annual monetary contribution?

As demonstrated under question 1.3, legally binding benefit-sharing *per se* is **not** the problem for manufacturers. It is the administrative and legal complexity that precedes it.

In my ABS legal practice, I have had the unfortunate privilege of witnessing first-hand how getting ABS wrong results in stifling R&D for public health. I have seen delays in vaccine production, and I have seen vaccines that well be less-than representative of global epidemiology. Therefore, getting PABS wrong is not merely a problem for companies but a major societal problem. As it stands, I am deeply concerned that PABS is likely to complicate pandemic preparedness.

To give one example. In your question, you refer to allocating "a certain percentage" of VTDs. While setting a percentage may be diplomatically and politically elegant, from a scientific and manufacturing perspective, it does not make sense. The allocation should not be a static percentage, but should be a dynamic figure that is adapted to the geographic and population needs, the timing and phase of the pandemic, while taking account of the intricacies of pharmaceutical manufacturing in compliance with (e.g. FDA, EMA) regulatory requirements. When industry questions the wisdom of a percentage, negotiators and NGOs should understand that they are not doing so because they're "against equity" or "not willing to contribute", but because they want the PABS to take account of these real-world complexities.

In short, may I implore the INB: do not create a huge administrative machinery simply out of mistrust for the private sector.

3.2. Would the manufacturers and commercial users of materials and sequence information consider not using the PABS system because of this required contribution?

You are asking the wrong question. Manufacturers and commercial users would not "consider not using the PABS system" because of the *contribution*. They (and public entities!) would consider not using PABS because of the *administrative burdens* it imposes. I am quite certain that users will not use PABS if it is disproportionately complex, if it does not provide legal certainty, and if it does not match the reality of pharmaceutical R&D. I should add that I have knowledge of public research entities that avoid ABS procedures under the Nagoya Protocol because they are too complex and burdensome.

Means to incentivize public and private users to participate in the PABS are:

- (1) ensure a legal guarantee that compliance with PABS implies the non-application and full compliance with any and all other ABS laws under the Nagoya Protocol and the CBD. I am confident that if the PABS can offer this, that many users would voluntarily sign up to it without there being a legal obligation to do so;

- (2) provide up-front predictability on cost, proportionate to the pharma sector's at-risk investment into R&D;
- (3) create a system that companies are not demonized but are publicly recognized for their contribution to global health;
- (4) ensure a low transaction cost through a single-window, cost-effective, and publicly accountable PABS.

I do not speak on behalf of the pharmaceutical sector, but I've worked with them closely for many years. Companies have shareholders, and investments are made to turn a profit. *C'est la vie.* But company employees, all the way up to CEO level, are not "merely in it to make money." The same even goes for a lawyer at a big US firm! Companies are people, and they all care deeply about public health-- just as much as WHO staff, health attaches, or NGOs. The private sector is very willing to look at discovery and development in an open-minded way, even where there are no obvious commercial market opportunities. They are also willing to contribute financially. But the design of the system matters a lot. The result of PABS cannot be grind public and private R&D to a halt; or to create a new bureaucracy that would absorb money with no clearly identifiable and accountable results.

3.3. If not a PABS system, are there other options which could facilitate rapid and timely sharing of materials and sequence information, and on an equal footing, sharing of monetary and non-monetary benefits arising from the use of materials and sequence information, and incentivize greater manufacturer participation? Would any of these options be preferable to a PABS system?

The GISRS ecosystem is the model to aspire to. The "benefits" arising from the "sharing" of samples and data between GISRS members and with non-GISRS members, include e.g. year-round surveillance on influenza epidemiology, updated lab reagent kits, updated reference and candidate vaccine viruses; and the resulting, updated vaccines for the Northern and Southern Hemispheres based on the bi-annual WHO recommendation. GISRS is a close and organic collaboration between the public and private sector, and a model of collaboration based on trust for the greater good: public health.

3.4. What would be appropriate and sufficient triggers for such benefit sharing under a PABS system?

Please see my suggestion under question 2.3 below. I believe that the French and Swiss ABS laws provides a orkable model for triggers that do not hamper the rapid and timely sharing of materials and sequence information. The key is to keep administrative burdens as low as possible, and to ensure that any negotiation on benefit-sharing can progress at a time and in a way that does not obstruct the speed and agility of the scientific process.

3.5. Should benefit sharing of VTDs cover: a) PHEIC, b) pandemic emergency, c) pandemic? What would be the public health impact of each of these options?

In my view, different triggers should result in different obligations. For instance, a PHEIC could trigger a request to screen a product portfolio or library of molecules for potential against the pathogen; whereas the pandemic could trigger the allocation of authorized and efficacious product against the pathogen.

3.6. How should the duration of the benefit sharing of VTDs be determined?

I am convinced that given if PABS is appropriately designed, companies would be willing to conclude legally binding multi-year commitments. Such legal commitments would need to take account of the commercial reality in which companies operate - such as licenses or transfers of assets, decisions to steer R&D into different areas, decisions to amend or terminate development or exploitation, and so on. A typical period would be two years, renewable as needed.

3.7. Is it necessary to make a reference to the Biological and Toxin Weapons Convention and, if so, what would need to be considered for the development of a PABS system that is consistent with the objectives of this Convention, in particular its article 10?

No comment.

3.8. What are the differences, in terms of legal obligations of those participating in a PABS system, between two terms: a) "benefits arising from the sharing (of material and sequence information)"; and b) "benefits covered by the PABS system"?

This question is Pandora's Box. First, it depends on how you define "those participating in a PABS system." Would you consider that entities that participate in GISRS, like the national influenza centers (e.g. Geneva University Hospital) or collaborating centers (the U.S. Centre for Disease Control) "participate" in PABS? They are certainly active in "sharing" materials, so do they have benefit-sharing obligations? Second, what "benefits" are we really talking about? Somehow, in all my years of experience, when public entities seek "benefit-sharing" from private users, what's really at stake is money. As a result, ABS seems to have turned into the a highly complicated global taxation regime on R&D with biological resources. This focus on "benefits as money" completely ignores the real benefit: the availability of global epidemiological data, and efficacious vaccines or therapeutics is far more valuable than any cash payment. As mentioned, GISRS is a well-functioning public - private collaboration that demonstrates that "benefit-sharing" for public health should be viewed holistically.

The Pandemic Agreement speaks of achieving "equity", but does not define it. INB should go back to the essence: what is the problem that PABS is seeking to solve? Equity in VTD distribution? Equity in VTD discovery? Reinvent the global market economy?

If PABS is about making sure that samples and data are shared globally, there should be legally binding obligations on public laboratories and countries to share. That did not happen consistently during COVID-19. In addition, if PABS wants to achieve equitable global distribution of VTDs, it should not only request an allocation from companies; but also impose legally binding obligations on countries as regards fair allocation and free trade (see question 3.10).

3.9. Are the expressions "benefits arising from the sharing", used in the PIP Framework, and "benefits arising from the utilization", used in the Nagoya Protocol synonymous? If not, what are the consequences of each for the PABS system?

No, they are not. The consequence for users is to make ABS nearly unworkable in practice.

In the context of ABS, concepts such as “access”, “sharing”, or “utilization” are often used and confused. This is one of the major legal challenges for users seeking to comply with ABS regimes, given that diverging definitions often leads to conflicting scopes of application. I will illustrate for both the Nagoya Protocol and the PIP Framework.

First, article 2 of the Nagoya Protocol defines utilization as “[to] *conduct research and development on the genetic and/or biochemical composition of genetic resources.*” In principle, ABS laws implementing the Nagoya Protocol should only apply if a public or private entity conducts “utilization”, i.e. conducts R&D, of a genetic resource. Unfortunately, in practice, there are significant differences in the definitions of “utilization” in the 100+ national ABS laws. For example, the definition of “utilization” in Costa Rica and Switzerland are identical to that of the Nagoya Protocol. In contrast, India’s ABS law requires a permit to obtain “any biological resource” for “commercial utilization”. This imposes payment obligations on all trade in biological resources, which, in my view, violates WTO trade law. But that is the topic of another conversation. In Brazil, the term “access” is defined as “utilization”. Finally, France’s ABS law defines “*utilization of genetic resources*” in line with the Nagoya Protocol, but then adds that it also covers the “*valorisation of genetic resources, the applications and commercialization that results from it.*” Finally, the European Union has published in 2021 a guidance document of 68 (!) pages to explain the meaning of “utilization” under its Regulation 511/2014.

In short, there are 100+ ABS laws in Parties to the CBD, resulting in 100+ partially overlapping and diverging definitions of “utilization”. The point is this: it makes complying with ABS an extraordinarily difficult task. Benefit-sharing with lawyers is guaranteed; benefit-sharing for biodiversity conservation, not so much.

Second, the PIP Framework is built on the GISRS ecosystem to share pathogens. It is a model of collaboration based on trust for the greater good: global public health. When I was interviewing stakeholders for the 2023 study on “global disease surveillance and pathogen-sharing”, a recurring theme was that the application of ABS has led to an increased “politicization” of pathogen sharing in GISRS and beyond. Multiple interviewees from diverging backgrounds ascribed to the view that “*politics appear to have replaced science and common sense.*” In this context, I wish to stress that interviewees from various backgrounds and who publicly would be seen to represent “opposite” sides in the global health arena, in the confidence of an anonymous interview, broadly ascribed to the view that the transactional approach to ABS fostered by the CBD and Nagoya Protocol does not work in the context of pathogen sharing and public health. ABS as implemented under the Nagoya Protocol causes delays. Delays cost lives. One interviewee explained it as follows: the Nagoya Protocol employs a transactional model to attach value to a public good. Namely, biodiversity is a public good. By making it obligatory to share benefits deriving from utilizing that public good (biodiversity), the owners of the public good (i.e. the provider countries) have an incentive to protect biodiversity as it provides them with a source of monetary and non-monetary benefits. Applied to pathogens, that model fails. The public good that should be protected is global

health, but pathogens are a "public bad" that should be eradicated. The PIP Framework, for all its imperfections, did get that right: in essence, it contains a presumption of prior informed consent so that no access permits are required for the sharing of influenza samples.

In conclusion, PABS should make sure that it does not attach value to "protecting" the public bad (*i.e.* the pathogen), but not to protecting the public good (*i.e.* global health). Effectively, countries should not be incentivized or permitted "pre-condition" access to pathogens to obtain non-monetary and monetary benefits, to the detriment of public health.

3.10. What are the WTO rules that should be taken into consideration, if any, in the design of a PABS system? Can Member States limit the export of VTDs that are identified as benefits arising from the PABS system, in light not only of the obligations agreed upon by parties to this system, but also of the public health goals emanating from it?

In my view, at least the following rules should be taken into account when designing the PABS, as well as any national implementing legislation by the Parties:

- Not to maintain regulatory export restrictions (*see* Art. XI of the General Agreement on Tariffs and Trade - "GATT");
- Not to impose fees and charges on exports other than duties and taxes, specifically not to impose charges that function as an indirect taxation of exports for fiscal purposes (*see* Art. VIII.1.a GATT);
- Not to maintain technical regulations that are more trade restrictive than necessary to fulfill a legitimate objective (*see* Art. 2.2 of the Agreement on Technical Barriers to Trade, or the "TBT Agreement");
- Not to create *de facto* or *de jure* disadvantages for companies seeking patent rights linked to biological resources as compared to other fields of technology, or disadvantages due to the place of invention (*see* Art. 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, or the "TRIPS Agreement");
- Not to interfere unreasonably with the exclusive rights of a patent holder and not to hinder unreasonably the normal exploitation of a patent (*see* Art. 30 of the TRIPS Agreement).

4. Legal issues related to the adoption of PABS system

4.1. What are the implications of adopting a PABS system under articles 19 (e.g. as a Protocol), 21 or 23 of the WHO Constitution?

From a user perspective, either option requires implementation into national ABS laws. However, the international legal instrument that provides the greatest level of legal certainty and a harmonized approach in applying PABS is preferable. Therefore, a Regulation under Article 21 WHO Constitution may be preferable, so as to create the greatest coherence in application and governance alongside the recently amended the International Health Regulations.