doi:10.1017/amp.2021.159

2021 DETLEV F. VAGTS ROUNDTABLE ON TRANSNATIONAL LAW PANDEMIC VACCINES: MARKET PRODUCTS OR GLOBAL PUBLIC GOODS?

This panel was convened at 1:45 p.m., Wednesday, March 24, 2021, by its convenor, Gian Luca Burci of the Graduate Institute Geneva, who introduced the presenter, Mark Eccleston Turner of Keele University School of Law, and the panelists: Yuvraj Dalvi of the Serum Institute of India Pvt Ltd; Suerie Moon of the Harvard Global Health Institute; and Beatriz Thome of the Federal University of São Paulo.

Introductory Remarks by Gian Luca Burci*

Hello. Good morning. Good afternoon. Good evening. My name is Gian Luca Burci. I am an adjunct professor of international law at the Graduate Institute of International and Development Studies in Geneva, and in my former professional life, a lawyer in the United Nations system for almost thirty years, including ten years as legal counsel for the World Health Organization (WHO).

It is my pleasure to introduce this roundtable, and I want to extend all my thanks to the American Society and to the family of Professor Detlev Vagts for making this roundtable possible, in particular, because it gives an opportunity for young scholars to present their work in progress and to receive feedback from a panel of commentators.

As you can see from the title, the roundtable is about "Pandemic Vaccines: Market Products or Global Public Goods?" There could not be a hotter topic that involves us individually and as a community. As you see from the media and from scholarly and policy discussion, a lot of attention goes to the question of allocation of equity, vaccine nationalism, manufacturing, which vaccines are safe, which vaccines are unsafe, and so on.

But today we look at a different angle, in particular, the fact that to produce a vaccine, you need to have access to a sample of the pathogen or the genetic sequence of the pathogen, and that, in turn, has its own international legal regulations, in particular, biodiversity law. This has generated quite a number of problems and controversies and interesting issues that have closely involved the public health community.

To introduce the topic and present his paper today is Dr. Mark Eccleston Turner. Mr. Eccleston Turner is a lecturer in law at Keele University in the United Kingdom, and his specialization in particular is on international law and communicable diseases, but in particular he has published extensively on vaccines. He has consulted with WHO on this topic. His paper is coauthored with Dr. Michelle Rourke, who cannot be here with us today; she is a CSIRO Synthetic Biology Future Science Fellow at Griffith University Law School in Brisbane, Australia, and a former officer of the Australian Army.

Without any further ado, I give the floor to Mark.

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Remarks by Mark Eccleston-Turner*

Thank you, Gian Luca, and thank you to the Vagts family for having me today and to the American Society. As Gian Luca said, this is a work in progress and these remarks are made on behalf of myself and my coauthor, Dr. Michelle Rourke, of Griffith University, though any errors are mine alone.

As Gian Luca outlined, pathogens play a vital role in public health research. Effectively combatting emerging and reemerging infectious diseases requires a coordinated international response, including testing, surveillance, risk assessment, and the development of strain-specific vaccines and other medical countermeasures. Each of these vital activities relies on prompt access to pathogens, and the international scientific community has been sharing pathogen samples informally for decades, monitoring the change in genetic sequences, and hoping to detect a pandemic strain before it starts to take hold in the human population.

But this soft global norm of informally sharing pathogen samples for scientific research and development has been eroded, and pathogen sample transfer is becoming increasingly formalized through a policy called "access and benefit sharing," or ABS. The ABS legal landscape is dominated by the Convention on Biological Diversity and its supplementary agreement, the Nagoya Protocol. The CBD and Nagoya are binding international instruments on contracting parties that aims to ensure that the benefits arising from use of genetic resources are shared in a fair and equitable way, and it does this by introducing a form of property rights over biological resources and allowing contracting parties to control access to those genetic resources. The ABS mechanism originates in the bioconservation space, but has now been extended beyond bioconservation and into international public health governance. It is our argument today that it is not fit for purpose in this space.

The extension of ABS from biodiversity into public health has most clearly occurred through the WHO Pandemic Influenza Preparedness Framework, or the PIP Framework. PIP codifies the use of the ABS transaction in the public health space with WHO acting as a multilateral mediator sitting at the center of a constellation of transactions between member states providing samples, and third-party users of influenza viruses with human pandemic potential. This transaction is framed as being particularly appealing for developing countries who, in a pandemic, may not be able to secure access to vaccines through purely commercial arrangements. These countries also happen to be the site of the most emerging and rare and, therefore, at a scientific and transaction level, valuable influenza strains.

However, PIP does not challenge the sovereign rights of countries over pathogens. In fact, it actively embraces sovereignty. Countries can exercise their sovereign rights over their pandemic influenza viruses by choosing to share their viruses *either* through the multilateral PIP Framework, or they can enter into a bilateral access and benefit-sharing arrangement through the CBD and the Nagoya Protocol. In fact, they can do both simultaneously. Either way, pathogen sharing, be it via the PIP Framework, the CBD, or Nagoya, is a transaction, the exchange of a pathogen sample for a benefit, one thing in exchange for something else.

These transactional approaches are meant to encourage developing countries to use their pathogen genetic resources as bargaining chips to secure enhanced access to diagnostics, medicines, and vaccines, and the mediating role of WHO in the PIP Framework is intended to deliver a more global, equitable solution that does not just benefit the country of origin or the party accessing the sample.

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https://doi.org/10.1017/amp.2021.159 Published online by Cambridge University Press

On the surface, this sounds like a good solution, a win-win, but the ABS transaction applied to pathogens introduces market solutions to what were two previously separate problems—the first, the need for public health researchers to secure access to novel pathogens for research; and second, the scarce availability of vaccines and other medical countermeasures during a pandemic, where rich countries dominate access and leave developing countries to fend for themselves, with limited or no access. In this paper, we argue that these are actually allocation efficiency problems, and the market-based solution of ABS that was designed to address a market failure in biodiversity is not the right approach to addressing this public health problem. Instead, linking these two public health problems through an ABS transaction solves neither problem.

It is important to recognize that ABS was never just about biodiversity conservation. It is also supposed to deliver fairness, equity, and redress some historical injustices, especially in post-colonial settings. Historically, botanists and natural scientists from the Global North traveled to the Global South and extracted local biological resources and plant and animal species without seeking permission from either the local community or the national government. They essentially saw these biological resources of the Global South as public goods. These biological resources were then expropriated to the Global North where they were used for a range of applications, from medicine to *objets d'art*.

These exploitative practices continue to this day when it comes to pathogens. There are very clear recent examples of exploitation in the field of public health from H1N1, Ebola in West Africa, Zika, and MERS, and we do not seek to downplay or minimize the exploitation of these marginalized people at the hands of researchers. But ABS has done little to achieve its goals in biodiversity conservation, and we do not believe that it can achieve its goals in public health. We are increasingly alarmed by the continued push toward using ABS in public health, where the incentives and goals are very different from those in environmental conservation.

At the moment, WHO is engaging in a process of researching pathogen-sharing practices and analyzing the potential impact that the Nagoya Protocol will have on public health. This process started in 2009, and there are discussions at WHO and in other forums about extending the PIP Framework to include other pathogens, using PIP as a model for multilateral ABS for all human pathogens or creating an entirely new multilateral ABS framework for pathogens. We think this is a bad idea for a host of reasons, and I will spend some of my time outlining some of what these are.

Now, whether bilateral or multilateral, pathogen ABS is a transaction. It is a quid pro quo, something in exchange for something else, and bilateral pathogen ABS means that benefits accrue to those who are best placed to negotiate them, and not to those who would benefit most from them. While multilateral pathogen ABS may be better equipped at pooling some benefits to distribute those to nations most in need during an emergency, it is always going to be vulnerable to nations acting outside of multilateral arrangements and engaging in bilateral ABS, which may be more beneficial for the country in question but not the world.

One of the key problems with ABS transactions is that they pit each party against each other in an adversarial process with opposing incentives, and while the providers and users of pathogen samples have some common interests, such as reducing transactional costs, there is a much stronger opposing interest. Each stakeholder is looking to maximize their gains and minimize their costs. Providers of sovereign pathogen samples want to maximize benefit sharing, whereas users would want to minimize benefit sharing. The PIP Framework was meant to ensure that this transaction was brokered more effectively by WHO for some specific strains of pandemic influenza, and in a multilateral ABS transaction with WHO acting as an intermediary party, the system is most attractive to providers of sovereign genetic resources if they can maximize the likelihoods that benefits will accumulate to *them* specifically. But, for users, the multilateral system is most attractive if all

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providers are using it, and nobody is prepared to provide similar genetic resources outside of the system at a lower cost. Providers would prefer strong monitoring, compliance, and enforcement, whereas users would likely prefer the opposite. The multilateral mechanism is a less direct transaction, but the opposing incentives of market dynamics are still at play here.

A second key problem is that the WHO, as a public health organization, can only provide benefits from a multilateral ABS system in a way that accords with public health need, but for multilateral ABS to work, the provider parties need incentives or rewards to incentivize them to actually provide pathogen samples. They want benefits in exchange for the act of sharing their sovereign genetic resources, but the WHO can only promise the *possibility* of benefits, not a one-to-one exchange of access to pathogens in exchange for vaccines and antiviral medications. The link between the act of providing access to the sharing of benefits is too weak to discourage free riding in this space. Countries can simply elect not to submit their influenza samples to WHO through the PIP Framework and can still expect to receive benefits if their country exhibits the greatest need during an influenza pandemic. This destroys the incentive required to ensure that the countries continue to provide samples to the system and that the system is not readily undermined by bilateral ABS agreements.

Another issue in creating a market for human pathogens is that it will introduce the dynamics of supply and demand. Some viruses will be common and easily available, and their value in the ABS transaction will be minimal. Some viruses will be rare and difficult to access, and their value will be comparatively large. The scarcity that can make a pathogen valuable in ABS terms is predicated on that pathogen being contained, whether in terms of in one country or within the sovereign territory of one or two nations. In such instances, there are limited options for potential users of these pathogens, such as pharmaceutical companies, to access these resources, and they will, therefore, be required to negotiate with the nation that happened to have the pathogen *in situ* at that time. At that point, the nation may be able to negotiate very favorable terms through a bilateral ABS agreement, securing benefits for their populations, possibly for the supply of vaccines or medical countermeasures.

However, it is a truism of public health that infectious diseases do not respect international borders, and the moment the pathogen crosses the territorial border of that nation and begins to spread internationally, the negotiation position of the originator's status is significantly hampered, or wholly eroded. This recently occurred with Zika. When Zika hit Brazil in 2015, U.S. and European researchers were keen to obtain new samples. As Brazilian lawyers negotiated the terms for their access and the use of the viral samples, the Zika virus spread into Puerto Rico, a U.S. territory, and at that point, the U.S. Centers for Disease Control could obtain new Zika virus samples from Puerto Rico. The negotiations with Brazil ended without the transfer of any Zika samples from Brazil, and the Brazilian government found out the hard way that their bargaining position disappeared as soon as the disease spread, and researchers could find alternative providers of pathogen samples.

Such are the dangers of pursuing bilateral ABS in a public health emergency from the perspective of a provider, or the supply side of ABS. The desire of provider governments to secure benefits to protect their populations by leveraging one of the few bargaining chips they have can backfire, leaving vulnerable populations even more vulnerable. When viewed through the lens of an ABS transaction, the most valuable pathogens are those that are both rare and stand to threaten the lives of the greatest number of people. This is clearly perverse, and the supply-and-demand dynamics can also undermine the delivery of fair and equitable outcomes, and this is what Brazil learned during the Zika outbreak.

WHO acting as a transactional clearinghouse connecting the provision of viruses to the provision of scarce vaccines is a folly, and it is potentially a very dangerous one. When we consider the

https://doi.org/10.1017/amp.2021.159 Published online by Cambridge University Press

way of protecting developing countries from infectious diseases, then we see that in the bilateral ABS transaction can create a situation whereby only one country gets benefits, despite the fact that those benefits might actually be more effectively distributed elsewhere. ABS negotiations can be threatened by the open availability of genetic sequence data or the pathogens spread into other nations, which dilutes incentives to share benefits.

On the other hand, while a multilateral ABS system managed by WHO could be more effective at accruing benefits, it can only share them on an as-needs basis, not in a manner that encourages provider parties to continue to engage with the sharing process. Such are the dangers of pitting stakeholders as buyers and sellers in an ABS transaction. It creates a market environment where individualism and competition are valued over cooperation, and in a public health emergency, as we have seen, cooperation is hard to come by. But it is absolutely key to effectively and equitably responding to a pandemic. The last thing we need is yet another system that codifies and enhances the incentives for individualism over cooperation.

Unlike most physical resources, in many respects, culturable pathogen samples can be non-exhaustive and their use non-exclusive. Some pathogens can be grown and replicated to the point where an infinite number of replicate samples exist. In that sense, anyone can consume as much of a pathogen sample as desired without diminishing the amount that is available for others. Therefore, in a marketplace, pathogens might be better understood as being information rather than as physical resources. Despite this, the current approach to pathogen ABS treats pathogens as tangible assets that a state can exercise sovereign rights over, something akin to property rights, where the rightsholders can exclude others from accessing or using the tangible resources without consent.

So far, we have covered some of the reasons why ABS transactions, a market-based solution, may not be appropriate for public health. These have all been technical issues about supply and demand and market-based incentives, but there is also a human rights argument to be made here. We go into this in a fair bit of detail in the paper itself, but ultimately, the framing of this issue of fair and equitable access to vaccines as part of an ABS transaction reduces equitable access to vaccines to something that can be traded if you are fortunate enough to hold a pathogen of value. Rather than view equitable access to vaccines as an innate right, which all people have claim to, regardless of how much their government happens to have engaged in the bilateral or multilateral trade in pathogens. Developing countries should not have to purchase fairness and equity with their sovereign generic resources. It really is as simple as that.

The ongoing COVID-19 pandemic provides us with a really interesting example of these issues. Within the context of COVID-19, there was no meaningful discussion around providing access to COVID-19 vaccines linked to the provision of samples of the SARS-CoV-2 pathogen. This could be for a number of reasons, but all of them point to the fact that ABS transactions cannot work in a public health emergency, and multilateral ABS instruments for the sharing of all pathogens ought to be reconsidered.

China released the genetic sequence of the novel coronavirus fairly quickly, and access to genetic and physical samples from other countries followed that soon after. By the time any source country had the chance to negotiate an ABS agreement in the early stages of the pandemic, in the hope of potentially securing fair and equitable access to vaccines to their population, the values of the samples were minimal, if not completely negligible. This again highlights a key problem with applying ABS in public health. The logic of ABS can actively discourage the sharing of pathogens in the early days of an outbreak, while the provider country attempts to negotiate the best possible ABS agreement with end users of the samples. This is precisely when the world most needs access to these pathogen samples.

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Thankfully, in COVID-19, there was no quid pro quo, and it is perhaps indicative of the problems of trying to connect these in the first place. Not all pathogens are like pandemic flu, and not all will have characteristics that conform as well to an ABS transaction. And influenza does not even conform well to ABS either. Rather than be an anomaly, COVID-19 might point to the fact that the ABS mechanism cannot be a solution to either of these two problems in public health. The previous failings of the ABS regime in Zika, Ebola, and MERS that we cover in our paper indicate that a transaction of a pathogen for medicines is neither fair nor efficient, and it is not fair or efficient for either the rapid access to pathogen samples or the fair and equitable access to vaccines resulting from their use.

To sum up, bilateral or multilateral ABS creates another space in which providers and users are antagonists, buyers and sellers, both of whom want to maximize their own gains, but this framing ignores the fact that there are mutual interests here. And the whole point of the UN system is to encourage cooperation between nations who sometimes have disparate but similar interests, and we need to start to think outside of the market-based mechanism that has perpetuated unfair dealings and continue to detriment developing nations. There was and there is a solid normative basis for the expectation that viruses and other pathogens should be shared openly between the scientific community.

To some extent, it was upheld by China when they shared the genomic sequence of SARS-CoV-2 quickly and freely in the very early days of pandemic. On the one hand, the world is relying on a norm to be able to respond to infectious disease outbreaks, but on the other, it is actively undermining this norm with the application of ABS policies in the public health space. The norm needs to be strengthened, and it could be strengthened if developing countries were not made to feel that ABS policies were their only opportunity to get access to vaccines and antivirals in an emergency. We should be looking to solve these problems in parallel. Linking these two issues in a mechanism designed to address market failure in biodiversity guarantees that neither access to pathogens nor the sharing of benefits associated with their use will occur in a fair and equitable manner. Thank you.

Gian Luca Burci

Thank you very much, Mark, for the very clear position against a market mechanism. We also need to look at other devices that you mentioned at the end of your talk, and obviously, human rights considerations can play a role there.

We are fortunate now to have a very interdisciplinary panel, which may be not so customary in an academic meeting of international lawyers, and I am very happy because we can have fairly diverse reactions and comments on Mark's presentation.

Our first commentator is Professor Suerie Moon, who is a colleague and a friend, and she is professor of practice in the Political Science Department at the Graduate Institute of International Development Studies in Geneva, and the co-director of the Global health Center at the Graduate Institute.

Suerie, the floor is yours.

Remarks by Suerie Moon*

Thanks very much, Gian Luca. My thanks also to the Vagts family and the American Society for the opportunity and to Dr. Eccleston-Turner for a really interesting paper and very thought-provoking presentation. I think that I will begin with two points on which I think we are in full agreement before I offer some areas where I see things a bit differently.

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Where am I in full agreement? I think, certainly, from a public health perspective, from an epidemiological and ethical perspective, we want free-flowing sharing of pathogen samples and genomic sequencing data. We want free and open sharing of vaccines and other technologies that might be derived from those genetic resources, and I think that would indeed be a much better world.

I am also in full agreement that the existing rules that we have do not produce either of those outcomes, and the existing system of rules is certainly not fit for purpose.

But what I would like to do is highlight three areas where I think the paper could be further developed and where I see things a little bit differently. The first is when we think about the existing rules not being fit for purpose, I think we have to look at what are the existing rules for access and how weak and practically non-existent those rules are for access to countermeasures. The second point is that legally binding rules, which are very scarce for those who are on the short end of the stick when it comes to access to technologies, are a useful leverage. They are an important legal leverage, and they have value in the global system that we are operating in today.

The last point I would like to make, which is somewhat counterintuitive, perhaps, is that rules are not enough, and that, certainly, the rules we have do not go far enough. That is important to keep in mind, and I think some of my other colleagues will speak to the importance of production capacity, et cetera.

Before I dive into these three points, I wanted to flag that I do not actually share the characterization of the current ABS system as a market or at least not as a purely market-based system. I think it is a system that is shot through with politics and power relations, and perhaps as a political scientist, that might be why I see power in politics everywhere. If we think about COVID-19 vaccines today as a strategic asset, not just as a market commodity, we can better understand the current distribution and why certain countries have access to those vaccines.

I think what we see when we look at the pattern of countries that do have access is the operation of quid pro quo everywhere, and so, indeed, it would be a more beautiful world if vaccines were not distributed based on the logic of quid pro quo, but that is the world that at least I observe today.

What is that quid pro quo? You give me vaccines; I give you money. That is a market transaction. But we also see you give me vaccines, I will allow you to run clinical trials in my country on my people, or you give me vaccines and I will give you a political favor. I will either vote with you on the Security Council or in the General Assembly or in some other intergovernmental political process for which diplomatic friends can be useful, and we see all of this playing out right now. It is certainly not a pure market situation.

But turning to the three points that I wanted to flag, first, existing rules are not fit for purpose. When we look at the situation today, it is very clear that we do not have effective rules to ensure access to vaccines or other health technologies. If we had them, we would not see the huge disparities that I think are obvious. Nobody disputes there are major medical global inequalities in access today.

We do have certain rules that protect those who develop and manufacture vaccines; for example, the TRIPS Agreement that sets minimum standards for intellectual property protection, which are binding, a number of trade agreements and investment agreements in which intellectual property rules are embedded.

We do not have binding rules, however, for access. We do have the PIP Framework, which was mentioned earlier, but interestingly, the governments did not agree to make the PIP Framework a treaty. They did not agree to elevate that to the level of international law, and so it is binding in other ways, through contracts, but we have very little leverage when we think about how can we use international law to improve access.

This leads me to my second point. Legal rules can offer leverage. So what do we have? What we do have is the Nagoya Protocol, which the government of Indonesia did use in order to strengthen

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its claims over its H5N1 samples about fifteen years ago, and other countries have similarly followed too since then. I do think that the few sources of legal leverage that are available to, in particular, developing countries who might not have the money or the political sway to get vaccines through other means, Nagoya will offer a very important source of power and leverage that countries are unlikely to give up.

Then this leads me to my last point: where can we go from here? We agree the existing rules do not work. I think different rules favor different parties, so how do we get out of this mess? I am not sure that human rights norms are going to get us out of this mess because, of course, these pre-date COVID, and certainly, they have not been strong or specific enough to change the current situation. I think there have been some very interesting proposals put forward and actively debated now for new rules, and I think until we have new binding rules that are reliable to indeed create multilateral arrangements for access to both samples and the benefits that might result, we are not going to see movement on resolving the spaghetti bowl that we had before.

As my last comment, I will just flag that at the end of the day, as I said, I think we do need these new rules, but that these rules only go so far, and that, indeed, when countries have the capacity to produce, whether it is vaccines or drugs or diagnostics, they are in a much stronger position than many developing countries in particular, who are either actively building up this capacity or certainly will be very interested in doing so post-COVID. I think that will be necessary in addition to any kind of new rules in order to truly ensure that we have global access.

There is a long way to go, and I share, certainly, Dr. Eccleston-Turner's concern that the current system we have is definitely not good enough. Thank you.

Gian Luca Burci

Thank you very much, Suerie. Very interesting remarks, in particular on the exercise of power and politics. Vaccine diplomacy has become a feature of the last couple of years. China, Russia, and India are using vaccines as an instrument to conduct foreign policy.

On the new rules, the director-general of WHO made a statement yesterday and he is a vocal proponent of the pandemic treaty. He also very much advocates the need for new rules to ensure, among other things, access and benefits, something that is missing at this point in the public health landscape, and so we will see how it develops. There is momentum building behind this proposal.

Our next commentator comes from a public health background, Beatriz Thome. She is a public health physician affiliated with the Preventive Medicine Department of the Federal University of São Paulo in Brazil, and she is also the co-chair of the WHO Ethics and COVID-19 working group, so a public health and ethics background. That is very interesting. I am looking forward to your comments, Beatriz.

Remarks by Beatriz Thome*

Thanks, Gian Luca, and thanks to everyone, particularly to you, Mark, for the opportunity to comment on such an interesting paper, and as Gian Luca introduced, if you work long enough in public health, you do go through these situations of exploitative sample-sharing and lacking access to the benefits, especially in research in Brazil. But you do not necessarily have all this background that you provided in your paper, so all that legal framework behind the mechanisms that we currently have and the deep dive into the legal bases are very interesting. Again, despite being from

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a very different background, I found the paper very fluid and easy to read, so congratulations for making a public health physician read a law paper, really well done.

A couple of things to comment on, and also so good to hear Suerie as well, I think one thing I wanted to start with is right in the introduction, you state that the discussion that you are going to have is based on the premise that access to resources, being vaccines and oxygen and all resources that we have needed to deal with the pandemic, is a human right. That resonates with me very much because being a Brazilian physician and a Brazilian citizen, you might be aware, we have a public health system that is based on health as a human right, which is secured in our constitution. It is in our legal basis that this data should provide health for all and with no co-participation, no enrollment. It is really health for everyone.

Of course, anyone that works in health financing will find it is impossible to put together. How can a system work for everyone in a country as populous as Brazil with such inequities? It is a challenge, and for me working in the public health system in Brazil for years, it is a day-to-day challenge, but what we have ahead of us is this goal. Our mission is to really provide health as a right. As we move forward in this conversation, picking up on Suerie's question how do we move forward, we should not lose this as our guidance.

As part of that, because I would second Suerie's question, your paper really describes why ABS is not an ideal way to be nor efficient, nor equitable. How do we do this, then? I think your discussion could be perhaps more enriched toward more than the legal frameworks that could be proposed, and you do bring some ethical principles without necessarily going too much in depth. But you do bring equity. You bring fairness. You bring justice. So you lay out at a high level what will be an ethical framework for this to happen, but my question to you moving forward would be, what would be a legal framework that would be more appropriate to be aligned with this ethical framework and to be aligned with this goal, which is to have access as a right?

If I can contribute, because again my lens is from a public health perspective, I would like to comment on a report that was published by the Nuffield Council on Bioethics at the beginning of last year, coincidentally together with the emergence of the new coronavirus crisis. In this report, we worked on the evidence that we had on other public health emergencies and what were the ethical challenges to conduct research. Research is the lens of this report, and again, what are the key challenges in conducting research in such emergencies? Then, at that time, we worked with experiences from H1N1, Ebola, and Zika. But I think you can take out some things from this report that can perhaps help you base your legal framework on, moving forward.

Around the world, we collected experiences from researchers, governments, and donors when dealing with these public health emergencies, and something that came out very strongly were the considerations of when and how biological samples provided during public health emergencies could be ethically used. The main thing that came out was that it was ethical that they should be used to the maximum of their possible benefit, but the focus was always on how access was provided to those benefits. The working group's approach to this was twofold. One, to really try to promote responsible sharing, which includes ensuring that samples, once they are shared, are again used to optimal effect to help reduce suffering, so always bringing it back to an ethical lens, and the second aspect of that, to promote equitable sharing. Again, it really speaks to the points that you raise in your paper how, in general, low-income environments will not have the same opportunities as stakeholders in high-income environments in terms of accessing benefits.

We brought this as a call for action that across the research endeavor from researchers, research participants, and donors and funders of research, these two issues, responsible sharing and equitable sharing, should be the top priorities when funding and conducting research. Again, it is a different perspective because it is focused on research, but I think you might find that helpful.

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Out of this work, we also report on an example after Zika, as you well mentioned. At the time when we were in Brazil during the Zika crisis, I can tell you there was a black market for Zika samples at this point because, as you well described, it was really hard to get samples out of Brazil. Of course, the black market was installed, as it normally is. But, after that, there were a couple of consortiums around Zika—Zika plan, Zika alliance—that are mostly funded through the EU. For example, there was a creation of a biobank to try to overcome these challenges of sharing and access to samples. Of course, this biobank has to respect governments and the regulations of each of the countries that are participating, but nevertheless, this is the idea of collaboration that you brought in your paper, s the backbone of how do we do this moving forward, and then everything else is how do we get there. "Collaboration" will be a keyword there.

I will stop there, but thanks again.

Gian Luca Burci

Thank you, Beatriz. I like, in particular, the reference at the end to of your statement to alliances, biobank, already showing possible alternative paths to make things more equitable and to hopefully improve access down the line. That is definitely something to discuss further.

Last but not least, I am very pleased that we have Dr. Yuvraj Dalvi. He is a Team Lead of the Intellectual Property Cell at the Serum Institute of India, which at this point is the largest vaccine manufacturer in the world, if not one of the largest manufacturers. I am very pleased that we can have the perspective of the vaccine industry from the Global South, and we are very much looking forward to your comments, Yuvraj.

Remarks by Yuvraj Dalvi*

Mark's paper set the foundation for the aspect that is the strain providers have been deprived of the benefits. That aspect is pretty clear with the preceding said and the examples given. But the paper does not elaborate on the alternative incentive mechanisms. It does not propose the mechanisms precisely.

First, we would begin with what are the inherent gaps of the ABS PIP. The framework should be applicable to any pathogen. It should go beyond viruses, beyond pandemics.

The second aspect is giving WHO vaccine doses for free, which is part of the PIP model, or giving royalty-free licenses to vaccine manufacturers of the country where the strain originated to manufacture the same product is not a feasible approach from the vaccine manufacturers' return on investment perspective because of due consideration of the extensive R&D, scale-up required for developing a safe and efficacious product, huge facilities, and skilled manpower investment.

The third aspect is WHO as a mediator for MTAs creates a lot of legal uncertainties, which need to be addressed.

The fourth aspect is that scenarios would be different for the natural virulent strains than the genetically modified strains, as far as the strain providers, the intermittent modifiers, and the final vaccine manufacturers are concerned. That is where we need to have out-of-box incentive mechanisms in place.

Here I would like to propose certain benefit-sharing mechanisms. I have segregated them as to individual capacity: the research organizations, the institutions, and then the governments. First, we will go with the individual capacity. Option one could be having an MTA stage 1 research,

* Serum Institute of India Pvt Ltd. Views expressed are in personal capacity and not endorsed or recommended by Serum Institute.

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commercial agreements at stage 2 product state, signed directly between the vaccine manufacturers and the strain providers to remove legal uncertainties.

Option two involving the national culture laboratories. For instance there is the European Culture Collection, ATCC, instead of WHO labs, which will be better positioned to ascertaining through MTAs that patent rights/ ownership of the strain provider is taken care of. This will happen in two ways. First is by designating the strain provider's name as an intellectual-property-joint applicant, and the second way is connecting the manufacturer to the strain provider for execution of necessary commercial agreements, providing financial rewards to the strain provider, in particular, when the commercial product is about to be launched.

We could designate most-favored-nation status to these countries who are providing the strain and following the facilities that they can be availing. The first is special discounted or differential pricing, which we have done before for the HPV vaccine and HCV drugs, for pandemic products or any existing or future products. Second is we could have differential licensing agreements; for instance, a minimum licensing fee for manufacturing and sales in their own country. The third thing is differential knowhow agreements along with infringement waivers of the work for manufacturing and selling vaccines in the origin country only. Then we have cross-licensing agreements with the set country manufacturers. The other thing is settlement of intellectual property litigation, if there are any, between the two countries. Donation to the origin country, to a pandemic emergency fund, is another option available. The first foreign country to receive vaccine supply, the strain provider could be given at least 30 percent of the population considered as tier 1, and the rest of the countries under a COVAX-like mechanism, tier 1, only 20 percent of the population may be covered.

Now the question that arises here is we have proposed mechanisms, but how do we ensure the compliance, and how do we encourage the vaccine manufacturers to comply with these proposed mechanisms? There are certain aspects here. Before the launch of any commercial product, there should be voluntary self-declarations by vaccine manufacturers indicating that the product utilizes the strains and that the requisite party has been given the benefit. Such declarations can be submitted to the ministry of health of each country where the vaccine is intended to be sold, like we already do for FTO. There are clearance letters that are required by the ministry of health of the respective country.

The second is fast-track processing of patent applications covering the product. There, also, we can have self-declaration.

The third option is fast-track processing of regulatory approvals. Again, we can have a self-declaration in place.

The fourth and the most important thing here is an example provided by Malaysia in 2019 and 2020. They have set up precedents, and they are way ahead in terms of incentive sharing with these strain providers. You can have random checks of commercial products by competent state regulatory authorities for presence of documents indicating benefit sharing agreement in the form of a permit that has been appropriately done. If not, then asking the manufacturer to comply. Now, this could be associated with nominal penalties.

That is all from my side, and I would like to thank the Serum Institute, Serum Management, as well as DCVMN fraternity for nominating me for this particular interesting discussion.

Gian Luca Burci

Thank you, Yuvraj. You definitely brought the industry perspective. You can see room for improvements and for alternative solutions to equity between strain providers and receiver.

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We have ten minutes before we adjourn, and I wonder whether Mark would like to react to some of the comments.

Mark Eccleston Turner

Yes. And thank you all so much for your helpful comments. I think it is really interesting and so helpful to get perspectives from three very different disciplines and also disciplines that are not just international lawyers talking to other international lawyers, because I think one of the things that is really interesting about this issue is that it does not just cut across international law, it cuts across private industry, it cuts across public health, and it cuts across power and global politics. It is not just a legal issue, and I think that is one of the things that makes it so interesting.

Just on that point of power, which is one of the things I have been thinking about, is that you are absolutely right, Suerie, that there are these huge power differentials at play here, and those power differentials exist within the Nagoya Protocol, the idea of providers and users, sellers and buyers. Developing countries are just not often in a position to be able to turn down deals that appear to be beneficial in the short term, even if they may not be beneficial or may even be detrimental in the long term, whereas developed nations and their industries are often very much in a position to make these strategic moves that will better secure their interests in the long term.

Sharing data and information and collaborative research with nations is often touted as one of the potential benefits from the ABS transaction, not just actual vaccines, and I think that is simply good research ethics. This is not about benefits coming back in turn, but framing ABS as if provider countries only deserve these benefits *if* they purchase them with their sovereign genetic resources. We have extended that into vaccines as well. You are entitled, or you are worthy, of receiving vaccines because you had a bilateral agreement here, and I think that really does distract from a normative basis, even if there is not a strong legal basis, of things like the human rights to health and access to medicine under the human right to health. That might not be a strong *legal* solution in this case, but I worry that framing these issues as transactions actually detracts from that norm, and I think that norm has value in a political sense, even if it does not necessarily have a strong, enforceable legal basis underpinning. That is one of the things I worry about in this push to further transactionalize these issues, whether bilateral or multilateral. I think that we are moving away from the importance of the norm itself.

Our paper sets out very well what the problem is. Now we want to know what the solution is, and I really wish I knew the answer to that one, and I really wish I could give you the answer in seven minutes because that is ultimately the million-dollar question here. It is one that I do not have on hand.

One of the problems we have with Nagoya, and with ABS transactions in general, is that it is presented as a solution, that we do not need to fix access to medicines because we have Nagoya. You can just use your pathogens as leverage to get those vaccines or antivirals you need, whereas we do not actually have any examples, either in the public health space or really in the environmental conservation space, of a low- and middle-income country being able to use their pathogens or use their sovereign biological resources as a leverage effectively. I cannot think of a single example where a country has been able to successfully do that.

But even if they were able to successfully do that, let us say Indonesia in 2007 had managed to get a really good deal for Indonesia, okay, that is great for Indonesia. What about Laos? What about Cambodia? What about any low- and middle-income countries around the world, not just countries that neighbor Indonesia? What about them? Because the bilateral ABS transaction says that it is an all-or-nothing game. All of the benefits go to the one country that was able to successfully negotiate this agreement in time, and we do not actually have an example of that occurring in practice. But

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even if it did, we are at a situation where one country gets everything, and all of the other countries who may have equal or greater need get nothing. I think that we need to think a lot more creatively about global solutions to these problems, and multilateral ABS is presented as if it is that global problem. But we think that it does suffer these huge market inefficiencies, which actually disincentivize access and pathogen sharing.

Michelle and I are very much on the record about what we think about the PIP Framework and the fact that we do not think it can distribute benefits when it is actually needed, and Michelle and I both have inquired a lot about that.

There has to be a solution here. I do not know what it is, but transactions are not that solution.

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