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2B Patent Law Session. Patents and the Public Health

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Session 2B

Emily C. & John E. Hansen Intellectual Property Institute

**TWENTY-NINTH ANNUAL CONFERENCE
INTERNATIONAL INTELLECTUAL PROPERTY
LAW & POLICY**

Thursday, April 21, 2022 – 12:35 p.m.

**SESSION 2: Patent Law
2B. Patents and Public Health**

Moderator:

John R. Thomas

Georgetown University Law Center, Washington, D.C

Speakers:

Joshua D. Sarnoff

*DePaul University College of Law, Chicago
Pandemic Vaccines and Inequitable Global Distribution*

Catherine Fitch

*Merck & Co., Inc., Rahway, New Jersey
Accelerating Global Access to Molnupiravir*

Justin Hughes

*Loyola Law School, Los Angeles
The TRIPS Covid Patent Waiver – Policy Substance and Geneva Kabuki*

Panelists:

James Love

Knowledge Ecology International, Washington, D.C.

Gustavo de Freitas Morais

Dannemann Siemsen Bigler & Ipanema Moreira, São Paulo

* * *

JOHN R. THOMAS: Hello everyone. My name is J Thomas from Georgetown University. It's great to have a pack that's thick as thieves here, extraordinary members of the American Academia. I'd like to welcome Justin Hughes from Loyola Los Angeles who I think wrote the greatest paper ever on geographic indications. The always salty and lively Josh Sarnoff and Jamie Love who's done a lot of good in this world. Thank you to each of you. I'm looking forward to interacting with Catherine Fitch and our Paulista friend Gustavo Morais from the legendary Dannemann firm. Who's up first? I'm going to sit back and let's pass the popcorn friends as we talk about the extraordinary lively topic of patents and COVID.

JOHN R. THOMAS: Josh, you're up first which is the first time I've heard you quiet when you had the chance to say something. Why don't you go ahead, Josh? Thank you.

JOSHUA D. SARNOFF: Sure. First, greetings to all the co-panelists. It's now 03:00 AM in Australia where I am. If for some reason either the technology doesn't work or if you can't hear me or if I fall asleep, prompt me. As many of you know, the big issue is and has been for a while the efforts to try to get a TRIPS waiver. My personal views on this are that it's neither necessary nor sufficient. Very quickly, many of you know the TRIPS waiver was designed to address, originally, all COVID products not just vaccines, and all of the different rights under TRIPS (for the most part) and enforcement provisions.

It's been on hold for a while, but what we've seen in the meantime is very, very differential distribution of vaccines. I should mention it's wonderful that we were able to get vaccines as quickly as we did, in part through massive government expenditures and advanced purchase commitments. But clearly, something is wrong when we have this kind of uneven distribution. What's wrong? Part of what's wrong is that manufacturing is not fully distributed. This graphic gives you a sense of where things are produced, but it doesn't give you a sense of how much is produced.

Most of the vaccines have been produced in Europe, the US, Russia, and China, and India. Many of them are not easily capable of being transferred to other countries because of cold chain problems. I'll come back to that. There have been a number of major issues that have led to the differentials in terms of distribution.

One of the problems is that countries that didn't have manufacturing capacity were going to rely on the COVAX facility. Because of supply chain choices to restrict supply chain distribution to certain areas and certain manufacturing centers, and because of repeal of commitments that were made, many of the vaccine doses didn't make it to COVAX. That's one of the many reasons why you ended up with the distributions that you've seen.

In terms of the TRIPS waiver itself, the argument is that you need the waiver in order to assure that generic suppliers will manufacture. But even the pioneers have infringed. The key question is really not about whether or not somebody is going to infringe to manufacture or to get clinical trial approvals and regulatory approvals. The key question is what is going to induce the companies with or without legal authorization to take these actions.

The most important reason for the TRIPS waiver is simply to encourage such action to distribute manufacturing much more broadly, generate much greater numbers of vaccines for distribution in the relevant time. Also, to avoid having the limited supply hoarded by various countries, which has obviously

led to the distribution patterns that we've seen. There are many reasons, as I say, why the TRIPS waiver may not be needed. You probably can just issue compulsory licenses on a generic basis by adopting an Article 30 exception in the context of a pandemic. You've got the Article 73 security exception and judges have the authority to refuse injunctions. It really goes back to the idea that we need the waiver mostly to encourage the actions that are needed. The second thing is not a patent issue at all, but that the waiver is clearly insufficient because it's really the undisclosed know-how that's most important here for vaccines, not necessarily for therapeutics.

For therapeutics, clearly, the waiver may be more important. But even for therapeutics, scaling up manufacturing is critical and we need to transfer the know-how. Even if the best mode is disclosed, it's not going to be the relevant information about how to produce at scale.

So the key issue, therefore, is that we need to compel know-how sharing. This is an area that I have a forthcoming article in *Hastings Law Journal* with another academic, David Levine. There are many government authorities that can compel know-how sharing. It's fully compliant with TRIPS. There may be some questions about investor-state dispute liabilities. But even in that context, the countries that would compel the sharing are actually the rich ones. We can always compensate for the sharing, and it would be a lot cheaper.

The last thing is we clearly need to build infrastructure. Here, I think the world has done the worst job. We've known for years that public health infrastructure is incredibly weak in Africa and in many other parts of the developing world. Think about the cost to society and lives, the cost to national economies. Clearly, we should have spent lots of money on cold chain distribution and all sorts of other things right at the beginning of the pandemic and we just haven't done it. I've got a couple of quotes from *The Lancet* and from the IFC about how much money in terms of billions of dollars we ought to be investing.

This is the area that we have a moral failure. But we also have moral failures in regard to vaccine hoarding and boosting in some countries, and others. With that, I'll turn it over to others to take over and try to chime in as my brain can function.

JOHN R. THOMAS: Josh, thanks so much. We appreciate your comments from the antipodes and next up is Miss Fitch. Thank you.

CATHERINE FITCH: Hi. I'd like you all to join me for a trip back in time to early July of 2020. Imagine you're in the New York metro area. The pandemic is surging. On July 9th, the US reported 65,551 new cases and 1,000 deaths recorded in the last 24 hours. On July 10th, another daily record of 69,000 new cases was set and 134,000 confirmed deaths. By July 24th, the US had surpassed 4 million cases. There are no vaccines commercially available. Store shelves are barren. When available, toilet paper and paper towels are rationed. Your hands are sore from frequent washing and hand sanitizer application. As an IT professional you've abruptly transitioned to working from home.

It's a makeshift corner of your living space, where I am now. Having though in March you'd work from home for a couple of weeks until this virus thing blew over, it is apparent it is not blowing over. Now as far as work goes, you've been busier than ever and you've been included in a team to assess the potential in-license of a promising orally available, small molecule, antiviral in early clinical development for the treatment of patients with COVID-19.

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Although clinical trial efficacy results are not yet available, it is known that phase one studies demonstrate the compound is well tolerated and pre-clinical studies demonstrate that compound has potent antiviral properties against multiple coronavirus strains, including SARS-CoV-2. Most importantly, it is recognized and appreciated by the team that an orally available, small molecule treatment that would be stable to transport and could be administered at home would be a game changer in the treatment of patients infected by this virus.

As a result, there is a potential that overwhelming worldwide demand could outpace supply. The license is executed and now you've been asked to participate in a cross-functional team to brainstorm, design, and implement a solution to ensure broad worldwide access to this potentially breakthrough therapy.

Something very similar actually occurred at my workplace in Merck Kenilworth, New Jersey, US, with the license of EIDD-2801, a molecule that is known as Molnupiravir after Mjolnir, Thor's hammer. Honestly not sure whether it's the mythological Thor or the Marvel Universe Thor. This molecule was initially developed by researchers at Emory University before being licensed by our partner, Ridgeback Biotherapeutics.

To solve one aspect of this access issue, the team proactively reached out to several generic manufacturers with a history of getting WHO pre-qualified products to low and middle-income countries to enter into bilateral licenses, to ensure availability of Molnupiravir to patients in low and middle-income countries during the pandemic.

By the end of April 2021, which is prior to the availability of phase two data, it was announced that the bilateral licenses had been reached with five Indian generic manufacturers to produce and sell Molnupiravir for India and over a hundred other low and middle-income countries. Cipla, Dr. Reddy's, Emcure, Hetero, and Sun Pharma and then additional bilateral licenses were subsequently issued to Aurobindo, Torrent, and Milan.

Under the license, each of these manufacturers need to obtain approvals or EUAs, Emergency Use Authorizations, from the national regulatory agency of each country but in addition to the patent license, knowledge sharing was provided as a technical package on drug substance and formulation and assistance in the design and conduct of local clinical trials, as well as assistance from our own files for the registrations in local countries.

These bilateral licenses to WHO pre-qualified manufacturers and the assistance with product development provides us with greater confidence that these efforts will actually enhance patient lives by ensuring that the quality product, backed with quality data is provided to the patients. In parallel, we work to build up our own supply of the product at risk.

By the end of 2021, we were in position to have manufactured 10 million treatment courses. We also recognized that our licensed partners would need some time to scale up and obtain regulatory approval, so in January 2022, we announced we would make 3 million courses of treatment available from the company-manufactured material to UNICEF for the first half of 2022 to provide the product to those 105 low and middle-income countries served by our bilateral licenses.

This is in an effort to ensure simultaneous access to the medicine in all three of low, middle and high-income countries. Recognizing a geographic risk

in having all our manufacturing partners based in India, we began working with the medicine's patent pool to reach an agreement to permit even broader access.

For those of you who are not familiar, the Medicines Patent Pool, MPP, is a UN-backed public health organization founded in 2010 with a mission to increase access to and facilitate the development of life-saving medicines for low and middle-income countries. They work to license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.

The MPP has broad geographic experience as well as experience in managing licenses. You can actually go to their website and find the licenses. We negotiated a master license with the Medicines Patent Pool and a separate sub-license agreement that the Medicines Patent Pool will use to license the individual manufacturers. Thus far, the Medicines Patent Pool has engaged 27 additional licenses providing geographic diversities to supply of Molnupiravir to low and middle-income countries because our first licenses were all to Indian manufacturers.

These efforts were coupled with a planned tiered pricing approach based on a country's ability to finance their response to the pandemic and healthcare more broadly. In countries not covered by the MPP and bilateral licenses, we are working with governments to accelerate access through advanced sales and purchase agreements.

We believe that the IP is actually a key incentive to the at-risk investment in the development of these novel medicines and that countries should contribute to the development based on their capacity to finance health care. Global access to treatment has been a priority for Merck and our partner Ridgeback since the inception of Molnupiravir collaboration.

We're committed to providing timely and equitable access to building Molnupiravir globally throughout our comprehensive supply and access approach, which includes, as I've talked about, investing at risk to produce millions of courses, a tiered pricing strategy based on the ability of governments to finance health care, entering into supply agreements with governments for over 30 countries, allocating 3 million courses of therapy through distribution through UNICEF, and granting voluntary licenses to generic manufacturers through them and to the Medicines Patent Pool to make generic Molnupiravir available in more than 100 low and middle-income countries.

We continue to discuss additional methods, measures, and collaborations to accelerate broad, global access. I got one second left. I'm actually at home because I'm still within 10 days of my positive diagnosis. [laughs]

JOHN R. THOMAS: Ms. Fitch, better to be in New Jersey and well. Good luck. I'm going to break with the program actually, because I would like to hear from professor Hughes next, actually. Then I think we're going to have a lively discussion. I would like to have professor Hughes speak next. I'm going to open the floor to Jamie Love, but, Ms. Fitch, while we're listening to the others, I would like you to think about what you think of law professors throwing shade at companies who are actually doing things to develop vaccines.

All right? That wasn't much of an intro, but Justin please go ahead. It is great to see you again.

JUSTIN HUGHES: It's great to see you, Jay, and I hope you can hear me. Catherine, I would say just as a preliminary matter, the story you just told

needs to be memorialized in a way that law professors can access it. Law professors criticize patent examiners for only reading patents, but law professors only read law review articles and court decisions.

That kind of factual story that you told us really needs to be memorialized in a way it can be accessed and used by academics. Perhaps not written by Merck's counsel, or written by Merck's counsel and someone who's somewhat more neutral. It would be very useful to have that history of Molnupiravir out there where we can actually deal with the facts and look at what happened.

Jay, I largely agree with a lot of what Josh said, in that at the international level a waiver of patent rights related to the COVID vaccines or if it's expanded is not by itself going to make any difference in global vaccine production and distribution. Josh and I agree on all the reasons why. There are shortages in supply of raw materials, there's shortages in production know-how that is not formalized in patent specifications and claims, and there's the lack of production facilities.

The really sad story and I think Josh and I would agree and I think Jamie would agree too, is that separate from the issue of mRNA vaccine technology, which is new, it's sobering and sad and disappointing that Africa's many bouts with Ebola has not in the past few decades prompted the building of pharmaceutical production facilities that the Sub-Saharan continent needs.

I remember back in 2007, the African Union had a pharmaceutical manufacturing plan for Africa and nothing came of that and every couple years there's a plan like that. When you look even at what the World Health Organization says in terms of production facilities in Africa, most of them are not in Sub-Saharan Africa and most of them are just packaging facilities.

That's the real story of what we need to solve in the future. This framework agreement that has come out in terms of a TRIP waiver can be viewed as an incremental development in compulsory licensing, which is good. It's severely disappointing to NGOs working the halls of Geneva. I think Jamie's going to tell us in ways that it is stricter than the current compulsory licensing possibilities under the TRIPS system.

If all that's true, the question we ought to be asking ourselves is why would South Africa and India agree to this framework that apparently has been agreed upon? I'm pretty sure South Africa would not agree to this proposal unless they believed they could bring the entire Africa group voting block along. So, to me it's very important that people appreciate what I regret to say is the sporting event aspect of Geneva. In sports you don't look for real-world effects for game outcomes. You simply ask yourself who won and who lost?

You know that whoever won or whoever lost today there's going to be a rematch next week or next season. All negotiations in Geneva have this iterated competitive aspect. I'm not saying that's all of what happens in Geneva. It's certainly not, but you need to understand this little aspect of Geneva to understand how international IP law develops, how international trade law develops, how telecommunications law develops, how refugee law develops.

It all is affected by that. I view the Biden administration's decision in May last year to agree to a kind of waiver as a purely political decision. I view that South Africa and India's decision to accept this deal if they have is also a political decision. The US decision recently, just a few weeks ago, to share all

of its government funded COVID research results with the World Health Organization technology pool is also again a political decision.

I guess what I'd say and I only have 30 seconds to say in five minutes, Jay, is that for IP holders, I have some bad news. That is, if the next few years of our lives are going to be the realpolitick of dealing with authoritarian regimes, when that's the game play, when that's the dominant mode, we will be making a lot of compromises of this sort across the board on all kinds of commercial laws. That's something that I think we all need to deal with and accept. I'll stop there, that's five minutes, J.

JOHN R. THOMAS: Justin, well done. We admire both the content of your presentation and also your timeliness. Before Jamie gets his word in, I would like to invite Mr. Morais from Sao Paulo and the legendary Dannemann firm to offer his observations. Thank you.

GUSTAVO DE FREITAS MORAIS: Thanks for the invite and I have just brief comments with regard to the TRIPS waiver. First of all, to highlight that my point of view is of humble authority that leads in the trenches. In general, trying to enforce patent rights or to defend patent rights in this country and in the region in Latin America. Maybe also an invitation for everybody to watch what is taking place in Brazil. Since last year, there has been enacted a law number 14,200. There are many laws. Our congress is like that legislates on manufacturing plans.

The fact is that in a sense Brazil is already implementing in practice the TRIPS waiver. We had since 1996, a number of compulsory license provisions. Brazil is an original member states of the TRIPS agreements and a number of compulsory license provisions before, since 1996, also deal with compulsory license on patents in case of any sort of emergency. Also, there are provisions regarding a forced technology transfer. This new law from last year basically reinforces this possibility.

It also includes a few other details in the sense that according to the new law, the current COVID pandemic situation is already considered as a national emergency. After the full enactment of these law, the government will have 30 days to prepare a list of patents and patent applications to be compulsory license and basically any private or state entity may raise their hands and say, "Hey, I need a compulsory license of these patent or patent application and I also need the manufacturing technology in order to start to manufacture locally in Brazil in order to attend to the local community."

Our beloved president veto basically three section of these laws, including the part of the list that should be prepared within 30 days. Now we are waiting that the Brazilian Congress analyze those vetoes, either support them and finally release these legislations where it is or to reject those vetoes. Once the Congress analyze those vetoes we will have this law in full force. I think that would be interesting for the international community to watch out what will happen in Brazil with regards to a TRIPS waiver situation that has been put in practice in this country. I hope that I respected the time.

JOSHUA D. SARNOFF: Jamie, it looks like Jay may be stopped, so why don't you go ahead?

JAMES LOVE: First of all, I'd like to compliment Merck for both a very good presentation but also the license itself, The Medicines Patent Pool was really important. It was the first Medicines Patent Pool license by any company related to COVID. It had, I thought, very good features as far as scaling that

production in the sense that they enabled production from anywhere in the world within the licensed area. They didn't have to do the license. They did the license and it was really quite welcome.

I think as a result of that, it probably contributed decision by Merck to do their license on Paxlovid which was also a very important license. There was some criticism of the Merck license in some quarters. We put out a very favorable statement, but some people criticized it. I think the more controversial features were probably not Merck's fault, but they were probably because of Emory University and Ridgeback were actually less willing to have a robust license in some areas than Merck itself was.

On the TRIPS waiver, it was extremely narrow proposal in the sense that it was temporary and it was limited to a single virus. I think a lot of people that debated the TRIPS waiver didn't really understand that it was just a temporary waiver of WTO rules and it would not free up anyone's patents, it would not change any issued patents, it would not change any national laws.

The only thing that would change is whether or not a country could pass a law that was otherwise not TRIPS compliant or a practice on, for example, trade secrets or something like that, where they may have been afraid of that, but there's already quite a bit of flexibility within the TRIPS agreement on that score as Josh mentioned. I think a lot out of the debate that you saw publicly on the TRIPS waiver was among people that didn't really know much about the WTO and didn't know much about patent law and it was the loudest voices in the room are not necessarily the people that were most informed about what was being proposed at the WTO.

The landing zone is very different than the initial proposal. The initial proposal was to waive 40 articles in the TRIPS for all countermeasures for COVID-19. The compromise proposal by the DG is to provide a substitute alternative to 20 words, one paragraph, and one article. You went from 40 articles to one paragraph and one article, a total of 20 words and to actually bypass those 20 words, there were five new conditions that were attached to it that were not otherwise in the WTO agreement.

That's attracted a fair amount of criticism. I don't believe that South Africa or India have yet endorsed the proposal by the Director General of the WTO. I think she really wants to push this thing through, so we'll have to see how it plays out, but for the most part, other things were more important than the conversation about the WTO. I think what the WHO has done with the messenger RNA hub with a different technology hub for vaccines with this new bio hub that they're creating, the fact that they've launched negotiations on a pandemic treaty is far more consequential.

The creation of the COVID Technology Access Pool in 2000 was essentially initially endorsed by Gregg Alton who was at one point the acting CEO of Gilead and for many years he held positions such as general counsel. Paul Fehlner who's a frequent participant in this conference, and at one point was the head of all intellectual property worldwide for Novartis.

There was actually a fair amount of support that the pandemic should be considered different than a normal situation because of the scale of the emergency. That did not happen. I think what we saw in terms of the response was a very conventional management of intellectual property in general. Very little innovations. I think that the actions by Merck and Pfizer on the acute therapeutics was quite welcome.

We didn't see anything really, very similar happening on the vaccine front. I don't want to exceed my time. I wasn't even allocated any time for the session, but I'll stop there. I've shared a few links in the chat for a few things I've written on this topic.

JOHN R. THOMAS: Friends, my internet connection is unstable. If I cut off, Josh, you are in charge. I almost regret having to say that, but I know you'll do a good job, Josh. Of course, it's great to see you, Jamie. Let's get lunch in DC sometime soon. Ms. Fitch, having heard from the academic scholars, what are your thoughts about waivers and patent rights and all that sort of thing as someone who's actually doing something to help people immunize themselves from COVID?

CATHERINE FITCH: Well, I think from our perspective, and I am coming from in-house at a pharmaceutical company, but I think having the intellectual property rights gave us the confidence to make the investments at risk and to proceed forward with these efforts. I think we did recognize there's the George Merck saying that medicine is for the patient and we should never forget that medicine is for the people, it is not for the profits, the profits will follow, and if we remember that they never fail to appear.

I really do think that that is something that we all try to live and breathe at the company. Well for me, I actually had to do a lot of research to make sure I knew what sections of TRIPS you guys were all going to be talking about because as a worker, day in and day out I don't actually think about TRIPS that much. I don't know.

Another thing is that this wasn't our only investment for the pandemic. We invested in four technologies. We invested in two vaccines and two therapeutics, and this is the only one that still has legs. There is this riskiness. There is this need to invest and to have some confidence that we're going to have enough to fund continued investment in a very risky area. None of these therapeutics and vaccines were a sure shot at the beginning. I don't know if that really addresses any of their statements though.

JOSHUA D. SARNOFF: Let me jump in, Jay, and just ask one follow-up question. The governments clearly were ready to make advanced purchase commitments on a massive scale. To what extent did that affect the risk calculus rather than the IP, because you knew you were guaranteed markets if you could produce?

CATHERINE FITCH: I'm not sure how to separate that out, but I just know that for me working in-house, the idea that we have the IP, the idea that we do have a degree of control so that through the IP we can make sure that the product is what the product should be and that the studies are rigorous and the patients are going to get a quality product. Maybe it's because I'm stuck in this sort of thinking. That is really how I'm thinking about it, but it might be because of my role being in IP, in a company. That's my framework.

JOHN R. THOMAS: Let me steer the conversation back to Mr. Morais. Mr. Morais, there's a bunch of Americans on this panel, so you're stuck with a bunch of Americans. Is there any sense from the BRIC countries which, sadly, you've been nominated to represent. I've been in your position as the only Americano on panels, so don't worry. Is there any sense from the BRIC countries that there ought to be more investment in public health?

Is there any sense that because of this pandemic, that there ought to be more innovation in pharmaceuticals or manufacturability, or is the sense that

everything is just going to come from abroad and foreign companies will take care of your problems for you?

GUSTAVO DE FREITAS MORAIS: Thanks, J. That's a very good point. I cannot speak about Russia, India, South Africa, but I can speak for Brazil and barely so. I would say that the prevalent feeling in this country is that thanks God there is innovation. Thanks God there are drugs, there are vaccines to fight this pandemic and this huge problem.

I think that now, maybe more than two years earlier, I would say that the vast majority of the society has been vaccinated number one. Number two, they know that innovation is necessary, especially in a situation like this one we are finishing, I hope. With regards to regard to IP leading to more innovation, there are still maybe more debates. I would say maybe that the elite members of our society, as a rule, they are against IP.

I teach at the local university. I always say to students that are in my first class of the year, nobody likes patent. Nobody unless the patent you invested, you created something new and you file a patent application and got a patent, then you'll love your patent. It secures like Ms. Fitch just mentioned. It gives you the trust to invest in something that's not granted and clinical testing being paid as we know.

I believe that right now, we have a different scenario in Brazil. Of course, there will always be a part of the society that will be against patents that drugs should be delivered for free, and the generic should come into the market ASAP. I would say that at least a part of these persons also know that without innovation, there will be no generic.

JOHN R. THOMAS: Mr. Morais, the Brazilian Supreme Court recently issued an opinion which allowed for a 10-year patent term extension for patents that have been delayed in prosecution for more than 10 years but excepting pharmaceuticals. Does that give us any hope for the future on this in Brazil or is it just emblematic of the things you just said?

GUSTAVO DE FREITAS MORAIS: Well, actually, the Brazilian Supreme Court ruled that the dual patent term calculation that we used to have, RP is against the constitution. Right now, we only have patents with a term of 10 years from filing. We used to have a second term of 10 years from grants when the Brazilian petrol took more than 10 years to prosecute the patents.

They ruled that this second patent term calculation went against the constitution and the decision retroactively affected the pharmaceutical patents, so a number ten dozen the hundreds of pharmaceutical patent applications had their term adjusted. So, J, no, I don't think that this decision is beacon of the new times, quite to the contrary.

Again, I think that it will be quite interesting to see what is going to happen with this new law 14.200 because this new law actually is directed to local entities that want to manufacture locally. In this area, I believe that we, Brazil, we need huge investment. I doubt that any local entity in Brazil and in many other countries that have been cited here, they will be able to manufacture drugs that require maybe a greater degree of technology.

JOHN R. THOMAS: Thank you very much, Mr. Morais. Jamie, if you had some questions for Josh or Justin, what would you ask them? In your ideal world, how would you set things up?

JAMES LOVE: I think that given the failure to scale the manufacturing of countermeasures in 2021. In 2020, there just wasn't much available that really

worked. In 2021, there was but it was really very unequal in terms of the timing of when products were distributed throughout the world. It's a little different situation today than it was then. You can imagine that a set of facts or even the outcome of that disparity would be even more horrific than it was. The current one was bad enough, but you can imagine an even worse outcome, I guess, in some cases.

My question is, would it make sense for the world to have an agreement so they would have sufficient resources so they could do things like patent and know-how buyouts so they could scale manufacturing in an emergency situation faster? I don't think you can do everything, do compulsory licensing and things like that, but in some cases, you may want to use money to compensate people, either voluntary or non-voluntary. I'd be interested in the thoughts on the role of buyouts of both know-how and intellectual property rights in an emergency situation where you're trying to basically make things more equal.

JOHN R. THOMAS: Other panelists may respond.

JOSHUA D. SARNOFF: Do you want to take this first, Justin? Or shall I go?

CATHERINE FITCH: Can I just say something? Maybe this is ignorant, but it seems to me that buyouts and all that stuff still doesn't address the core issue that we need supply in Africa. We need manufacturing facilities that don't just package in those areas. That kind of groundwork has to be laid beforehand. Waiving IP and doing other things like that doesn't address that. Throwing money at supply, maybe later on helps, but to allow the supply, but we still don't have the places to make it.

JAMES LOVE: Your company actually did offer open licenses for one-year therapeutics, so I think you probably don't see the licensing as completely irrelevant. It was the whole point of your presentation. I think that on vaccines, there's a lot of focus on the messenger RNA vaccines which got 98% of the conversation, but there were actually many different vaccine platforms, the protein vaccine. The protein subunit recombinant vaccines were relatively easy to manufacture in wide areas.

The Bayer vaccine, for example, right now is being manufactured for less than \$1 a dose, widely rolled out right now in India. Cuban vaccine is, I think, considered a pretty good vaccine. I think that it is true that there's always these challenges of supply chain, and facilities, and training, and things like that. Things don't happen overnight. There was hoarding of technology, particularly in the vaccine, particularly in the messenger RNA because people thought it was proprietary technology.

I don't think that you thought that the therapeutic you had had a highly valuable know-how because you were willing to share the know-how widely. I don't think that Pfizer took the same approach for its vaccine that it had sort of therapeutic, because I think that they think the messenger RNA manufacturing know-how was a valuable corporate asset in a way that they didn't think the therapeutic was. I think whatever you want to do on know-how and technology transfer I think money will grease the wheels.

JOSHUA D. SARNOFF: I'll jump in. What's critically important to understand is that as a dry run for an even more severe pandemic, this is an abysmal failure, even though we were lucky enough to generate a number of vaccines and a number of therapeutics relatively quickly. If you think about variant development, it is largely a function of the number of mutations that

occur in particularly immuno-compromised people, which tends to be in the same places that vaccines were in much more limited supply. Again, although I want to join the crowd in praising Merck, Molnupiravir adds to the mutation burden and it raises concerns about its use in developing Omicron as a possibility.

If we think about the need for rapid distribution of responses to any infective product around the world in real-time, to prevent serious development of variants of much more serious, much more lethal viruses (or even bacteria that are antibiotic-resistant), we're nowhere close. That's why the pandemic treaty is really so critical to try to get the world to totally restructure its worldwide health system.

The last thing I'll say is that the governments have always had the power to compel the transfer of this information and technology to buy out all of the rights. It's just a failure of political will. The US was not about to ship its vaccine around the world on an equal basis. Even if it could, there are cold chain issues as I mentioned. But we're not going to save other people before we save our own, because it's political death. We just need to change our entire worldwide health system. This, as a dry run, is an abysmal failure and we're setting ourselves up for some serious future pandemic. I'll just add that climate change makes that incredibly more likely. That was my cheerful version.

JOHN R. THOMAS: What do you think, Justin?

JUSTIN HUGHES: I don't think it's an abysmal failure. I think in the history of the world, this would be a little blip. It barely affected global population, Josh, so it's not exactly a cataclysmic event in world history. Second, yes, of course, whether you're an authoritarian leader or you're a democratically elected leader, your first responsibility is to protect your people. One thing I've admired President Biden for, whether it is COVID or it's the Ukraine, is that he's very clear about that.

He's very clear in his moral vision that his obligation under the social contract is to the 350 million Americans primarily. You want to get us to a different world that requires a different moral foundation, but you don't want to have the difficult and almost intractable discussion about that moral foundation.

JOSHUA D. SARNOFF: I'm happy to have that discussion.

JUSTIN HUGHES: But that discussion will take a really long time.

JOHN R. THOMAS: As lawyers, do we have the training to do that? Let's stick to our lawyerly role [laugh] so however we trained and what we're professionals in. All right. Thank you.

JUSTIN HUGHES: Whatever the pandemic treaty might turn out to be, it will be a limited surrender of sovereignty. You can be assured that those countries who have the maximum capacity to protect the health and wellbeing of their own people will surrender very little of that sovereign ability to protect their own people. This is just the tough moral issues we just skirt around, that we don't discuss and we say, "We should do this. We should do that." Every *Washington Post* op-ed about what we should do about global vaccine distribution never touches on this issue. That's what I find dissatisfying. It's a non-nutritious discussion.

JAMES LOVE: The elements of know-how, data, sequences, IP rights, which are not rivaling consumption, the failure to share those things in the middle of a pandemic was, I think, the policy failure. I agree with Justin that it's unrealistic to think that national leaders are going to not have a certain amount

of nationalism. I think people would throw them out of office if they didn't do it.

I'm not even going to criticize that, to a certain degree, but I do say that not everything had to be hoarded. Certainly, know-how, data, sequences, IP rights, things like that because they're not rivaling consumption, the policy failure was the way to compensate the people that needed to be compensated to ensure that those things weren't shared. It was a very costly mistake, in my opinion, in terms of the health outcomes.

JUSTIN HUGHES: Jamie, you would agree, of that list you gave, some of the things are nonrivalrous. When it comes to know-how, know-how that is not actually formalized in specifications and claims in a patent is actually rivalrous in the sense that it sits in the head of X number of people. That X number of people is finite. I think you'd agree on that.

Do we take time from someone who is using their know-how to run a vaccine production line for your own people, whether your own people are in China or your own people are in Germany or your own people are in the US, and say, "You have to step away from the production line to transfer your know-how to a different group of people"? I think you would agree that that's not purely nonrivalrous.

JAMES LOVE: Yes, I agree that, Justin, it's not the same as waiving a patent right or sharing exclusive rights and data. That the know-how is a hands-on thing. The WHO was very keen on this. They'd tried to build out the idea that there would be technology transfer hubs where you'd have teams of people that would help, and it'd be supervised in the sense of like with the recipients were. Some things are very clear. For example, on the Johnson & Johnson vaccine, a Canadian company was unable to get the working cell lines for the vaccine. Now, that's a pretty straightforward technology transfer.

JUSTIN HUGHES: I agree on that. But, Catherine, let me ask you this question. What can Merck do long-term to take people from developing countries and actually not just get them ready for the next pandemic, but start building the set of know-how and knowledge in their brain that when it becomes time, as Josh would say, to flip the switch on production facilities, you don't have a situation where there's really nobody in a particular country or, say, the entire South African Development Community, who can do this? How do we improve, in an amorphous, big way, not knowing what our ultimate needs will be, the human knowledge capacity to run things.

JOSHUA D. SARNOFF: And are you willing to do that recognizing that that will diminish long-term profitability and trade advantages from those countries precisely because they won't be selling from one country to another?

JUSTIN HUGHES: Josh, I think you're being an academic egghead. I don't think Merck worries about profits from Mali or Niger very much.

JAMES LOVE: Oh really? You don't think Merck cares about profits? Really? Okay.

JUSTIN HUGHES: No. I said profits from Mali or Niger.

JOSHUA D. SARNOFF: Not if they can't scale up enough to develop it.

JAMES LOVE: Okay.

JOHN R. THOMAS: Catherine, please forgive-- Since my internet connection is flaky, I'm going to impose my moderator privilege. Cath, I know these are some difficult questions to ask and that's not your area of responsibility because you have enough to deal with. I'm going to ask Jamie. Jamie, I'm going

to turn the tables on you. As you know, you've filed a march-in petition again, which is almost certainly to be denied.

JAMES LOVE: Oh really? Why hasn't it been denied? Because all the other ones were denied within a really short amount of time. This one's sitting out there.

JOHN R. THOMAS: They'll write a few more pages in the denial. That's true. What's the role of the US government in this? Let's not call on private entities like Merck become charities.

JAMES LOVE: You did read the presidential executive order which went to the issue of march-in requests.

JOHN R. THOMAS: Yes, I've read it. Jamie, tell me what you think the role of the US government ought to be in this, rather than imposing the blame on actually companies that are producing vaccines. Why don't we ask about the US government?

JAMES LOVE: I don't think I really placed much blame on companies. In fact, I actually took a lot of heat in my own community for issuing a very positive statement for both Merck and Pfizer. I think, Catherine, you probably saw our statement when we put out a positive statement. I was savaged in my own community for being too favorable to what Merck did. I think for the United States, the perception that the US is the world is a US mindset. We're now well less than a quarter of world GDP and I think that it's not our responsibility to provide healthcare for the whole planet.

I think that what's important for us to do is engage other countries in a multi-lateral sitting. In the beginning of the pandemic, Germany passed a law basically wiping out exclusive rights on patent rights for COVID-related technology because they didn't know who was going to end up with the technology that would be an effective countermeasure. As soon as they figured out that CureVac and BioNTech looked like they had something promising in the vaccine area, that was forgotten and they moved on. Even members of Congress, bipartisan, suggested the US engage with other countries in the beginning because they said the same thing.

They didn't know who would have the effective countermeasures. I think in the pandemic treaty, you have the veil of ignorance. You don't know whether it'll be China, Japan, France, Brazil. You don't really know who is going to end up owning some magic bullet for the next pandemic. This is the right time to have some cooperative agreement on the sharing of things, but also some realistic things as relating to money. Just expecting everything to be done out of the goodness of someone's heart, I think, is a mistake.

It has to be a feasible commitment that there's a larger economic value in having countermeasures. People should commit, in the beginning, to both receive whatever technology is out there, but to contribute money and help pool the cost of compensating the people that do put money at risk in developing countermeasures. It should be perceived all around, when nobody knows who will have what, as some kind of fair deal. That would be, I would hope, a forward-looking thing. The US could provide an important role of leadership in that.

JOSHUA D. SARNOFF: Catherine, you're certainly welcome to respond to any of the part of the discussion and then maybe since we're getting toward the end, we can give Gustavo another opportunity to weigh in.

CATHERINE FITCH: I don't have-- Maybe Gustavo.

GUSTAVO DE FREITAS MORAIS: Cathy, you want to go first? No. Again, my point of view is of a humble lawyer that lives in the trenches. What I can see, and maybe judge, and give some sort of a comment on, is something that have a possibility of working in practice. From my point of view, from what I know about the companies, it would be very, very difficult for them. It would be very difficult to be approved by the CFO of a major company to perform clinical tests on a drug or on a technology that's not patented.

Maybe it's not the ideal world, but I see this every day that it would be very difficult for the companies to commit funds to perform the clinical tests that we all know that are quite expensive to a drug that will have no patent protection or if the patents will have risk to be compulsory licensed. I believe that this would be the point of, maybe not of the companies, but of a lawyer of such companies.

I see also maybe some difficulty in implementing what is being discussed before WTO unless the congress of any country is willing and able to pass a law and to determine what's going to happen in practice. I'm not praising what the Brazilian congress did, but at least, nowadays in Brazil, we have the proper detail, the proper data, and the proper guidance on how some sort of TRIPS waiver should be implemented. Again, it's quite difficult to comment on something that nobody really knows how it will be implemented.

JOSHUA D. SARNOFF: Let me just add-- Yes. Go ahead, Catherine.

CATHERINE FITCH: What I'm struggling with, maybe I'm going down the wrong path, but what I'm struggling with is how we have investments between pandemics, between outbreaks of Ebola in the areas where there's under-investment in order so that when there is a surprise, there are the people who have the skills and there's some infrastructure to rely on.

There's one thing where we can always look for solutions that don't require refrigeration or something in order so that they could be used in certain areas, but maybe there's also a way somehow. I don't think the answer's patents to get refrigerated transportation available in areas that need it. I'm just struggling to articulate how it-- I think that this is a problem that minds way greater than mine have been working on for a while, and we're still where we are right now.

JOSHUA D. SARNOFF: I think the answer--

JOHN R. THOMAS: Friends, it is my job to point-- Josh, I got to cut you off.

JOSHUA D. SARNOFF: No. Quick point. You got two minutes, Jay.

JOHN R. THOMAS: Okay. Go ahead, Josh.

JOSHUA D. SARNOFF: The answer is we need to focus on the opportunity cost of failing to make those investments. If you think about how much money was spent on the economy from this pandemic compared to the incredibly little that's invested in the public health infrastructure, or in patent buyouts, or in paying for clinical trials, it pales by comparison. All we need is to generate the political will. Back to you, Jay.

JOHN R. THOMAS: All right, Josh. Sadly, my duty is to shut off this conversation. I seem to remember a little more fireworks between you, Josh and Justin last year at this event. Josh, I think you've come around to Justin's point of view. That's my sense of the conversation, but we'll talk about that in a week or two in Washington when I invite you over. I wouldn't mess with Justin Hughes or with Jamie Love. How lovely it is to see three men who I very much

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admire. Miss Fitch, thank you for all the work that your firm has done. We're very grateful. Mr. Morais, I'm more of a Carioca guy, but when I go to Sao Paulo, I'm looking you up.

GUSTAVO DE FREITAS MORAIS: Thank you.

JOHN R. THOMAS: How does that sound? Friends, thank you so much. It's my sad duty to close this conversation. I'm sorry for my flaky internet. Thanks to everyone who listened to this panel.