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2B Patent Law Session. Patents and the Pandemic

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SESSION 2: PATENT LAW
2B. Patents and the Pandemic

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***Speakers*:**
Joshua D. Sarnoff
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TRIPS Waiver: Needed but Not Nearly Enough!

John Todaro
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The Role of IP Rights in the Development and Production of Medicines in Response to the Pandemic

James Love
Knowledge Ecology International, Washington, D.C.
The Response to the COVID-19 Pandemic

Justin Hughes
Loyola Law School, Los Angeles
Keeping Everyone to the Bargain

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PENNY GILBERT: This is perhaps one of the most topical and relevant discussions we're going to have today bearing in mind where we are at the moment, and the one place that we're not, is in New York. We're all joining remotely from our various places around the world, in various stages of lockdown and watching as we see waves of infection ripple across the globe.

I have to say, the work of scientists has been absolutely phenomenal in responding to the pandemic. We've seen evolving levels of testing to identify where infections are happening, we've seen genomic sequencing to identify and monitor the spread of new variants. We've seen the re-purposing of drugs and development of new drugs to treat COVID-19. Perhaps most remarkable of all, we've seen the production of these highly effective vaccines in record time. It's taken less than a year from the first sequence of SARS-COV-2[1] virus, through regulatory submissions and clinical trials, to seeing effective vaccines rolling out and being used now in various countries across the world.

Vaccination programs clearly offer a way out of the pandemic, or so we hope, but a return to any kind of normality is going to need vaccines to be made available not just in our own countries, but also worldwide as soon as possible.

That brings us on to the topic that we're here to discuss with the panel, the role of patents in responding to COVID-19. What has that been and has it ensured that we're going to have access to vaccines? How are we going to cope with access to vaccines in poorer countries and facilitate additional manufacturing to make sure we have adequate supplies for everyone? Have patents provided the motivation for investment in research into this rapid development of coronavirus vaccines or do we think that they are actually getting in the way of a broader rollout?

With that introduction, let me move on to introducing the panel and I'm hoping most of you are here by now. We've got four speakers, Joshua Sarnoff, who's a professor of law at DePaul University in Chicago, John Todaro, the Executive Director and Managing Counsel of IP at Merck. James Love, who is director of the Knowledge Ecology International, and Justin Hughes, who's professor of law at Loyola Law School. Our panelists are Miquel Montañá, who's a partner at Clifford Chance's Barcelona office, Kevin McGough, Vice President of IP at Takeda Pharmaceuticals, and John Lee, who's a partner at Gilbert and Tobin based in Sydney, Australia. Before I go any further, I just wanted to make clear, on behalf of John Tadora, and Kevin McGough, that they're here in their personal capacities and their views are not necessarily those of their employees, so we hope that you'll bear that in mind so that we can have a free discussion.

As you all know, after each speaker, we're going to have about five minutes for discussion, and then a longer session at the end, but please do put your questions in the Q&A session panel and I'll try to pick them up as we go through and do raise your hand if you'd like to actually take the floor and make a point yourself. It's a bit difficult to see the hand raise, but I'll do my best to spot them. With all that said, let's move on to our first speaker.

[1] Severe acute respiratory syndrome coronavirus 2.

First of all, we're going to have Joshua Sarnoff who's going to talk to us about the TRIPS[2] waiver[3] and whether it's needed, but not nearly enough.

JOSHUA SARNOFF: Okay. First, I'm going to assume everyone knows about vaccine nationalism and the TRIPS waiver. What I want to focus on is the logic of why we need the TRIPS waiver. Pfizer was sued by Allele Pharmaceuticals for using the patented mNeonGreen fluorescent protein technology during mRNA vaccine clinicals.[4] The reason that we now have the Pfizer and BioNTech vaccine is likely because the law made the unauthorized non-compensable use of that technology, the fluorescent protein technology, possible by Pfizer and BioNTech. That's the reason we need to have a waiver; to assure that patented R&D,[5] in the form of research tools and other processes, etc., does not stand in the way of our getting the vaccine in time.

In contrast, this is the hypocrisy of what Pfizer is saying. They're claiming in the case that the suit should be stopped before it becomes another burden on Pfizer and BioNTech as they continue to work on this vital vaccine. First, it's ridiculous because the vaccine is already done and approved. But more importantly, what they're saying is that the patent rights are a burden to vaccine development, although it's really just about money for them. Compare what Pfizer actually said during the COVID-19 patent-pooling efforts: "[Companies are] investing billions to find a solution, and keep in mind, if you have a discovery, we are going to take your [intellectual property], I think it's dangerous."[6] But that is precisely what they did in regard to developing the vaccine, and now they're complaining they shouldn't have to pay for it.

Why are we in this position? Because the patent and know-how[7] bargain is badly out of balance. The premise of the patent system is that you get a quid pro quo of temporary exclusive rights for disclosing how to make and use the patented invention. Yet, the whole premise here is that if we're now seeking patents on the vaccines that were just made, and we need the know-how to be able to make it and to be able therefore to use it. What we're essentially seeing is fraud on the entire public, or theft of the public's rights, because the public is now being excluded from doing so without disclosure of the capacity to do so. More importantly, if that disclosure was adequate to make and use, then the TRIPS waiver *would* be sufficient to permit rapid scale-up of manufacturing around the world.

Without patent rights, which is where the waiver might lead, we would still need to compel know-how sharing for any rights that were not retained by

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[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 50 (7), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

[3] *See* Jana Titievskaia, World Trade Organization TRIPS Waiver to Tackle Coronavirus, EUROPEAN PARLIAMENTARY RESEARCH SERV. (June 2021), https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf.

[4] Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc., No. 20-CV-01958-H-AGS, 2021 WL 1749903 (S.D. Cal. May 4, 2021).

[5] Research and development.

[6] Albert Bourla, Remarks at IFPMA Global Biopharma CEO/Top Executive COVID-19 Media Briefing (May 28, 2020).

[7] "The learning, ability, and technique to do something; specif., the information, practical knowledge, techniques, and skill required to achieve some practical end, esp. in industry or technology. Know-how is considered intangible property in which rights may be bought and sold." *Know-how*, BLACK'S LAW DICTIONARY (11th ed. 2019).

the government (a subject for a different day) when the government is paying for vaccine development. How do we compel know-how sharing? Voluntary licensing is good, but it clearly isn't enough when there is a larger need and facilities around the world are not being licensed because of the loss of long-term profits that will result from the loss of trade secrecy and know-how constraints.

In wartime, we often recognize the need to place public needs above corporate profits. We should be treating this as a matter of wartime efforts against the virus. The corporate sector should volunteer to donate its intellectual property. It's been done in every sector except the biopharma industry, and that speaks volumes about their commitment to saving lives. There are also wartime examples of how governments can direct know-how sharing – including penicillin production during World War II – to gear up production among competitors, which then may lose the trade secrecy. If so, the world can compensate for any compelled know-how transfers that result in lost value. It will be much cheaper overall than the cost of failing to vaccinate rapidly, particularly because we'll generate so many variants that will come back to kill us if we don't do it. In fact, compensating for any lost intellectual property rights is going to be significantly less than the 9 trillion of economic costs that were projected to result from the pandemic, and those estimates are probably too low. But more importantly, companies should not seek compensation, but should be encouraged to authorize or to make uncompensated uses in emergencies, just like Pfizer did.

The bottom line is, we know that we can compel know-how sharing and compensate it if we need to. But we shouldn't need to, and companies should "just do it," not just as a matter of voluntary licensing where they can control the information restrictively, but as a matter of public need. That's it. "I'm here till Thursday. Try the veal…" Penny, was that heard?

PENNY GILBERT: No, it was heard. Thank you. Yes. Then your five minutes. Right, I'm going to throw that over to the panel and to the audience for commentary. Do we think that really there should be know-how sharing, and what puzzles me is how we incentivize the investments into research to get to this point, if we're not going to allow patenting.

JOSHUA SARNOFF: Read my article in *Emory Law Journal* about the many ways that governments can fund innovation.[8] Quite frankly, intellectual property is a government grant, it's a subsidy. Government can provide other kinds of subsidies that aren't exclusive rights. It just means that we have to get over our love of the private sector and treat this like wartime where we are in a government-private cooperative measure to try to save massive numbers of lives around the world and in the US. We are not doing that; we need to.

PENNY GILBERT: Do we think it's enough to leave it to individual governments? Don't you then risk even more of a problem with individual governments?

JOSHUA SARNOFF: Of course not, but it is the governments that actually control the production that have the ability to share and compel the know-how. That's the key until we have a world government, which we're not going to get to this week. We have to have the governments that have the power

[8] Joshua D. Sarnoff, *Government Choices in Innovation Funding (With Reference to Climate Change)*, 62 EMORY L. J. 1087 (2013.).

to use things like the Defense Production Act[9] to force the know-how transfers to places like Africa, where they might have capacity, and to other places around the world, where they more clearly have capacity.

Let's face it, we now know AstraZeneca is not going to be the main vaccine for the world. People are going to be relying on the Russian and Chinese vaccines, but of course, Moderna and Pfizer could provide their technology to the same facilities that are doing AstraZeneca or Johnson & Johnson or something else. If we forced them to share that technology, we could gear up production much more rapidly for the world with a much more effective vaccine. Why are we not doing it? Because then we would lose our trade surplus and they would lose their trade secrets. Let's just have the world compensate for the lost value and have everyone better off.

PENNY GILBERT: Perhaps, let me pass it over to one of our panelists. John Lee, would you agree that patents are a problem in rolling out the vaccine development?

JOHN LEE: I don't think so in terms of the incredibly rapid development we've seen of a number of different vaccines. It sounds to me like the real concern is about production and distribution and notwithstanding the topic here is patents on the pandemic. Again, it seems the concern here is really about know-how, and enabling that very massive scale-up that we need of production and distribution to all countries, but based on the speed of the development of these key vaccines, I certainly can't see any evidence that the patent regime has hindered that.

JOSHUA SARNOFF: Let me just say again, Pfizer has either illegally infringed, which is the reason we've gotten it, or Pfizer is not engaged in infringement, because it's not legally defined as infringement, yet they're using unauthorized products that are patented. It is precisely because the patent system has *not* prohibited such conduct that we have not had a problem. We have no idea how many other patents they may have avoided. Same with Moderna and everyone else. I don't know that we'll ever get to find that out. But you can say that it has not been a problem because the patents were avoided. It's only not been a problem precisely because we've effectively implemented the same effects as the TRIPS waiver by either exempting the particular uses or by illegal infringement. It's just about money now.

PENNY GILBERT: Kevin, perhaps I could turn that over to you. What do you think about the suggestion that there should be compulsory sharing of know-how as an effective solution to increase manufacturing?

KEVIN MCGOUGH: Yes, thank you. I have to take issue with the number of points that the professor has made with respect to the district court infringement case. I believe, although he can correct me if I'm wrong, I believe that is a case brought by a party that holds a patent on a fluorescent tag. I believe in the defense cited by Pfizer in the litigation, the activity at issue actually falls within the safe harbor. In a safe harbor defense to infringement the whole purpose of which is to further drug development. Some facts, I've heard a lot of generalities—

JOSHUA SARNOFF: Precisely my point.

KEVIN MCGOUGH: I've heard a lot of generalities mentioned, but you should look at the cold hard facts, which are as follows. 90% of the therapeutics

[9] Defense Production Act, 50a U.S.C. §§ 2158–2166 (2012).

that are being employed or that will be employed to combat COVID have been developed by the private sector. 50% of those have been developed in the United States. The entire premise of the innovative activity and risks associated with those undertakings has been a robust intellectual property protection. Again, it's just been mentioned that this really, probably all parties could agree is a problem, perhaps it's distribution. Well, if you read this Sunday's *Financial Times*, there was a wonderful article about how BioNTech in a matter of 30 days, implemented a new messenger RNA factory in Marburg, Germany, and is already producing vaccine to share with the world.[10]

In fact, Moderna, to the best of my knowledge has agreed it will not enforce its intellectual property during the pendency of the pandemic. To point in a broad brush at the pharmaceutical and biotech industry and say that they are somehow motivated by greed, that they are somehow frustrating efforts to help people during this pandemic, is just wrong. I don't think the facts support it.

PENNY GILBERT: Thank you. At that point, it's probably a good time to pass on to our next speaker, John Todaro from Merck, to discuss again the role of IP rights, from a different perspective this time.

JOHN TODARO: Thank you, Penny. I'm happy to be here. I'm really honored to be on this panel. Well, IP professionals have done a lot of thinking on this issue and I'm glad to have the debate. I'm also really glad to be participating at Fordham seminar as a longtime fan of the program.

I think we all agree that the goal here would be to get safe and effective medicines, get them developed, and get them manufactured in sufficient qualities, and ensure access to medicine around the world so that everyone is able to be treated and the world is safe. That's the only way it's going to happen. My position is that IP rights have really been crucial in getting the world to this point in fighting the virus and saving lives, and we need to safeguard those IP rights now to continue the fight against the pandemic and also to confront the next pandemic, whenever and however that may come about.

We also need to think about how far we've come, and Penny made a good illustration of that point. In the beginning, it was late 2019 when we first heard of the virus with reports from China. Early 2020, the virus sequence was put online by researchers in China, and right away, research scientists in industry and academia got to work on looking for ways to combat the virus. Now a little more than one year later, we have not one but several available vaccines which have been proven to be safe and effective, probably more safe and more effective than we had thought really possible.

Previous efforts to develop vaccines required years of research and testing, at least four years, and now we are producing those vaccines at much greater amounts than ever before and therapeutics are in development. At least one therapeutic, Remdesivir, has been approved, so how did we get here? The answer is through building on years of scientific research, all supported by IP and by patent publications, and by entering into collaborations in specific response to the pandemic. We talked about vaccines first, of course, everyone talks about Pfizer and BioNTech.

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[10] Erika Solomon, *'Where the Magic Happens' — Inside BioNTech's Innovative Vaccine Plant*, FINANCIAL TIMES (Apr. 2, 2021), https://www.ft.com/content/cf5d6113-3698-4cc7-9d5b-8f0f29fd6a35.

They started their collaboration in January, just after the sequence of the virus. They had a previous collaboration on a flu vaccine, so the two companies were used to sharing IP and working together. That gave them the confidence to go forward. That's of course not the only IP issue related to the story of the vaccines. Both of Pfizer/BioNTech, and Moderna vaccines are messenger RNA-based vaccines. That vaccine technology was developed by researchers in the 1990s. It has been taken years to develop that technology to the present point. Years of research which needed to be funded, which required licensing, which required patents. The researchers needed to address issues such as mRNA instability, and immunogenicity. There needed to be also significant advances in delivery technology, including the development of lipid nanoparticles. Some of the other vaccines, J&J, the one of the CanSino biologics vaccine, and others, and AstraZeneca relying on adenovirus vectors, another technology that was years in development, had earlier been used in gene therapy that had failed but, nevertheless, researchers continue.

Like all innovations, these innovations built on each other one step at a time and were protected by IP rights. The researchers use these IP rights to obtain funding to continue their research. All these investments were made at risk. We all know how risky drug development is, how many years it takes to develop a medicine. Also, keep in mind how patent rights permit and encourage publication, so all of these patents were published giving the world a knowledge of the technology and encouraging researchers to develop further and better technologies.

Not only has the research and development, part of this has been outstanding but also the breadth of the manufacturer has been much more significant than in past years. Companies have entered into collaborations to share IP and know-how to permit manufacture. Pfizer and BioNTech have worked with Fosun Pharma of China, J&J is licensing to Merck & Co. here in the US to conduct manufacturing, and the AstraZeneca Oxford vaccine, the technology, and know-how has been transferred and licensed to Serum Institute of India for manufacture.

For all these vaccine manufacturers, there's just a network of suppliers, producers of excipients, producers of materials, everything, all that is part of the manufacture that needs to be done. Much of it done at risk, all working together to produce treatments for patients.

That's only about vaccines. Of course, there are many small molecule therapeutics or biologic therapeutics in development.

I did a search on the FDA[11] website some time ago and I think they acknowledge or— Well, you can find various lists of the numbers of drugs in development but it's somewhere in the hundreds. We've come far but the world has far to go, that's for sure. I want to be clear about that.

There are ongoing broad efforts to share IP in the interest of public health and the interest of getting vaccines and medicines to the world including to low-income countries. I'm talking about the ACT-Accelerator,[12] which is an organization of the World Health Organization, is a sponsored organization, working with various partners including NGOs, such as the Bill & Melinda Gates Foundation. The ACT-Accelerator is dedicated to procuring and

[11] U.S. Food and Drug Administration.

[12] Access to COVID-19 Tools (ACT) Accelerator.

delivering COVID tests, therapies, and vaccines for use around the world. It's trying to use the expertise of its volunteers and partners to work together to develop and provide medicines.

This is not a time to be distracted by arguments against IP rights. The argument against IP rights has been around for a long time and, of course, in the mid 20th century, several countries including India, South Korea, Brazil did not permit patenting on pharmaceuticals. There is always the concern that pharmaceutical patenting may impede access to medicine. Going forward, in November 2015, we had the UN Secretary-General's High-Level Panel on Innovation and Access to Health Technologies,[13] which also criticized IP rights and alleged a threat or how it would impact access to medicines. Now, we have the waiver provided by India and South Africa.

This is not a new argument, it has been around before and I just don't see any evidence for it. Waiving IP rights now will cause companies to hesitate in investing in technologies, it will not bring more vaccines or more therapeutics forward at this time. It's not a time to lose focus on what is being done.

I mean, even the new WTO director Ngozi Okonjo-Iweala has acknowledged the difficulty of large-scale vaccine manufacturing and the complications of sharing know-how.[14] It certainly can be done but it requires a willing and capable partner who has the resources and abilities to accept the technology and implement the new practices.

I see I'm out of time, Penny. I will stop there. I just point out that the COVID-19 pandemic, I think we all will agree, is probably not the last pandemic that we will have to face, and we need to maintain IP rights in order to effectively fight this one and prepare for the next one. Thank you.

PENNY GILBERT: I think that makes a good point that actually what we've seen, although there's been rapid development, is built upon years of underlying research and development to get to the point where we've been able to adapt to face the pandemic. Can we really say that the patents are problematic here? Can we dissect IP rights from all the other factors that are in the way of a broad rollout? Don't know whether any of our panelists would like to comment on that?

MIQUEL MONTAÑÁ: Yes. If I may give my two cents. I would like to go back for a minute to Professor Sarnoff's initial presentation. When I read the waiver proposal submitted by India and South Africa, I was surprised by the contrast between the thin justification of the proposal and the breadth of the proposal. Against that background, it is not surprising that the UK representative within the TRIPS council nicknamed the proposal an extreme measure to address an unproven problem.[15]

Today, I was expecting Professor Sarnoff to give some evidence of the problem but hearing the Pfizer story, I think that he gave additional evidence that there is no problem in the first place. I mean, if Pfizer has been able to

[13] U.N. Secretary-General, *Promoting Innovation and Access to Health Technologies*, (Sep. 12, 2016).

[14] *See* Ngozi Okonjo-Iweala, Director-General, World Trade Org., Chair Summary Following "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" (Apr. 14, 2021).

[15] *UK Statement to the TRIPS Council: Item 15 Waiver Proposal for COVID-19*, GOV.UK (Oct. 16, 2020), https://www.gov.uk/government/news/uk-statement-to-the-trips-council-item-15.

develop that vaccine within the legal framework of TRIPS, that illustrates to my mind that TRIPS is fit for purpose already and that it has the necessary flexibility to allow companies to develop their vaccines without having to modify the current provisions of TRIPS.

Actually, what India and South Africa are proposing from a technical point of view, it could not be called a waiver. That would be a suspension of four entire sections of an international treaty, the approval of which would require the unanimous consent of all the contracting parties. It's a very big thing and the proposal had, as I said, a very thin justification.

If I may echo the words of John Arne Røttingen**,** the chair of the World Health Organization Solidarity Trial of COVID-19 treatments, the problem of access to vaccines is not patents, it's the complexity of vaccines which are very complex biological products, the scarcity of production plans, and the lack of appropriate health infrastructures in many countries.[16] To wrap up, I think that the patent system should be looked at as a friend, not as an enemy, and TRIPS already has the necessary flexibilities to address this type of pandemic.

PENNY GILBERT: Thanks, Miquel**.** That's probably an appropriate time to go on to discuss TRIPS and the waiver that's been sought and the other issues arising around TRIPS perhaps. Can I invite James Love to give us his views?

JAMES LOVE: Okay, fine, thank you. First, there are a lot of comments about how great the innovation story is and that's really been true but there were billions of dollars that were gifted to the companies working on vaccines from both the United States primarily, but other governments as well, particularly in Europe. Moderna, everything was paid for by the US. J&J, deeply subsidized by the US government. Novavax, CureVac by Germany in the EU, Pfizer by the EU, big advance purchase agreements, de-risking. Every single major vaccine that's out there had something I've never seen in my entire life. That should just at least be mentioned somewhere that where the money came from and who de-risked everything.

I just want to make a comment also on the complexity of manufacturing. Bill Gates has been on YouTube saying that it's harder to make a vaccine than a jet airplane or a jet airplane engine. It makes it really sound like it's just super-duper difficult. I'm sure it is challenging for some vaccines, for the people on this call. It's not challenging, of course, to everyone out there. Not all vaccines are really that difficult. I know that we were recently talking to the NIH[17] about one vaccine that's out for licensing and it was described as something that a high school science teacher can make.

It depends a little bit on the platform and there's quite a few different platforms in development. Our take is on a TRIPS waiver, I'll say briefly that, and I'll just try and make it as simple as possible. The TRIPS waiver for most countries doesn't change their national law at all. Unless your laws specifically reference a TRIPS agreement, it doesn't change your patent law and that's one thing. It just allows you to change your patent law without WTO sanctions. Plus it's narrow. It only applies to COVID-19. It only applies during the pandemic. It's a ridiculously narrow proposal actually. My guess is that if the US was to support it and we go through, wouldn't make much of a difference because I

[16] *See* Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patents Ban*, 396 THE LANCET 1790 (2020).

[17] National Institutes of Health.

don't think too many countries would actually change their patent law because of the waiver. It takes too long to change their patent law and the change would be too narrow.

That said, it's probably more of a political thing. There are some provisions in the TRIPS it would fix. Articles 31F and 31bis of TRIPS, in particular, are quite toxic and it would solve those problems and that has to do with the export which is actually a big deal right now. That alone might make it worth it. Then now that it's out there, people debate it. It actually has become a bigger discussion about intellectual property. You're stuck taking sides for and against at this point. We've been a little bit discouraged about the lack of sophistication in the debate but there it is.

We just told the US, why block it? You'll just be blamed for people not getting vaccines. It's not going to make that much of a difference by itself. I agree with everyone that said that know-how is really the strategic issue. I disagree with anyone that suggests that somehow we're at the production frontier for vaccine manufacturing. One thing that we've learned is that every week there's a couple of new announcements of some new production-sharing agreements that didn't exist the week before. This idea that everyone that was doing it was already doing it was just clearly crap.

Companies that had the capacity to do it weren't really being engaged, it was just poorly organized to do things. Companies that had vaccines to develop that failed. It took a while to get them back engaged. There's a lot of companies that have facilities that can be repurposed for this. The average time for an outsourcing manufacturing contract for vaccines is about six months. It's surprisingly fast. That's another thing that was a bit of a surprise. We've talked to companies in Canada, two of them. Companies in Denmark, companies in South Africa, in Pakistan, and Bangladesh, different countries. They clearly cannot get a voluntary license for either the patents or the know-how to make vaccines which is unfortunate.

The World Health Organization had a proposal in the spring of last year which has really gone nowhere which is to have voluntary licensing of not just the patents but access to the working cell lines and access to the know-how. The laws about patents, I'm not going to go on and on about this. I'm going to wind up right around here. The laws about patents are easy to implement compared to the laws about know-how. You can just declare that a patent is not enforceable in a country where you can issue a compulsory license and a judge can do that or something like that.

To do manufacturing know-how really requires the cooperation of the people that are doing the manufacturing. That's a much more challenging task. I agree with everyone that says that that should be the focus and that's actually the weakest part of the whole process right now is to address that. Going forward, I know that the contracts we spent billions and billions of dollars that were sent by public institutions did not have good contract provisions on sharing of know-how, IP, or access to cell lines and that was a mistake.

Right now, I think what's left to countries in that area in many cases, beyond whatever leverage the Defense Production Act or something can do, would be to really mobilize on trying to do know-how buyouts. I think if you do patent and know-how buyouts pretty effectively right now, it would be very cost-effective because there's so many vaccines out there. You don't have to do it for all of them. You just have to do it for some of them, the ones that work

and the ones which are relatively easy to manufacture and can be done cheaply and are appropriate in developing countries.

For developing countries, we're talking about some countries 2023 before they're vaccinated. If you think that's okay, fine. I don't think it's okay. Even if you don't care about people in developing countries, you should care about the fact that that's the breeding ground right now as we're seeing for Brazil and other places for new variants. Thank you.

PENNY GILBERT: Thanks, James. Kevin, would you like to respond to that?

KEVIN MCGOUGH: Everyone on this panel, I believe, and almost everyone in the general public is hit by one desire. That is that the maximum, that everything that can be done reasonably to protect the public health and the health of the greatest number of people on the planet should be done. No one disputes that. I truthfully think admittedly from a pharmaceutical perspective perhaps but also as a private citizen, I truthfully think that the vast, vast majority of the people in the drug industry share those views. Everyone will agree the public must be protected to the greatest extent possible. Working backwards, how do we do that? Again, I speak as a private individual here. I liked the citation of the jet engine because it brings to mind the following comparison. You can't help someone start an airline by giving them an airplane.

If you take an airplane, if you have an airplane and give it to someone, they don't have an airline. They have an airplane. Even if they know how to fly, they need airports. They need ticket agents. They need certification from the FAA.[18] They need all of the complex interrelated components of running a successful airline. I submit personally that it's far better to take an approach like the United States took during the AIDS crisis, another insidious threat to public health that sadly remains with us. That was PEPFAR[19] where, as I understand it, great thought was given to the fact that every life counts, whether it be a person in Africa or a person in the United States or wherever, everyone should be entitled to the safest drug and to the most effective drug. The way perhaps to get them those drugs is to maximize production. Let the experts produce using their know-how and then let governments intervene to buy those drugs at whatever price and distribute them as quickly as possible to as many people as possible in the globe. That to me would do the greatest good.

I think it would be a reasonable approach. Trying to help someone establish an mRNA factory in Bangladesh will be a distraction, as opposed to a government saying to a manufacturer, "Make as much of this as you can, expert. Negotiate the price at whatever basis you choose to do that and get those drugs out there to people quickly," as opposed to taking experts from the various drug companies, sending them around the globe, and having them build little factories for everybody. To me, that's just not efficient.

PENNY GILBERT: I guess one thing that concerns me is the way that we have seen the Oxford University vaccine taken up and licensed by AstraZeneca and sublicensed to the Serum Institute in India, for example, but product then being blocked for export from India by the government. I'm not personally convinced that just allowing rollout to other countries to manufacture is necessarily the way forward. I think there is an issue beyond just being able

[18] Federal Aviation Administration.

[19] The President's Emergency Plan for AIDS Relief.

to manufacture around the intervention of governments in exports. Having said that, let's perhaps go on to our final speaker, Justin Hughes, who's going to talk about keeping everyone in the bargain.

JUSTIN HUGHES: I actually think that the [unintelligible] and I [unintelligible] the public-private biopharmaceutical industrial complex has done an excellent job in [inaudible]
focusing of, and pivoting research and development and manufacturing resources toward COVID vaccines. Now, Josh likened this to war. I think we need to be very careful about not using that word lightly. But the analogy to war [sound cut]

Anyway, [inaudible] these resources as quickly as we have is going to produce a lot of confusion and opacity and waste. I was mainly going to talk about the bargain, but I do want to say a little bit about patent pools and the TRIPS waiver and whatnot. I had an academic meeting this summer on Zoom, where a professor expressed sadness that big pharma was treating the pandemic as business as usual in terms of intellectual property and profit-seeking.

While that may be true to some extent, everyone needs to understand that the TRIPS waiver is business as usual in Geneva. That's just how Geneva operates. India and South Africa have very sophisticated diplomats. They know that this proposal has little or no chance of success. Jamie Love correctly characterized it as political and that it might not have much difference. It is a standard completely normal in Geneva to bring diplomatic pressure on an issue. Now, you might say, that's cynical and that's not fair but here's the challenge I give you.

If you think this proposal is real, go get every piece of information you can find about the Quad meeting where Prime Minister Modi and President Biden along with the Prime Ministers of Japan and Australia laid down a plan to increase vaccine production in India with help from the United States and Japan.[20] There was no discussion of the TRIPS waiver. Prime Minister Modi had every opportunity to do that. As far as I can tell, even in the work up to the meeting, that was not an ask on the Indian side. Now, if anyone has evidence of that, I'd like to know that. If I am correct on that, that it didn't come up in the Quad meeting, that's how much the TRIPS waiver is just part of the spark and pastime of Geneva.

As everyone knows and as already been discussed, the Moderna patents have, in fact, offered a waiver. In October 8th, 2020, Moderna said it would not enforce any of its patents against other producers of RNA vaccines during the pandemic.[21] We all agreed that the issue is not for mRNA patents. It's not patents, it's know-how and manufacturing facilities. Now, Josh, I have to take you to task on something. You said, there are other facilities, the same facilities can be used for the Pfizer or Moderna vaccine.

No, they can't. All right? On March 8th, at a WHO[22] forum, the chief medical officer of BioNTech said very expressly you cannot just repurpose

[20] *See Quad Leaders' Joint Statement: "The Spirit of the Quad,"* WHITE HOUSE (Mar. 12, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/12/quad-leaders-joint-statement-the-spirit-of-the-quad/.

[21] *Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic*, MODERNA (Oct. 8, 2020), https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19.

[22] World Health Organization.

existing facilities.[23] When we talk about facilities and capacity, and I think Jamie Love is right, that we do need to figure out where exactly there is capacity. You've got to match up capacity with the kind of vaccine you're going to produce.

In the case of the RNA vaccines, it's just not the case that our existing facilities can do it if we are to [inaudible] who created the vaccines.

As someone already said, Moderna has had one taker, but that is a Swiss company that has built a greenfield facility in Switzerland to produce the vaccine [inaudible] vaccine. We all agree that know-how is the problem. We all agree that that requires co-operation. We can't really just indenture people who have the know-how and send them around the world. I think that we would generally agree that the patent [inaudible] is not the issue. The co-operative means of getting is the issue. [sound cut]

PENNY GILBERT: I think we lost Justin again, but, hopefully, he finished [chuckles] but if not-- I think what I'm going to do now is to turn to the questions and answers. I know that Josh has got some questions for me to read out as well. Let me take them bit by bit, and then, perhaps I can invite everybody to comment on them, and we can just open this up to discussion with the participants in the audience as well.

First of all, there's a question from Giuseppe Mazziotti. It says, "Moderna's statements about its intent not to enforce patents of its vaccine does not mean much. Third parties have no access to information. These patents are still binding. No publication rights." That's the question. I think that may ignore the fact that actually much of the research has been put into the public domain as I understand, and obviously, builds upon earlier work. I don't know whether [crosstalk]

JUSTIN HUGHES: It doesn't [inaudible] in the public domain if you don't [inaudible] in the art.

PENNY GILBERT: I think that's [unintelligible]. Sorry.

JOSHUA SARNOFF**:** Just a second to you Justin, simply to say that that's precisely why you need to have the know-how compelled to actually get the other facilities up and running, because otherwise they can't make it. But they could with the adequate know-how transfers.

PENNY GILBERT: Another point that's made in the Q&A column by the same person, is to point out that actually nobody is mentioning is even if you manufacture and you have the know-how and you have the access to the patent rights, there will still be the requirement to produce clinical trial data which is going to be submitted for authorization, subject itself to data protection rights or regulatory data protection. That is also another issue for anyone trying to bring their product to the market. I don't know whether anyone has any thoughts or comments on that?

JOHN LEE: John Lee here. I just think it's another example of, there are so many complex pieces to this matrix in trying to achieve what is clearly the common goal. It just shows that patents, I think, are only a very small part and perhaps even not a very significant part of it. We've heard a lot more about know-how, but there's much more, I think, in the logistical, political issues that are going to either enhance us getting to that common goal more quickly or slow

[23] *Media Briefing on #COVID19*, World Health Org., YOUTUBE (streamed live on Mar. 9, 2021), https://www.youtube.com/watch?v=ePOw53cXNmI.

us down. I think we cannot overstate the significance of patents and IP generally.

PENNY GILBERT: It's true. I think we've already heard concerns about the availability of plastic tubing and all sorts of other components in the production process as well. It comes down to more than just, I think, availability of the IP rights to manufacture a vaccine. Anyone else got any thoughts on that?

JOSHUA SARNOFF: Again, we could compel the transfer of trade secret information to ensure that third-party manufacturing gets clinical approval. And that requires intrusive intervention by the public sector. I also just want to respond briefly to Kevin. Kevin, I am, again, delighted that we threw lots of public money at the problem and that industry has moved so quickly to generate the vaccines.

The problem with the way we've done it is truly offensive. That way was to create vaccine nationalism where we hoard the vaccines in the countries that produce them, principally, and then throw out the lives and value of the rest of the world. If we had donated all of the increased production to World Health Organization to distribute equitably and to those at highest risk, then maybe it would be a meaningful discussion. But we didn't do it that way. It's offensive. The government shouldn't have entered into those contracts and the pharmaceutical industry shouldn't have asked to make it that way.

PENNY GILBERT: Would you want to respond to that?

JUSTIN HUGHES: Sure, if you can hear me. Can you hear me?

PENNY GILBERT: Yes, we can hear you.

JUSTIN HUGHES: Josh is a very idealistic person and he has frequently, in our discussions, recommended what I would consider political suicide for any democratically elected person or any dictatorially kept-in-power person. The first obligation of a political leader is to protect their people. Josh, I don't understand how you find it offensive, but I don't think the average American or average person of any country would find it offensive. Now, Penny, you said that India had put a ban on exports. That's according to the Ministry of Foreign Affairs inaccurate. They haven't technically banned the export of Serum Institute's doses. They have simply, at this moment, reallocated [inaudible]. It probably is effectively the same thing as a ban but [inaudible] and its importance the [unintelligible] of it. When India says the previous position of the Serum Institute had been [sound cut]

JOSHUA SARNOFF: Justin dropped off the call. I'd respond to him briefly. Every moral code is based on the golden rule that we treat others as we would want to be treated ourselves. We are acting immorally here, and we can actually use our politics to achieve a moral result. Every democratic government is obligated to follow the will of its citizens. Even if its citizens prefer to protect others rather than themselves. We just need to marshal the democratic support to act morally. Thanks, Justin.

JUSTIN HUGHES: I don't disagree, but I disagree with you that any democratic society would choose first to vaccinate everyone else. I think every democratic society would preserve itself first and that's not morally unreasonable.

JOSHUA SARNOFF: Not morally unreasonable, just morally wrong.

PENNY GILBERT: We've got another question from the Q&A panel, from Heli Pihlajamaa who's from the European Patent Office. She points out that actually the whole part, part of the purpose and function of the patent system

is to distribute technological information. It's part of the patent bargain. You disclose your invention in return for the monopoly that you're rewarded with. What can we do to direct people to that information to make use of it, I guess is the question.

JOHN TODARO: Penny, if I may, I'd like to respond to that issue. I think we need to be careful about, there's two types of laws here. There's the patent laws, IP laws, and then there's the public health laws. The patent laws protect an invention, in this case, the invention may be a vaccine. To satisfy the public health laws, to get an approvable drug product, there are other laws that need to be complied with. The issue that I'm trying to point out is that the patent rights provide support for the invention and how to enable the claims of that invention.

There is a separate set of laws in order to comply with public health law that is really encased in the know-how, a lot of it. Also in the patents, but in the know-how and protected by the data exclusivity rules, which is part of TRIPS, which would, of course, be subject to the waiver, so that is one of the issues addressed earlier about how the waiver may impact the ability to rely on clinical data. Nevertheless, the point I'm trying to make is there are two separate provisions. I think it's important not to confuse them and to understand why the value of the know-how is so important.

PENNY GILBERT: Actually, there's a question from Jamie who I think is on mute at the moment. He said, what should be in the new WHO pandemic treaty? I think Jamie wants to answer his own question.

PENNY GILBERT: Actually, you're still on mute at the moment.

PENNY GILBERT: We would have to wait for an answer in the Q&A tab perhaps [chuckles]. Perhaps, it's not so of much a question, but a comment. It comes from Gordon. He says, "This is not a moral argument, it's a practical one. Until the world is vaccinated, we'll not be able to open borders and return to normal business." I'm not sure that anybody disagrees with that, but I'm not sure that it's an answer to how we get to that.

JUSTIN HUGHES: Well, actually I do have an answer to that, Penny. The vast majority of people living in democratic societies don't worry about crossing borders. It's a very elitist thing to say, "Oh, we can't get back to business as usual." It's your business as usual. It's not the 90% of the world that doesn't worry about crossing borders all the time. Folks, if you're going to talk about what democratically elected societies want, not what we, this very elite group of international lawyers, want, it's a different want.

JOSHUA SARNOFF: There are two important things to add to Justin, one is that by prioritizing according to vaccine nationalism. First, we actually are going to increase the number of deaths around the world. And we are going to increase, as a result of not vaccinating those most at risk first the number of variants that are developed, which will come back to kill us. The second and more important point in response to the question is, we know that the economics have impacts, $9 trillion[24] according to the ICC.[25]

It's probably much more than that. The more we could vaccinate the rest of the world according to the highest priority, the less economic damage will result to our own country, which our country does care about. Also, perhaps

[24] Cem Çakmaklı et. al., *The Economic Case for Global Vaccinations*, (Jan. 2021), https://iccwbo.org/publication/the-economic-case-for-global-vaccinations/.

[25] International Chamber of Commerce.

even more people then become poor, unless we continue to put the costs of these economic losses on to a future generation and then default on our debt 10 years from now.

JUSTIN HUGHES**:** I think that we should vaccinate the world as quickly as we can and we should bankroll it and I agree with that. I just say, it's completely explicable in terms of democratic preferences that every democratic society seeks to vaccinate itself first. I have no problem with the Indian Serum Institute. "You may have wanted to do a 50-50 split, but until we get the surge under control in India, your production goes principally to Indians." Makes perfectly good sense to me. Now, Josh, you may disagree. You may think that the Indian government, while Indians are dying should say, "Hey, Serum Institute, you should continue sending 50% of your vaccines out of the country." You may think that's the moral decision, I don't.

JOSHUA SARNOFF: I think that we need a world health system where all of the vaccine production goes to the WHO for distribution, according to the highest priorities to save the most people worldwide. Very simple.

PENNY GILBERT: I've got to pass the discussion to Jamie Love because I think he's off mute now so hope you can hear him.

JAMES LOVE: Well, we always assume that the products were going to be a mess, that there would be the export restrictions and things like that. I think Justin's correct. If you're a politician in a country, you're going to be expected to take care of your own people first. That's what Biden's doing, that's what the European Union's doing, that's what most countries have tried to do that like India. It's not just the United States, it's around the world that's kind of normal.

But the manufacturing know-how has been hoarded. This idea that that companies are doing everything they can, it's just empirically not true. We have a whole spreadsheet on companies that have some capacity, they have been unable to obtain agreements and things like that. The big failure has been that manufacturing know-how has been hoarded. If there's a pandemic treaty with WHO, which is what the proposal is, what the European Commission has proposed, what the WHO is negotiating right now. What should be in the pandemic treaty for the future?

Should the manufacturing know-how for new vaccines, for the next pandemic, be treated as a global public good? Or should it be this commercial thing where basically you've got companies hoarding the know-how, and putting everything under what the WHO calls toxic technology transfer agreements to limit the actual transfer of manufacturing know-how? Certainly, where manufacturing capacity exists has never been, more obviously, a problem of access. Where they manufacture the vaccines is where people get the vaccines right now.

PENNY GILBERT: Anyone else have any comments to weigh in on that? Do you think these discussions, at a time when the world has a pandemic and we are trying to cope with that, will lead to an overall review of patenting system and perhaps the next generation of harmonization? I think John Lee, that was something you proposed might be something that happens as a consequence of all this.

JOHN LEE: Seems to me that there's been a lot of high-level discussion of the patent system and intellectual property, generally, over the last 12 months and a lot of discussion of the pros and cons and the impact on what we are all

trying to achieve here, even though I think that it's a relatively small piece of the puzzle. Intellectual properties being pretty high profile at government level and I wonder whether it may stimulate some further discussion on harmonization and review.

I think ultimately the proof is going to be in the pudding here and at some point, perhaps in a year or two down the track we will look back and be able to weigh this up and perhaps with some quantifiable evidence about what the impact was, if anything out of the patent regime. Decisions will then be able to be made about what do we do to ensure as people say, the next time we face a pandemic we get to the end goal more quickly.

PENNY GILBERT: Anyone else have any other thoughts? Miquel, do you think you would like to comment?

MIQUEL MONTAÑÁ: Yes, before we finish, in relation to the morality point raised by Joshua, I don't think that's something that can be fixed by the TRIPS waiver. Assuming that this morality problem would exist, which I doubt, the solution lies in taking advantage of the current flexibilities already existing in the TRIPS agreement, and also in giving corporate social responsibility a prominent role.

It's time for solidarity I think, it is not time for vaccine nationalism. I agree with Justin in the sense that this proposal of India and South Africa is a diplomat pastime because it will not get anywhere but, at least, it has had the advantage of *frapper les esprits*[26] as my French colleagues would put it, raise the awareness of the international community on the need to make vaccines quickly available to everybody, everywhere. I think we would all agree that that's the ultimate goal, and the tricky point is how we get there.

PENNY GILBERT: I think we have probably come to the end of our time and that's not a bad comment to end on, frankly, I think. Thank you everybody for your contributions towards an interesting discussion and one that I think is going to run on for some time. I think at least we can all say that we are grateful that at least at the moment we do have vaccines available. We have got them, and they will hopefully make their way around the world as quickly as possible. With that thank you, thank you, everybody.

[26] Striking their hearts.