#GlobalDigitalEncounters

#12: The Race for the Vaccine: IP as a Tool or as a Toll?

Global Digital Encounters

Encounter 12: The Race for the Vaccine: IP as a Tool or as a Toll?

Report Encounter 12

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Speakers:

Prof. David MIRCHIN, Professor in Technology Licensing Law at Tel Aviv University Law School and Academic Fellow (Robot and AI Law) at Bocconi University and the Head of Technology Transactions and Licensing Group of Meitar.

Prof. PATRY, CEO at France Brevets. ESCP Business School, The London School of Economics and Political Science (LSE) and an Academic Fellow at Bocconi University.

Moderator and Speaker:

Prof. Dr Michael GEIST, a Law professor at the University of Ottawa and Canada Research Chair in Internet and E-commerce Law.

INTRODUCTION

Prof. MANDERIEUX remembered that the Global Digital Encounters started in the wake of the pandemic, aimed at a better understanding of the complex need for an evolution of the Intellectual Property ('*IP*') system needed for a post-pandemic world. He remarked that for the anniversary of the encounters there will be discussed an issue that has put IP and its complexity in the forefront of worldwide news: the issue of vaccines, which are IP supported for inventing them, producing them and distributing them among societies.

Coordinator, Javier FERNANDEZ LASQUETTY highlighted the importance of finding a solution that will balance the needs of human and respects IP.

GENERAL OVERVIEW

The encounter took the following format:

- Discussion of ground questions
- Reply to questions posed by participants.
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1ST QUESTION: VACCINE SITUATION IN DIFFERENT COUNTRIES, HAVING EXAMPLES LIKE ISRAEL WITH HIGH-RATE VACCINATION AND OTHERS NOT DOING SO WELL. WHAT ARE THE KEY INGREDIENTS FOR SUCCESS IN THE VACCINATION RATE?

Prof. MIRCHIN: mentioned that in his view the main type of factors which are not connected to the health system, but to the country that contributed to the success of vaccination in Israel:

- ✓ Contrary to many European countries, Israel has a relatively young population with only a 12% of people over 65 years old.
- ✓ Around 80% of elderly people get at least one visitor from the family each week, and these family members can accompany the elderly to the vaccination site.
- ✓ Israel generally deals well with national emergencies (since, unfortunately, it has lots of experience!).

He also mentioned other factors that are directly connected to the health system:

- ✓ In Israel, there are four competing HMOs, and every single person must be a member of one of them. This has facilitated information to be available, contact information, health history, so it is easy to get in contact with people.
- ✓ Many people were immediately available to receive the vaccine since health care is community-based (due to the socialistic agricultural roots, where every worker should be able to walk to a health centre). Every town has a community health centre.

Finally, there were factors connected to the specifics of the Covid vaccine rollout:

- ✓ Public opinion and information were given by opinion leaders for each ethnic group, in their native language (Arabic, Hebrew, Russian, Amharic and English).
- ✓ In addition, the media gave a platform to government members like the Ministry of Health, the heads of each of the HMO, etc.
- ✓ The MOH did not take down information against vaccines, but they counteracted it with factual information.

Prof. GEIST: stated that the structural foundation which made Israel a successful case would work only if you have access to vaccines, and some countries are struggling to get access. He then mentioned that countries have tools going into the negotiations such as compulsory licenses to gain access, and introduced the:

2ND QUESTION: HOW TO ENABLE ACCESS TO VACCINES?

Prof. PATRY: The primary thing to remember is that we need vaccines. In this view, one good example is Oxford and how it managed to come up with a vaccine very quickly and strike a deal with pharmaceutical companies, in particular AstraZeneca. Oxford were able to offer a formulation for a vaccine quickly because they anticipated the situation. The research started in 2017 with the first MERS virus and SARS-Cov1. Compulsory licenses were not in the discussion when governments started negotiations with pharmaceutical companies. What

was and is still today the most important, is access to the material needed to produce the vaccine, the cost of supply, productions lines and production facilities and the pace of the regulatory approval. The latter is crucial because you cannot put a vaccine on the market without regulatory approval and this needs to be considered very seriously, as it can take some time.

Prof. GEIST: agreed that regulatory approval plays a big role but for some countries, even after approving the vaccines it is still an issue to gain access to them. With this background he introduced the:

3RD QUESTION: CAN YOU TELL US HOW ISRAEL WAS ABLE TO ACQUIRE AS MUCH VACCINE AS THEY DID? / HOW DID PFIZER MANAGED TO MEET THE REQUIREMENTS ITSELF?

Prof. MIRCHIN: stated that the whole process and the agreement with Pfizer are public. Extensive anonymized/aggregated information in the electronic health records were provided to Pfizer, including a dashboard updated daily and aggregated data on how the vaccine was doing, incidents or side effects etc. Although it was not an explicit or formal *quid pro quo*, in exchange for this data, Pfizer was more willing to allocate a sufficient stocks of the vaccine to Israel. This was beneficial for the world as many medical papers were produced as a result of this Israeli data. This allowed Pfizer to test the vaccines on their own.

He stated in the first days of the pandemic began, the government in Israel exercised, for the first time ever, the Government Use exception in the Patent Law. "Government Use" is different from Compulsory Licenses and could be applicable when there is not enough supply. In such circumstances, the government could go around the patent (like it did with the drug called *'Kaletra')* and import it from third countries but with paying compensation. This exception was there in the background during negotiations between the Ministry of Health and pharmaceutical companies, but it was not brought into the discussions. In his view, this was because both sides wanted to facilitate rapid access to vaccines. Indeed, he remarked that AstraZeneca makes no profit on the vaccines, as it sells them at cost.

Prof. GEIST: remarked how interesting is to note the different models. He mentioned that in Canada, for instance, the immediate response to the pandemic was to pass legislation giving the government power to work around patents to give access to vaccines and medical technology to tackle shortage supply. However, he also mentioned that this has been very much discussed, especially due to Canada's history with pharmaceutical companies and drug pricing. Against this background, he asked:

4TH QUESTION HOW HAVE THERE BEEN DIFFERENT NATIONAL MODELS IN EUROPE FOR ACCESS TO THE VACCINE?

Prof. PATRY: stated that in Europe the decision taken was to centralize the access and distribution through the EU. The EU negotiated the contracts with the pharmaceutical companies and then organized the distribution. It is up for debate whether this worked and remains controversial in the political sphere. In France, the questions being asked are whether EU countries have given up their national sovereignty through this decision and therefore whether it would have been better to negotiate directly at the country level. We must learn from the Israeli model, as they were quicker to enter into negotiations compared to the EU. Indeed, another aspect from the Israel's example is that they did not negotiate by "*threatening*" to use a compulsory license. Rather, their approach was a collaborative one. A similar approach was taken by Oxford which was able to impose its business model onto AstraZeneca and have the vaccine sold at cost.

Prof. MIRCHIN: remarked that the negotiations and agreement were done very quickly. The government agreed in November to overbuy the vaccines in advance. They bought enough vaccines from Astra Zeneca for two-thirds of the population and they have agreements with Pfizer and Moderna. The Government chose the "carrot" in the '*carrot vs stick*' (incentive) approach and thus did not use the compulsory license or Government Use exceptions. Instead, they changed the Vaccine Law to give protection to the pharmaceutical companies so that if anyone got injured the Government would compensate them. This was done in recognition that the pharmaceutical companies were able to make a potentially safe and effective vaccine in record time. So, in exchange for getting the vaccines quickly, the Government was willing to cover the downsides.

Prof. GEIST: mentioned that overbuying is an interesting and common issue. There are a lot of countries that are not in a position to overbuy, who cannot get access, or struggling to buy vaccines and do not have the production capacity. Under the World Trade Organization rules, they could create a patent waiver and open the door for greater vaccine production in many countries. Some of these countries are calling for a patent waiver. He then introduced the

5TH QUESTION: WHAT IS THE POTENTIAL ROLE OF A PATENT WAIVER WHEN IT COMES TO ACCESS?

Prof. PATRY: believes that the patent waiver is not a solution to Covid-19 as we do not need freedom, but we need an increase in production capabilities and production facilities. The big production facilities are located in India, which is the vaccines and drugs contractor for the world.

The problem with the compulsory licenses, in this case, is that many governments are just learning what compulsory licenses are used for. In France, compulsory licenses can only be used for granted patents, and since many Covid 19 vaccine patents are still applications, this tool would be ineffective. This has led actually to suggestions to review the whole Compulsory Licensing process for the future crisis. Further, he believes that the incentive

model works better for carrying out serious research and attracting solid investors and is far more efficient, thus he concluded that we should look with insight at the AstraZeneca and Israeli Models to improve and do better next time.

Prof. MIRCHIN: remarked that supply has not been an issue in the West, but the problem is distribution. The vaccines must be brought together with the people to be vaccinated and the medical care (the nurses and medics to administer the vaccines) to efficiently deliver them together. Especially with the Pfizer and the Moderna vaccines which have a short life once thawed. In some places such as Romania and Greece, they are only using forty per cent (40%) of the supply that they have and one of the reasons for this is the Anti-Vaxxer sentiment. In other words, there are more issues than just the physical number of vaccines.

He emphasized the difference between Government Use and Compulsory License, which differs slightly between countries. Israel used Government Use because it is less restrictive and can be applied at any time. Compulsory Licensing, in contrast, can only be used if four years has passed since the filing of the patent application or three years has passed since the patent has been granted. Moreover, there are hearings and logistical/ bureaucratic hoops to go through etc. Therefore, it is less useful in Israel and some other countries.

Prof. PATRY: added that France has also looked at their Compulsory Licensing system and determined that presently it is useless and needs to be reviewed. He mentioned that a new bill has been drafted and placed in Parliament to address the future crisis. Another issue in France is the waste of vaccines; having more freedom of exploitation and lifting patents are not the primary issues as there is a waste rate of twenty-five per cent (25%) on the AstraZeneca vaccine. The logistic of distribution is missing and this should be looked at instead of thinking about looking at patents who act more as a diversion and a distraction.

Prof. GEIST: acknowledged that there are issues around distribution, but he mentioned that there is a balance around these issues. Over 100 Billion Dollars of public money from global taxpayers were used to support these pharmaceutical companies as part of the research and have no say now. There are countries that have the capacity to produce these vaccines and not being able to do this as the companies have not granted the license. Compulsory Licensing is specifically made to address global pandemics but is not being used. There is an urgency for the rules to be negotiated to ensure that people are getting access to the vaccines. With a hundred countries saying that this is something that they would like to do. Yet the West has stepped up to create their series of exceptions and stand in the way of the others creating their own.

6TH QUESTION: WHAT HAPPENS TO THE OVERBOUGHT VACCINES? THERE IS AN ISSUE OF WASTAGE THAT WAS MENTIONED.

Prof. PATRY: has not heard of any vaccines being overbought in Europe. In his view, the problem in Europe is that we have not properly anticipated how many people would like to be vaccinated. Far more people than we thought wish to be vaccinated but cannot do so because they do not have the right age or the right condition. In his view, the matter is rather an administrative/ distribution issue. In some countries such as the US, everyone can access

the vaccines, but this is not the case -for instance in France, where it is very structured. The flow of vaccines is working relatively well, but there are pitfalls with the age-range based distribution.

Prof. MIRCHIN: mentioned that in Israel AstraZeneca is not looking to force the Government to take vaccines that they do not need. There was a situation in that Israel was giving the extra vaccines to other countries. But a political decision was taken to not do the redistribution of the vaccines and let the pharmaceutical companies keep the extra doses and figure out the redistribution. Note that this issue is still in flux, and subject to political considerations.

Prof. GEIST: mentioned that Canada did overbuy, but the system is struggling with the distribution campaigns.

7TH QUESTION: WHAT HAS THE EU DONE AND WHAT CAN BE DONE TO ENSURE GREATER HARMONIZATION ON THE ISSUE OF COMPULSORY LICENSES AND THESE ISSUES?

Prof PATRY: suggested having a look at the different regimes of Compulsory Licensing and harmonizing the rules at the EU level. If this isn't done it can create a lot of risks such as "*vaccination tourism*". There should be a central body that should have the administrate power to decide when to trigger Compulsory Licensing. Further, the EU should recognize the value of licensing as it is good for the economy and should be pushed forward.

He further mentioned the importance of being "*generous*" and that "*we have to share*", especially considering the different price structures for the vaccines. There are significant price differences between countries and poor countries can't afford vaccines at a high price. Thus, we need to understand why Oxford was able to impose its business model onto AstraZeneca and have this price structure at cost. He suggested that this was possible due to Oxford's patents and Oxford's IP and how they used it to get some leverage and impose their business model.

8TH QUESTION: WHETHER DONOR ORGANISATIONS SHOULD HAVE BEEN MORE AGGRESSIVE IN SHARING THE KNOW-HOW, TECHNOLOGY TRANSFER AND CAPACITY BUILDING?

Prof. MIRCHIN: clarified that is not just a matter of patent rights or waiver or non-enforcement of patents. Vaccine manufacturing involves complex technology and complicated supply chains, especially in Moderna and Pfizer's vaccine. Hence, there are not only patents but also trade secrets and know-how and this gives an extra-economic advantage. We should question whether it is fair to ask pharmaceutical companies to disclose such valuable information. In his view, the way out is to encourage tech transfer, and collaboration in manufacturing, i.e., by building more facilities.

Prof. PATRY: agreed on the need to invest more in production capabilities and tech transfer to third world countries as the next pandemic might be soon and we have to be ready. He pointed out the importance of public investment in vaccine research as it resulted in the creation of these vaccines.

9TH QUESTION: WHAT OTHER MODELS OR TWEAKS TO THE EXISTING MODELS SHOULD WE THINK ABOUT TO ENSURE VACCINE ACCESS?

Prof. PATRY: pointed out the importance of leverage in any negotiations, especially if we want a specific price structure. Patents are necessary to push for a specific business model and a specific price structure, and supply many countries at a "*decent*" price.

Prof. MIRCHIN: expressed that compensation and public image is where the governments' leverage lies during negotiations with pharmaceuticals. He indeed remarked that both Government Use and Compulsory Licensing exceptions include a compensation component, and pharmaceuticals companies do not want to appear as if they are taking advantage of a pandemic.

Prof. PATRY: emphasized the importance of protecting pharmaceutical companies, and investors as they are taking risks ahead to produce vaccines and we need vaccines. Thus, governments should create a safe environment to prevent pharmaceutical companies from being sued by others, or to avoid the risk of not being able to produce or getting a license. Abusive litigation and expensive licenses are a heavy burden on their price structure.

Prof. GEIST: confirmed the importance of pharmaceutical companies and public support. He posited if to use the balancing principles of Copyright to have incentives to create while ensuring adequate levels of access.

10TH QUESTION: WHAT ABOUT THE REPORTED EU THREAT OF SUING ASTRAZENECA FOR NON-COMPLIANCE ON THE SUPPLY SCHEDULE, ESPECIALLY WHEN THEY ARE BEING SUPPLIED AT COST?

Prof. MIRCHIN: reported that AstraZeneca has no incentive to not deliver on the supplies. The delay is not a result of a lack of trying to deliver. He further mentions that vaccine nationalism is a worrying trend as we must think across national borders to get out of this situation. There is no absolute ideal of what is the right distribution and the equitable distribution model. He noted that the vaccine nationalism's response will be to have separate manufacturing in each country, which would be a disappointing result.

Prof. PATRY: This is a potential litigation as the EU has not decided yet if they will sue AstraZeneca. This will be an issue of commercial law and breach of contract. The issue is that the EU was not fast enough to cut a deal with AstraZeneca, unlike Britain which did so much

more quickly. We have to rethink our negotiation teams - and be better - and how our governments or regions deal with companies such as AstraZeneca.

11TH QUESTION: THE UNITED KINGDOM VACCINE ROLLOUT FAR OUTPACES EUROPE; HOW DID THEY MANAGE TO ACHIEVE THIS?

Prof. PATRY: The United Kingdom chose to vaccinate a lot of people as quickly as possible with the first dose and not wait for the second dose. France took a different approach, where it is a step-by-step process of vaccinating the elderly and vulnerable persons first. Their model apparently is working better. They also organized the vaccine distribution better as they have a culture of local dispensaries, unlike France.

Prof. GEIST: This provides a good closing point of the debate that will be ongoing. There will be different views on the role that IP plays in these issues and how to best ensure access. Issues around vaccine nationalism represent a whole other challenge. These are challenging and complex issues and we need experts to explain what has been taking place and the ongoing challenges.

CONCLUSION

Prof. DESANTES highlighted that it was a great and valuable discussion on a crucial but also very controversial issue, which is dear to our common future. He thanked the panel, the support team and attendees.

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